



# ISPO 17th WORLD CONGRESS

Kobe Convention Center Kobe, Hyogo, Japan

5 - 8 Oct 2019

**BASICS TO BIONICS** 

# **ABSTRACT BOOK**



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### **Preface**

The World Congress is the flagship meeting of the International Society for Prosthetics and Orthotics (ISPO): a unique interactive event where professionals involved in the care of persons in need of prosthetic, orthotic, mobility, and assistive devices come together to learn about the latest scientific and clinical advances, products, innovative technologies, designs, and materials in prosthetic and orthotic care.

Held over four days, the theme of the 2019 ISPO World Congress, 'Basics to Bionics,' reflects the breadth of the rehabilitation field and assistive technology, including traditional rehabilitation approaches and more complex interactions between humans and machines (rehabilitation robotics), while embracing the relevance and importance of both basic and emerging technologies. The interdisciplinary program featured 4 Keynote Speakers, 25 Symposia, 28 Instructional Courses (11 Basic and 17 Advanced), 57 Free Paper Sessions and 129 Poster Presentations as well as Exhibitor Workshops. As illustrated in this Abstract Book, the scientific program highlights the state of the art in prosthetics and orthotics and tries to look beyond current horizons, with the aim of inspiring delegates to work together to create a world where individual rehabilitation needs can be met.

Abstracts submitted for Symposia and Instructional Courses were reviewed by the World Congress Scientific Committee for quality and relevance. Symposia present thematically related research addressing significant problems or controversies in prosthetics, orthotics, mobility and assistive devices. Symposia present differing perspectives on a particular topic. Instructional Courses present information on specific topics at a level suited to the practitioner. These might be topics that receive limited coverage in undergraduate curricula or may be suited to experienced clinicians who have already specialised or who are entering a specialised area of practice or research.

Abstracts submitted for Free Paper and Poster presentations were peer reviewed by external experts invited by the World Congress Scientific Committee for relevance, appropriateness of method and conclusions, and overall quality. The review process for Free Paper and Poster abstracts was double blinded, meaning that author and reviewer information was not shared with either party. A Free Paper may describe a technique, case study, case series, clinical trial, systematic review, experiment or qualitative research delivered as a podium presentation during the congress. By comparison with free papers, a poster may present preliminary results or works in progress. Abstract reviewers are acknowledged in this Abstract Book for volunteering their time and expertise. No other remuneration or incentive was provided for their efforts.

The Abstract Book was compiled using Oxford Abstracts. In each abstract, the name of the presenting author is underlined. A limitation of this electronic submission of documents is that figures are often compressed or minimised in size at various times in the process of upload from the authors and compilation into the final Abstract Book. As such, we apologise in advance where figures have not been depicted clearly in this final compilation.



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## Saturday, 5 October

### **Keynote Lecture 1.0**

### **Knud Jansen Lecture:**

# AT Changed My Life - Practical Solutions and Education Enabling a Lifetime of Human Potential

David Constantine<sup>1</sup>

<sup>1</sup>Motivation, Bristol, United Kingdom

#### **Abstract**

The World Health Organization estimates that 1 billion people currently require assistive devices, and that by the year 2050 this number will have doubled.

Since 1991, Motivation, a UK-based organisation that designs and provides low-cost wheelchairs to the developing world, has been working to put wheelchairs on the global agenda of the international development community. Through a rewarding and positive cooperation with ISPO, Motivation has made enormous strides in the integration of wheelchair and P&O services, has co-created WHO guidelines, and has developed training programmes for wheelchair provision.

# IC2A Inspirational Lecture: Stronger

Desmond Tong<sup>1</sup>

Ottobock HealthCare, Singapore, Singapore

### **Abstract**

This is the inspiring story of Desmond Tong, a young man who lost his leg as a result of a road traffic accident. In order to finally become 'normal' and 'acceptable' again, he had to overcome many obstacles and struggles, physically as well as mentally.



## Symposium Education

#### 1.1.1

## Footprint of P&O School Establishment in South East Asia

Eiji Tazawa<sup>1,2</sup>, Yasunobu Ishii<sup>3</sup>, Carson Harte<sup>4</sup>, Wesley Pryor<sup>5</sup>

ISPO Japan, Kobe, Japan. <sup>2</sup>Cooperation 254, Tokyo, Japan. <sup>3</sup>Nippon Foundation, Tokyo, Japan. <sup>4</sup>Exceed World Wide, Phnom Penh, Cambodia. <sup>5</sup>Melbourne University, Melbourne, Australia

#### **Abstract**

The Nippon Foundation has been supporting South East Asia (SEA) region more than 20 years by establishing P&O schools including CSPO (Cambodia School of Prosthetis & Orthotics) – this school was established by Cambodia Trust but supported by the Nippon Foundation financially more than 10 years, SLSPO (Sri Lanka School of prosthetics & Orthotics), SSPO (Sirindhorn School of Prosthetics & Orthotics), PSPO (Philippines School of Prosthetics & Orthotics) and MSPO (Myanmar School of Prosthetics & Orthotics). And a number of ISPO Prosthetist & Orthotist (formally Category I) and Associate Prosthetist & Orthotist (formally Category II) was educated and working in the SEA region as a result of the Nippon Foundation's contribution.

This symposium will consist of Dr.Eiji Tazawa as chair person, Mr. Yasunobu Ishii from Nippon Foundation as speaker 1 talking about – Assessment criteria of donation, Mr. Carson Harte from Exceed World Wide as speaker 2, talking about – A strategic approach to Prosthetic & Orthotic development in South East Asia and Sri Lanka, and Mr. Wesly Prylor from Melbourne University as speaker 3, talking about – Assessment report from ISPO regarding the Nippon Foundation Investment in SEA region.

This symposium will conclude overall activities of the Nippon Foundation and discuss how further involvement is needed for the development of P&O in SEA region.

### Statement of the objective / learning objectives

How does relationship between funding agency and recipient activities such as developing infrastructure to meet international standard.



## **Basic IC**

### **Orthotics: Lower Limb Orthopaedic**

#### 1.1.2

### Osteoarthritis of the Knee Joint: Individual Orthotic Treatment Concepts

Thomas Schmalz<sup>1</sup>, Ryosuke Kurodam<sup>2</sup>, Heiko Drewitz<sup>3</sup>

Ottobock SE&Co. KGaA/Clinical Research & Services, Goettingen, Germany. <sup>2</sup>Kobe University Graduate School of Medicine, Kobe, Japan. <sup>3</sup>Ottobock SE&Co. KGaA/Competence Center, Goettingen, Germany

#### **Abstract**

Orthotic fittings are part of the non-operative treatment strategies for osteoarthritis of the knee. The good clinical and biomechanical results reported in the last 20 years are indisputable. However, the potential of this conservative treatment is far from exhausted. The goal of the symposium is to show that a clear patient benefit can be expected from orthotics if the fitting strategy is individually planned and optimized.

In particular, the symposium will give an overview about the known treatment concepts for osteoarthritis of the knee joint. Within the context of the non-surgical procedures, options and limitations of orthoses are critically discussed from different perspectives (medical, technical, biomechanical).

The symposium presents a classification of all known orthotic concepts that can be used in the treatment strategy (KO, AFO, FO). This incorporates both a systematic overview on the functional principles of the different types of orthoses and a comparison of the knee unloading effects that can be achieved with them. The correlation between biomechanical and clinical results will be discussed. Case studies will show that individually optimized results can be achieved by planning the fitting strategy based on both the consideration of the specific clinical situation of the patient and the results of biomechanical analyses.

### Statement of the objective / learning objectives

The symposium will show that orthotics for knee joint osteoarthritis may result in good clinical results with profound patient benefits if the fitting strategy is individually planned and optimized.



# Free Paper Session Orthotics Lower Limb Orthopaedic - Foot

#### 1.1.3.a

## Biomechanical Analysis of the Plantar Pressure Distribution in Athletes with Cavus Foot

<u>Sergio Luis Orozco-Villasenor</u>, José de Jesús Mayagoitia Vázquez, Israel Miguel Andrés, Karla Daniela de la Cruz Alvarado CIATEC, A.C., León, Mexico

#### **BACKGROUND**

The cavus foot is a musculoskeletal pathology with an increase of the medial arch of the concavity of the foot. Furthermore, an increase of pressure in the anterior and posterior part of the foot can appear during static or dynamic conditions. The etiology of the cavus foot is still enigmatic, it is related with neurologic conditions, Charcot-Marie-Tooth disease, Fredreich's ataxia, and cerebral palsy.[1-3]

#### AIM

The aim of this research was to analyze the plantar pressure distribution of the feet on young athletes with cavus foot pathology.

#### **METHOD**

Eighty-three young athletes between 9 and 20 years old, that presented cavus feet pathology were recruited. The mass and height average were  $56.9 \pm 12.36$  kg and  $1.61 \pm 0.10$  m respectively. All the participants were informed about the protocol and experimental procedure. Plantar pressure distribution of the feet was recorded during static conditions. The participants were placed on the pressure platform in standing position, then the data was recorded during ten seconds. The plantar pressure distribution of the feet was analyzed. The hindfoot and forefoot pressure were compared in each foot. The data was analyzed using descriptive statistics.

## **RESULTS**

The results of the plantar pressure distribution were categorized in three groups. In the first group the participants presented higher pressure in the hindfoot than forefoot, in the second group, the athletes showed similar pressure in the posterior and anterior region of the feet (<16%) and in the last one, the subjects revealed higher pressure in the forefoot. To be considered in one of the three groups, the difference between the posterior and anterior part of the foot was established at 16%. For the right foot, 60.2% of the athletes presented higher pressure on the hindfoot than the forefoot, 33.7% were considered as normal and 6% showed higher pressure in the anterior part of the foot. There were similar results for the left foot, 72.3%, 22.9% and 4.8%.

### **DISCUSSION AND CONCLUSION**

Many musculoskeletal disorders in the human body are biomechanical in origin and related with foot anatomy. The cavus foot is a pathology with high prevalence in athletes and it is related with the mechanical forces over the feet during dynamic conditions. The high pressure in the hindfoot and forefoot could produce ulcers or callus on the sole of the feet. Furthermore, the cavus foot is related with ankle sprain.

## **REFERENCES**

[1] Maynou, et al. EFORT Open Rev 2017.

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[3] Hillstrom et al. Gait Posture 2013.

## **ACKNOWLEDGEMENTS**

The authors would like to thank Centro de Innovación Aplicada en Tecnologías Competitivas (CIATEC, A.C.) for supporting the research.



#### 1.1.3.b

## Effects of Custom-Made Orthotic Insoles on Clinical Status of Patients with Plantar Fasciitis – A Pilot Study

Sulenur Yildiz, <u>Nilgun Bek</u> Hacettepe University, Ankara, Turkey

#### **BACKGROUND**

Plantar fasciitis is a debilitating condition, which is related with pain and function problems. The usage of custom-made orthotic insoles is one of the treatment options, which aims to decrease tension by supporting the pressure on plantar fascia, correcting foot posture and supporting the pressure on plantar fascia.[1] Although there are studies, which evaluate effectiveness of custom-made orthotic usage in plantar fasciitis, there is no consensus about the effectiveness and change with time.[1, 2]

#### AIM

The purpose of this study was to investigate effectiveness of custom-made orthotic insoles and compare baseline, 6<sup>th</sup>, and 12<sup>th</sup> week results.

#### **METHOD**

Twenty-eight feet with plantar fasciitis aged 20-70 years (8 females, 7 males) participated in the study. Subjects' demographics and anthropometrics characteristics were recorded. The Foot Function Index (FFI) scores were calculated as total, pain, disability, and activity restriction subscales. Higher scores indicate worse condition. Custom-made orthotic insoles were fabricated hand-made by orthotics according to patients' need. Medial or transvers arch supports and medial heel wedges were was applied as if needed. All evaluations were repeated in 6<sup>th</sup>, and 12<sup>th</sup> week.

#### **RESULTS**

The mean baseline results were 36.41±20.63 for FFI-Total, 49.07±21.04 for FFI-Pain, 34.47±22.98 for FFI-Disability, and 24.85±22.96 for Activity restriction. Sixth week results were 19.79±8.60 for FFI-Total, 22.06±20.99 for FFI-Pain, 20.45±21.72 for FFI-Disability, and 6.5±11.87 for Activity restriction. The final results were 15.22±14.78 for FFI-Total, 22.32±21.61 for FFI-Pain, 15.26±15.31 for FFI-Disability, and 5.42±13.90 for FFI-Activity restriction. There was meaningful difference between baseline, 6<sup>th</sup> and 12<sup>th</sup> week evaluations (p<0.001). Post-hoc analysis demonstrated significant difference between all parameters for baseline and 6<sup>th</sup> week evaluations with between baseline and 12<sup>th</sup> week (p<0.001). There was no difference between 6<sup>th</sup> and 12<sup>th</sup> weeks range (Table 1).

Table 1: Comparisons of the parameters within time

	Baseline-6th week	Baseline-12th week	6th-12th week
FFI-Pain	0.000*	0.002*	0.807
FFI-Disability	0.001*	0.023*	0.386
FFI-Activity Restriction	0.001*	0.001*	0.206
FFI-Total	0.001*	0.002*	0.861

<sup>\*</sup> p<0.05 (Bonferroni correction was used for post-hoc analysis.Wilcoxon signed ranks test)

#### **DISCUSSION AND CONCLUSION**

The findings demonstrated that custom-made orthotic insole was effective in pain, disability, and activity limitation in a short time, and it is also sustainable till 12<sup>th</sup> week. Because of improvements were mostly related with first 6 weeks of treatment, other interventions might be thought to add to the treatment program after 6th week.

#### **REFERENCES**

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#### 1.1.3.c

## Smart Insole and Smartwatch System with Big Data Analytics to Improve Balance Training and Walking Ability

<u>Christina Zong-Hao Ma</u><sup>1,2</sup>, Alan Kai-Lun Chung<sup>1</sup>, Yan To Ling<sup>1</sup>, Zihao Huang<sup>1</sup>, Connie Lok-Kan Cheng<sup>1</sup>, Yong-Ping Zheng<sup>1</sup>

<sup>1</sup>Department of Biomedical Engineering, The Hong Kong Polytechnic University, Hong Kong, China. <sup>2</sup>Department of Rehabilitation, Jönköping University, Jönköping, Sweden

#### **BACKGROUND**

Applying wearable motion sensors to capture balance/gait performance and provide the corresponding biofeedback/reminder have been proved effective in improving users' balance/gait.[1-5] Unfortunately, previous approach of providing pre-set biofeedback did not consider user's individual balance performance or training process during various tasks. Big data analytics and machine learning technologies have been widely used to monitor the daily physical activity.[6-8] However, few previous studies have utilized these technologies to improve balance/gait training.

#### AIM

This study aimed to develop a foot-motion based smart insole and smartwatch system integrated with big data analytics, and investigate its effect on improvement of balance training in patients with stroke.

#### **METHOD**

The newly-developed system with big data analytics can collect and store patients' balance performance & their response to the reminder/biofeedback during each session of balance/gait training. With the collected huge amount of data (big data) of patients' balance & response to the biofeedback, the system can identify and extract the feature of patients' response upon receiving the biofeedback, and further deliver the customized biofeedback (that gradually changed according to the balance improvement) for patients to further improve balance & gait training outcomes (machine learning). A randomized controlled trial will be conducted on 12 patients with stroke by evaluating patient's balance/gait training outcomes with and without using the developed system.

#### **RESULTS**

The developments of hardware of the system were completed, while those of software were in progress. The system contained: 1) personal unit with force and motion sensors placed at both feet to capture the foot motion, and a smartwatch at wrist to collect data from both feet via Bluetooth and then transmit the data to the central cloud server via WiFi; 2) central cloud servers for data transmission and storage; 3) user interface for data

analysis, which included a smartphone, tablet, and/or laptop; and 4) workstation for big data analytics (Figure 1). The collected data involved all sensor signals the system received before and after delivering biofeedback, and from day to day monitoring of patients. The customized biofeedback pattern included various type, frequency, magnitude, and amount/dosage of biofeedback.

## **DISCUSSION AND CONCLUSION**

The introduced system adopted big data and machine learning technologies to provide the repetitive targeted balance and gait training based on each patient's condition. With further optimization, this system can also be applied in elderly and other patients with balance disorders for various daily tasks,

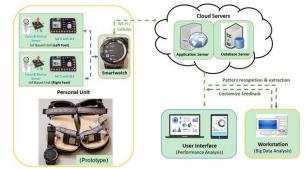


Figure 1. The foot-motion based smart insole and smartwatch system

including standing, walking, and obstacle crossing. This will enhance the balance training outcomes and potentially reduce the risk of falls in the future.

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## **ACKNOWLEDGEMENTS**

This work was partially supported by The Hong Kong Polytechnic University [grant number: G-YBRN].



## 1.1.3.d

## Insole Tool to assist Orthotists in the Design of Foot Orthoses

Veerle Creylman, Eveline De Raeve, Inge Van den Herrewegen, Tom Saey, Mario Broeckx, Luiza Muraru, <u>Kris Cuppens</u>

Mobilab, Thomas More, Geel, Belgium

#### **BACKGROUND**

Although foot orthotics are used as a conservative treatment of various foot and lower limb conditions.[1, 2] for decades, there is a lack of scientific evidence regarding the efficacy and working principle of these orthoses.[3] Furthermore, existing studies try to link a foot pathology one-to-one to an orthosis design.[4] However, the design of a foot orthosis should also depend on patient specific factors.

#### AIM

This study aims to make a software tool which will help practitioners to integrate scientifically proven foot orthotic concepts into their everyday clinical practice.

#### METHOD

27 common foot and lower limb related disorders that could benefit from treatment with foot orthotics were identified in literature. We performed a meta-analysis of the literature to set up a database that contains these pathologies and corresponding foot orthotics concepts and orthosis designs. In addition a series of interviews with Belgian experts in the field of foot orthotics was conducted to capture the current common practice. This databank is used to set-up a software tool useable in clinical practice.

#### **RESULTS**

In the database we set-up relations between the pathologies; associated "features" (symptoms, risks and properties); different foot orthosis concepts (the aim of the insole) and the foot orthosis design. The features of the pathology are divided into different categories such as pain, kinematic compensation mechanisms, deformations. The foot orthosis concepts include amongst others, motion control and cushioning a painful spot. The foot orthosis designs are documented and include e.g. the location, stiffness and shape of the orthosis adjustment.

## **DISCUSSION AND CONCLUSION**

By setting up a database, we constructed a link between all the features of a pathology and the appropriate design concepts of the foot orthosis. By using this database and the associated software tool, scientific evidence is integrated in clinical practice and translated to common practice. However, there remains a need for overall scientific guidelines and recommendations to fill in the missing links and improve patient care.

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## **ACKNOWLEDGEMENTS**

This research was supported by Flanders Innovation & Entrepreneurship (VLAIO) [TETRA HBC.2016.0128].



# Free Paper Session Prosthetics: Lower Limb Transtibial – Gait

#### 1.1.4.a

## Effects of Balance Support on Energy Cost of Walking in People with a Lower Limb Prosthesis

<u>Suci Anatasia Nazier</u><sup>1,2</sup>, Ilse Blokland<sup>1,3</sup>, Saskia Castenmiller<sup>1</sup>, Iris Van Den Heuvel<sup>1</sup>, Trienke IJmker<sup>1</sup>, Han Houdijk<sup>1,3</sup>

<sup>1</sup>Faculty of Behavioral and Movement Sciences, Amsterdam Movement Science, Vrije Universiteit, Amsterdam, Netherlands. <sup>2</sup>Jakarta School for Prosthetics and Orthotics (JSPO, Polytechnic Health Jakarta of The Ministry of Health Republic of Indonesia, Jakarta, Indonesia. <sup>3</sup>Heliomare Rehabilitation Center, Wijk aan Zee, Netherlands

## **BACKGROUND**

People with a lower limb prosthesis expend more metabolic energy when walking compared to able-bodied peers. Th magnitude of this increase varies with cause and level of amputation.[1] Factors that could explain this higher energy cost (EC) of walking are not fully understood. Lower limb amputees (LLA) experience deterioration of balance control following amputation, which might negatively influence their EC during walking.

#### ΔIM

The main objective of this study was to examine the effect of balance support on EC during treadmill walking in LLA with different levels and cause of amputation.

#### **METHOD**

Twenty-five persons with a unilateral lower limb amputation participated. Level of amputation: 16 transtibial, 2 knee-disarticulation, 7 transfemoral. Cause of amputation: 9 vascular, 16 non-vascular. Age: 5814 years. Participants performed two walking trials for approximately 5 minutes on an instrumented treadmill, in random order, once without support and once while holding one handrail on the contralateral side. In both conditions they walked at their comfortable walking speed established without handrail support. Metabolic energy cost was assessed through respirometry. The effect of handrail support was tested using two separate ANOVA's with level amputation and cause of amputation as between subjects' factors.

#### **RESULTS**

The main effect of handrail support on energy cost for the entire sample was borderline significant (p=0.051). With handrail support energy cost was on average 5% lower. There was no interaction effect of handrail support with level of amputation. However, a significant interaction effect of support and cause of amputation was found (p=0.028). With support energy cost decreased by 11% in people with a vascular cause of amputation and only 1% in those with non-vascular cause.

#### **DISCUSSION AND CONCLUSION**

Reduced balance control might explain part of the increased energy cost in people with a lower limb amputation, specifically in those with an amputation due to vascular problems. Improving balance control should be taken into consideration when striving to reduce the metabolic cost of walking in this population.

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#### 1.1.4.b

## Displacement of Center of Mass During Perturbed Walking on a Treadmill in Active Subjects after Trans-tibial Amputation – Preliminary Results

Helena Burger<sup>1,2</sup>, Matjaž Zadravec<sup>1</sup>, Andrej Olenšek<sup>1</sup>, Zlatko Matjačić<sup>1</sup>
<sup>1</sup>University Rehabilitation Institute, Republic of Slovenia, Ljubljana, Slovenia. <sup>2</sup>University of Ljubljana, Faculty of Medicine, Ljubljana, Somalia

#### **BACKGROUND**

People with lower limb loss have a higher risk of falling and dual-task interference in standing is greater compared to healthy population.[1, 2] Understanding problems of people with lower limb loss during unexpected perturbations during walking can influence prosthetic interventions and training.

#### ΔIM

The aim of our study was to find out whereas active people after trans-tibial amputation with no severe limitations in functioning have problems in center of mass (COM) displacement during unexpected perturbations.

#### METHOD

Until now we included five very active subjects (3 men) after unilateral trans-tibial amputation willing to participate (will include more and present the results of all). Subject were walking on the instrumented treadmill with the BAR device at speed 0.5 m/s. After initial warm-up period magnitude of perturbations was determined followed by a period of perturbed walking where perturbations to pelvis were delivered randomly seven times in forward, backward, left and right directions at either left or right hell contact.

#### **RESULTS**

We found out that there was a difference in amplitude and occurrence of the maximal displacement of centre of mass whereas perturbation occurs during heel contact of the amputated (A) or non-amputated (H) side. COM displacement amplitudes were higher after outward perturbations (in frontal plane – FP), and after both forward and backward perturbations (in sagittal plane – SP) triggered on the amputated side (Figure 1). In the case of outward and backward perturbations, the maximal COM displacements occurred later, when subjects were already standing on the non-amputated side.

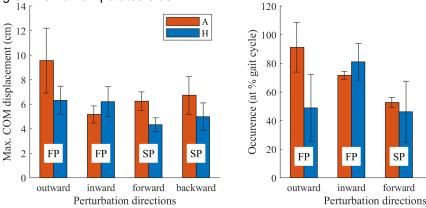


Figure 1. COM displacements during perturbations

## **DISCUSSION AND CONCLUSION**

In included subjects' responses at the non-amputated side were very similar to responses observed in healthy individuals. Responses to perturbations that occurred when the amputated limb entered stance phase have shown lack of both "ankle" and "hip" strategies while the subject relied solely on the stepping strategy. That means that their capacity to successfully recover from loss of balance during walking was very much reduced and this type of perturbations is more fall-threatening and should be adequately addressed by training.

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backward



#### 1.1.4.c

## Gait Strategies in Ramp Negotiation in Subjects with Trans-tibial Amputation using Two Different Prosthetic Feet: A Biomechanical Analysis

Merkur Alimusaj, Daniel W. W. Heitzmann, Thomas Kaib, Julia Block, Sebastian I. Wolf Heidelberg University Hospital, Heidelberg, Germany

#### **BACKGROUND**

Prostheses are in principle aligned for walking on level ground. Walking on inclines is therefore a challenging task for amputees using a conventional prosthetic carbon fiber foot. Rigid construction and the lack of adequate adaptation to such walking conditions modify lower limb kinematics and kinetics, and lead therefore to non-physiological loads.[1] The adaptation to an incline might therefore be beneficial and could lead to a more physiological load in both the involved and the non-involved limb.

#### AIM

Walking on inclines is challenging for subjects with transtibial amputation (TT).[1] The current study monitors the effect of two different prosthetic feet (VariFlex vs. ProFlex, Össur Iceland) on gait of TT ascending and descending a 10 degree ramp.

#### **METHOD**

23 unimpaired subjects (REF) and 14 TT were included. Participants negotiated an instrumented ramp (2 force plates, AMTI, USA) TT underwent the protocol twice using two different feet (Variflex (VA) and ProFlex (PF), Össur, IS) in a randomized order (cross-over-design) after an adaptation time of two weeks for each foot. Prosthetic alignment was verified in each condition by L.A.S.A.R. Posture (Otto Bock, Germany).[2] Kinematics and kinetics (Plugin Gait (Vicon, GB)) and the sole angle (angle between foot sole and ramp) were calculated. Patients' feedback was assessed using the PEQ [3] in both, PF and VA condition. Wilcoxon signed-rank tests for paired samples (p<0.05) were used for statistical Analysis.

#### **RESULTS**

Ramp up: Using the VA, TT showed two strategies, with three showing a pronounced knee flexion during midstance compared to REF (subgroup FLX) and eleven showing an extension of the knee (subgroup EXT). TT walking with PF showed only the latter and therefore a consistent strategy. Correspondingly, higher external knee extending moments were seen during mid stance when compared to REF in the TT utilizing PF and in the VA user subgroup EXT. While the VA subgroup FLX showed external knee flexing moments.

Ramp down: Ankle range of motion and angular velocity of the sole angle was closer to REF using the PF, while with VA greater deviations of these parameters were seen, when compared to REF. This indicates an early and prolonged period of foot flat.

The PEQ ambulation scale showed improvements over VA when using PF.

#### **DISCUSSION AND CONCLUSION**

FLX showed a flexion strategy with corresponding moments, late foot flat and early heel rise compared to PF, similar to the findings in level ground walking, indicating reduced stability.[4] Using PF showed a consistent pattern, analogous to EXT when using VA, indicating that PF allows for an easier adaptation and reduced compensatory effects, which was also seen in ramp descend. Correspondingly TT ranged PF higher in the PEQ than VA in ambulation scale, which includes sloped Walking.

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#### **ACKNOWLEDGEMENTS**

We would like to thank all participants for their attendance. Financial support of Össur hf Iceland is acknowledged as well.



#### 1.1.4.d

## Effects of Toe-in/Toe-out Angles of Prosthetic Feet on Socket Reaction Moments During Walking in Individuals with Transtibial Amputation

<u>Hiroshi Hashimoto</u><sup>1,2</sup>, Toshiki Kobayashi <sup>3</sup>, Fan Gao <sup>4</sup>, Michael S. Orendurff<sup>5</sup>, Masataka Kataoka<sup>1</sup>, Kuniharu Okuda<sup>1</sup>

<sup>1</sup>Osaka Prefecture University, Osaka, Japan. <sup>2</sup>Pacific Supply Co. Ltd, Osaka, Japan. <sup>3</sup>Hokkaido University of Science, sapporo, Japan. <sup>4</sup>University of Kentucky, Kentucky, USA. <sup>5</sup>Lucile Packard Children's Hospital Stanford, Stanford, USA

#### **BACKGROUND**

The alignment of transtibial prostheses is determined under the observation of clinicians and user feedbacks. However, this method is unreproducible. Socket Reaction Moment (SRM) is defined as the moment of force measured with a load cell under the prosthetic sockets. Systematic relationships between SRM and alignment change in the coronal and the sagittal plane have been reported. Thus, SRM may be useful in evaluating prosthetic alignment.[1-3] However, the relationship between SRM and toe-in/toe-out is still unclear.

#### **AIM**

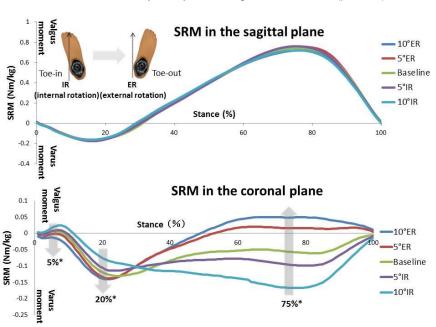
The aim of this study is to investigate the effects of transverse alignment changes (i.e., toe-in and toe-out) of prosthetic feet on SRM during walking with transtibial prostheses.

## **METHOD**

Nine persons with transtibial amputation participated in this study. A load cell was embedded under participants' sockets and the most acceptable alignment was set and defined as Baseline. Each participant was asked to walk straight in five alignment conditions (5° and 10° toe-in and toe-out, and Baseline) at a self-selected walking speed for data collection. SRM was measured using the load cell device and walking speed, cadence and step width were measured using a 3D motion capture system. The minimum and maximum sagittal SRM, and coronal SRM at 5%, 25%, and 75% stance were extracted and statistically analyzed using mixed models (p<0.05).

#### **RESULTS**

No significant changes of walking speed, cadence and step width were seen under all alignment conditions. There were no significant changes in maximum and minimum sagittal SRM in all alignment conditions. In the coronal plane, the SRM showed significant changes at 5% (p=0.04), 20% (p=0.04), and 75% (p<0.01) stance under alignment changes. It was found that the more internally rotated the foot was, the more varus moment was decreased at 5% and 20% stance. However, there seemed an opposite effect at 75%; the more internally rotated the foot was, the more varus moment was increased (Fig 1).



## **DISCUSSION AND CONCLUSION**

When the prosthetic foot is rotated

internally, the forefoot shifts medially and the hindfoot shifts laterally, and vice versa when it is externally rotated. These changes may have altered the lever arm in the coronal plane and affect the coronal SRM in the early and late stance diametrically. From these findings, SRM may be beneficial in evaluating the transverse alignment changes of transtibial prostheses

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#### 1.1.4.e

## The Relationship Between Step Length Symmetry and Oxygen Consumption During Split-Belt **Treadmill Walking in Persons with Transtibial Amputation**

Tanu Bhargava<sup>1</sup>, Brad Hendershot<sup>2,3</sup>, Caitlin Mahon<sup>2,3</sup>, Benjamin Darter<sup>1,4</sup> <sup>1</sup>Virginia Commonwealth University, Richmond, USA. <sup>2</sup>DoD-VA Extremity Trauma and Amputation Center of Excellence, Bethesda, USA. <sup>3</sup>Walter Reed National Military Medical Center, Bethesda, USA. <sup>4</sup>Hunter Holmes McGuire Veteran Affairs Medical Center, Richmond, USA

#### **BACKGROUND**

Temporal-spatial gait asymmetries are common in individuals with transtibial amputation (TTA) and such asymmetries are believed to contribute to higher rates of oxygen consumption (VO2) during walking.[1] Split-belt treadmills can test locomotor adaptability by prompting asymmetries that improve through trial-and-error as the person walks, thereby offering a method to explore the relationship between step length asymmetry and VO<sub>2</sub>. While this strategy has been used in individuals without amputation, [2] only anecdotal data is available for individuals with amputation.[3]

To examine the relationship between step length symmetry and VO<sub>2</sub> during split-belt treadmill walking for individuals with and without unilateral TTA.

Eighteen individuals (10 with TTA and 8 without) completed a single split-belt treadmill test according to established testing procedures.[4] During testing participants walked with the belts moving at the same speed before (baseline: 0.5m/s) and after (post: 0.5m/s) a split-belt (SB) condition in which one belt moves 3 times faster than the other (fast 1.5m/s, slow: 0.5m/s). VO<sub>2</sub> and step length symmetry (SYM) were calculated for each walking condition (Baseline, Early SB, Late SB, Early Post, and Late Post). Pearson correlation coefficients were calculated between VO<sub>2</sub> and SYM for each condition and for the magnitude change from early to late during SB and Post conditions.

#### **RESULTS**

All participants exhibited improvements in SYM and VO<sub>2</sub> from Early SB to Late SB walking, and Early Post to Late post. Correlations were generally poor between VO<sub>2</sub> and SYM for both groups (Table 1). A moderately strong correlation was found between the magnitude change from Early SB to Late SB in individuals without TTA (r=0.79), however this correlation was poor among those with TTA (r=0.19).

## **DISCUSSION AND** CONCLUSION

Improved step length symmetry was associated with improvements in VO<sub>2</sub> only in those without TTA. In persons with TTA, the SB condition may have perturbed walking such that other factors, such as stability, may have been prioritized over SYM or VO<sub>2</sub>. Table 1. Correlations between VO<sub>2</sub> and SYM values for individuals with and without TTA, by condition.

	Individuals with TTA (r)	Individuals without TTA (p-value)	r	p-value
Baseline	0.05	0.89	0.29	0.49
Early SB	0.04	0.92	0.59	0.13
Late SB	0.29	0.42	0.42	0.30
Early Post	0.34	0.33	0.08	0.85
Late Post	0.05	0.90	0.03	0.94
Change Early SB – End SB	0.19	0.60	0.79	0.02
Change Early Post- Late Post	0.28	0.43	0.01	0.98

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## **ACKNOWLEDGEMENTS**

Funding: CTSA number KL2TR000057 from the National Center for Advancing Translational Sciences, and BADER Consortium via CDMRP Award number W81XWH-11-2-0222.



#### 1.1.4.f

## A Method to Identify Patient-Specific Characteristics of Gait in Individuals with Unilateral Transtibial Amputation

Maria Bisele<sup>1</sup>, Martin Bencsik<sup>1</sup>, Martin G. C. Lewis<sup>2</sup>, Cleveland T. Barnett<sup>1</sup>
Nottingham Trent University, Nottingham, United Kingdom. <sup>2</sup>University of Derby, Derby, United Kingdom

#### **BACKGROUND**

Prosthetic rehabilitation is a complex procedure. The ability to walk well with a prosthesis increases the likelihood of using it following rehabilitation,[1] but the number of people who can use a prosthesis efficiently is 49%.[2] Extensive research has been done to understand group effects of lower-limb amputee (LLA) gait, whilst clinical practice is patient-specific. Thus, being able to identify patient-specific gait characteristics could help translate information from research into clinical practice, potentially improving treatment outcome.

#### AIM

To determine patient-specific gait characteristics of an individual with unilateral-transtibial amputation (UTTA).

## **METHOD**

Eleven UTTAs (age 50±12years; height 1.7±0.1m; mass 83.94±13.59kg) and thirty able-bodied individuals (ABs) (age 39±20years; height 1.7±0.1m; mass 73.76±14.02kg) provided informed consent to participate. Participants walked along a 15m walkway at self-selected walking speed. For all trials, full body marker-set was used to measure gait biomechanics. Kinetic and kinematic data were captured at 1000 Hz and 100 Hz, respectively. Principal component analysis (PCA) was applied to twenty biomechanical parameters (Figure 1) to identify patient-specific gait characteristics of a UTTA when compared to a group of ABs.

#### **RESULTS**

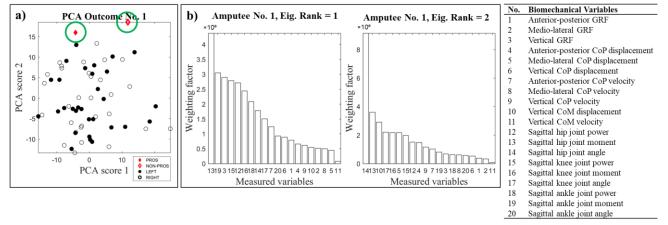


Figure 1. Exemplar PCA outcome (a) and Eigenspectrum (b) of gait in the comparison between a UTTA and ABs. In the Eigenspectrum high bars showed high variability during the comparison and low bars showed low variability. The numbers underneath each bar correspond to the parameters presented in the table.

The UTTA in the example above does not deviate from AB gait in PC1 but deviates in PC2. This is illustrated by the prosthetic (PROS) and the intact (NONPROS) limbs which sit at the edge of the cloud of AB limbs (LEFT and RIGHT). The Eig. Rank 2 shows that parameter number 14, 13 and 10 are the causal factors for this deviation, corresponding to sagittal hip joint angle and moment and vertical centre of mass displacement.

## **DISCUSSION AND CONCLUSION**

Using PCA, patient-specific gait characteristics of a UTTA could be identified. In a clinical setting, such a method can be used to identify parameters that can be targeted, tailoring treatment and thus increasing the prospects of prosthetic use after rehabilitation.

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### 1.1.4.q

## Centre of Pressure Progression Velocity as a Measure of Sagittal Prosthetic Alignment in Transtibial Gait

Alexandria Tsimiklis<sup>1,2,3</sup>, Martin Robertson<sup>4,5</sup>, Stacey R. Zhao<sup>1,2</sup>, Matthew Faris<sup>4</sup>, Tim Bryant<sup>1,2</sup>

<sup>1</sup>Mechanical and Materials Engineering, Queen's University, Kingston, Canada. <sup>2</sup>Human Mobility Research Centre, Kingston Health Sciences Centre, Kingston, Canada. <sup>3</sup>Clinical Methods in Orthotics and Prosthetics, George Brown College, Toronto, Canada. <sup>4</sup>Physical Medicine and Rehabilitation, Queen's University, Kingston, Canada. <sup>5</sup>V2 Innovations, Inc., Kingston, Canada

#### **BACKGROUND**

Few metrics are available to describe lower limb prosthetic system performance during clinical dynamic alignment.[1, 2] One potential approach is the observation of the "dead spot" phenomenon (DSP), defined as an interruption of forward progression during stance as measured by the centre of pressure (COP) velocity.[3] Of significance, specific features of DSP in the rearfoot are associated with reduced energy efficiency and changes in gait symmetry.[4]

#### **AIM**

The study assessed whether COP progression velocity reflected clinical goals of dynamic alignment by measuring rearfoot and forefoot DSP in eight unilateral transtibial prosthesis users under two alignment conditions.

#### **METHOD**

COP location for both limbs was measured during gait at self-selected speeds using a customized portable force plate system (Bertec, Inc, OH, USA).[5] Experimental conditions corresponded to the beginning (pre-alignment) and end (post-alignment) of the dynamic alignment process of the clinician-investigator (MR).[5] The COP velocity in the forward direction (mm/s) was determined using the methods of Klenow et al.[3] The DSP region was defined when COP velocity fell below 60% of the COP mean sagittal velocity and within two target regions: rearfoot (10-50% stance) and forefoot (60-80% stance).[3, 5] The

DSP progression metric was quantified as shown in Figure 1.

#### **RESULTS**

The post-alignment condition was the endpoint of dynamic alignment, where measured DSP progression represented clinically acceptable values specific to the participating Prosthetist. Maximum DSP progression of 4.0mm was observed in the rearfoot of the prosthetic limb, based on a 95% confidence interval across all subjects. DSP progression above this value was statistically significant for this clinician, and provides a target threshold for DSP progression during dynamic alignment. Rearfoot DSP progression showed increased symmetry between intact and prosthetic limbs in post-alignment, as compared to pre-alignment. Clinically significant thresholds of 3.5mm were established for rearfoot DSP progression asymmetry. Intact limb forefoot DSP progression significantly increased with alignment, averaging 4.0 mm. In the prosthetic limb, forefoot DSP progression variably increased or decreased in response to the alignment strategy for the individual subject.

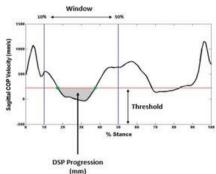


Figure 1 Quantification of DSP progression from sagittal COP velocity in the rearfoot.

The area below the critical velocity in the DSP region corresponds to the COP displacement in mm during the dwell in forward velocity and termed DSP progression. A similar method is used to determine forefoot DSP progression.

## **DISCUSSION AND CONCLUSION**

DSP progression is sensitive to changes in dynamic alignment and reflects the clinical objectives for prosthetic foot progression of the participating Prosthetist. This may be a tool for the documentation of outcomes for a specific alignment protocol, which can help establish evidence-based practices. Future work will investigate improved feasibility of clinical integration and should consider developing rigorous nomenclature for this phenomenon. For example, rearfoot DSP is thought to inhibit smooth gait and, conversely, forefoot DSP is thought to promote propulsion.

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## **ACKNOWLEDGEMENTS**

Motion Specialties (participating Prosthetic facility), NSERC (funding), Megan Saftich and Sarah Coles (technical support), Gordon Ruder and Amy Richardson (revisions).



# Free Paper Session Prosthetics: Upper Limb – Control

#### 1.1.5.a

## Performance and Satisfaction with Intuitive Multifunctional Hand Prosthesis Control

Andreas Hahn<sup>1</sup>, Ivana Popovic<sup>1</sup>, Sebastian Amsuess<sup>1</sup>, Birgit Bischof<sup>1</sup>, Thomas Fuchsberger<sup>2</sup>
<sup>1</sup>Otto Bock Healthcare Products GmbH, Vienna, Austria. <sup>2</sup>Department of Plastic and Reconstructive Surgery, Hand Surgery, SOB-Kliniken AG, Traunstein, Germany

#### **BACKGROUND**

Prosthetic technology for upper limb prosthetic fitting has significantly advanced. As an innovative prosthetic control technique, pattern recognition (PR) control uses many electrodes and intuitive movement mapping to control several movements seamlessly.[1] The majority of previous PR studies have been performed on non-amputee subjects and only virtual arms had been controlled with PR systems instead of real prostheses.[2] Information on prolonged home-use of such devices is still sparse.

#### **AIM**

We aim to explore the performance and satisfaction of transradial amputees as well as to obtain feedback from certified prosthetists and trainers when transitioning from prosthetic systems with conventional control (CC) to the equivalent system with pattern recognition (PR) Control.

#### **METHOD**

Transradial amputees currently wearing prosthetic systems with CC, single opening/closing hand and active wrist rotation were enrolled. Each participant underwent a structured training process during transition. Functional assessments were 1) with CC prosthesis (baseline), 2) with the PR prostheses after fitting (1st follow-up), 3) after 1 month of PR home use (2nd follow-up), and 4) with re-fitted CC prosthesis (3rd follow-up). Performance-based (Modified Box and Blocks test (mB&B), and Clothespin Relocation Test) and self-reported assessments (DASH; project specific questions) were taken. The fitting and training process were rated by certified prosthetists and trainers by scoring points between 1 (very good) to 5 (very bad).

## **RESULTS**

Six subjects were enrolled and analyzed for 1st FU, 5 for 2nd FU. Subjects were predominantly male (83%), mean age 45 years ( $\pm$  16 years). etiology all trauma. All subjects were fitted with PR during the first visit. The fitting and training process score was 1.7  $\pm$  0.34; training process score 1.7  $\pm$  0.46. The clothespin test, was improved immediately after PR fitting and remained consistent after 1 month of PR home use (vertical to horizontal bar +34%; horizontal to vertical bar +18%. mB&B, times increased 19s ( $\pm$  31.7s) immediately after fitting and remained 9s ( $\pm$  16.4s) above baseline after 1 month (Fig.1). No difference was observed in DASH. 50% of participants would prefer PR over CC.

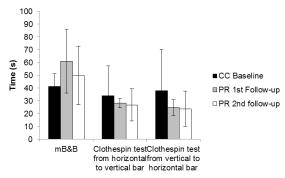


Figure 1: Performance-based tests conducted at baseline with CC, and at 1st and 2nd follow- up with PR

## **DISCUSSION AND CONCLUSION**

PR improved the unilateral gross manual dexterity and ability to control two DoFs. The longer patient accommodation time and optimized product development might minimize mild problems in fine and gross motor movements observed during the first month of PR home-use.

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## **ACKNOWLEDGEMENTS**

AH, IP, SA and BB are full time employees at Otto Bock. The study was sponsored by Otto Bock.



## 1.1.5.b

## Serious Game Training versus Conventional Training in Machine Learning Controlled Prosthetic Hands: Results on Functional Outcomes

Morten B. Kristoffersen<sup>1</sup>, Andreas W. Franzke<sup>1</sup>, Alessio Murgia<sup>2</sup>, Corry K. van der Sluis<sup>1</sup>, Raoul M Bongers<sup>2</sup> University of Groningen, University Medical Center Groningen, Department of Rehabilitation Medicine, Groningen, Netherlands. <sup>2</sup>University of Groningen, University Medical Center Groningen, Center for Human Movement Sciences, Groningen, Netherlands

#### **BACKGROUND**

User training is required to operate machine learning controlled hand prostheses. The goal of training is to make myoelectric activation patterns more distinct from each other and more repeatable. Conventional user training is based on trial and error and is dependent on a phantom hand sensation, which might limit its efficacy. As an alternative, we propose to train using a serious game paradigm that gives feedback on pattern distinctiveness.

#### $\Delta IM$

The goal of this study is to compare serious game training for machine learning controlled hand prosthesis with conventional training using functional test outcomes.

#### METHOD

Participants wore a plaster socket with 8 electrodes. The Michelangelo hand was used and a neural-network regressor calculated the control commands. Participants were assigned to either game or conventional training. Game training consisted of controlling an avatar using a direct mapping from electrode orientation to avatar direction. Each movement that successfully moved the avatar in a certain direction was considered distinct and was used to control the prosthesis. Conventional training followed the principles of Powell.[1] Outcome measures were the spherical subset of the SHAP test, the clothespin test and myoelectric pattern distinctiveness (interclass distance). Results are reported using the mean ± SEM without statistical testing.

#### **RESULTS**

Six individuals with trans-radial level limb absence participated in 1 fitting session, 2 pre/post-test sessions and 7 training sessions. Preliminary results indicate that for the game training group the SHAP spherical score increased from  $20.2 \pm 1.3$  to  $24 \pm 5.15$  and for the conventional group from  $9.8 \pm 4.6$  to  $23.76 \pm 3.68$  from pre- to post-test respectively. Clothespin time for the game training group decreased from  $1:37 \pm 0:09$  minutes to  $1:33 \pm 0:04$  minutes and for the conventional group it decreased from  $2:24 \pm 0:16$  to  $1:11 \pm 0:09$  minutes. Interclass distance from pre- to post-test increased by  $10\% \pm 7.5\%$  for the game group, while for the conventional group it decreased by  $10\% \pm 12.5\%$ .

## **DISCUSSION AND CONCLUSION**

Preliminary results suggest that both groups improved after training, but that the conventional group improved the most. This might be due to pre-test differences, since the conventional group had very low baseline scores. In the game group interclass distance increased over game playing, showing that the game leads to more distinct patterns. However, the conventional group increased their functional performance while decreasing their interclass distance. This suggests that interclass distance might not fully reflect gains in functional performance.

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## **ACKNOWLEDGEMENTS**

This work has received funding from the European Unions's Horizon 2020 programme under grant agreement number 687795 (Project INPUT).



#### 1.1.5.c

## Initial Results Following Targeted Muscle Reinnervation in Individuals with a Transradial Amputation

Todd Kuiken<sup>1,2</sup>, <u>Kristi Turner</u><sup>1</sup>, Laura Miller<sup>1,2</sup>, Levi Hargrove<sup>1,2</sup>, Ann Simon<sup>1,2</sup> <sup>1</sup>Shirley Ryan Abilitylab, Chicago, USA. <sup>2</sup>Northwestern University, Chicago, USA

#### **BACKGROUND**

After transradial amputation, replacing a missing hand with a multi-articulating hand capable of different hand grasps hand remains challenging. Targeted muscle reinnervation(TMR), a surgical technique where amputated nerves are transferred to residual muscles, in combination with pattern recognition, an advanced control method to decode natural muscle contractions, can provide improved prosthesis control for high-level amputations.[1] A recent clinical trial has shown that TMR surgery at the time of amputation can reduce amputee-related phantom and residual limb pain.[2]

#### AIM

The study's goal was to perform and evaluate the benefits of targeted muscle reinnervation in individuals with a transradial amputation.

#### **METHOD**

Four individuals with a unilateral transradial amputation were fitted with a Touch Bionics i-limb Ultra Revolution hand, passive wrist rotation, and a Coapt Complete Control System with pattern recognition. They participated in two 8-week home trials pre- and 6 months post-TMR surgery. For TMR surgery, the ulnar nerve to the flexor carpi ulnaris muscle and the median nerve was transferred to either the flexor digitorum superficialis or brachioradialis muscle. Following each home trial, individuals performed a suite of outcome measures to measure prosthesis control. Additionally, self-reported level of phantom limb pain and sensations were recorded pre- and post-TMR surgery.

#### **RESULTS**

All participants were successful in performing various hand grasp patterns with their residual limb musculature to control the multi-articulating hand prosthesis at home with pattern recognition control both pre- and post-TMR surgery. They reported performing similar activities of daily living with the study prosthesis during both 8-week home trials. At 6-12 months post-TMR surgery, individuals reported decreased incidence of phantom limb pain and/or neuroma pain as well as increased phantom limb movements and sensations. The Jebsen-Taylor Hand Function test showed an improvement post-TMR surgery compared with pre-surgery measures (paired-t-test, p<0.05). Other outcomes measures including the Box and Blocks test and Southampton Hand Assessment Procedure (SHAP) did not show a significant change.

## **DISCUSSION AND CONCLUSION**

Individuals reported clinical benefits of TMR surgery including pain reduction and increased phantom hand movements. While not all outcome measures showed post-TMR improvements, individuals maintained their level of function post-TMR surgery. Limitations include that results are only from four individuals and the prosthesis was only used for 8 weeks at home prior to testing. We will continue to evaluate subjects for the TMR surgical benefits following transradial amputation.

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## **ACKNOWLEDGEMENTS**

This work is being supported by the National Institutes of Health NIH R01HD081525.



#### 1.1.5.d

## Motor Coordination in Closed-Loop Prosthetic Control via Implanted Electrodes and Osseointegration

<u>Enzo Mastinu</u><sup>1</sup>, Leonard Engels<sup>2</sup>, Francesco Clemente<sup>2,3</sup>, Mariama Dione<sup>4</sup>, Paolo Sassu<sup>5</sup>, Oskar Aszmann<sup>6</sup>, Rickard Brånemark<sup>4</sup>, Bo Håkansson<sup>7</sup>, Marco Controzzi<sup>2</sup>, Johan Wessberg<sup>4</sup>, Christian Cipriani<sup>2</sup>, Max Ortiz-Catalan<sup>1</sup>

<sup>1</sup>Chalmers University of technology, Göteborg, Sweden. <sup>2</sup>Scuola Superiore Sant'Anna, Pisa, Italy. <sup>3</sup>Prensilia SRL, Pontedera, Italy. <sup>4</sup>Gothenburg University, Göteborg, Sweden. <sup>5</sup>Sahlgrenska University Hospital, Göteborg, Sweden. <sup>6</sup>Medical University of Vienna, Vienna, Austria. <sup>7</sup>Chalmers University of Technology, Göteborg, Sweden

#### **BACKGROUND**

A human-machine interface based on direct skeletal attachment of the prosthesis, and implanted electrodes on nerves and muscles, has been proposed and proven to be an effective alternative to conventional prosthetic solutions.[1] However, recent findings indicate that such a osseo-neuromuscular interface alone does not fully normalize motor coordination. Despite the superior prosthetic control provided, incidental sensory feedback such as visual, auditory, and osseoperceptive do not appear sufficient for restoring natural grasp behavior in amputees.[2]

#### AIM

We investigated if closed-loop control via somatotopically appropriate neural sensory feedback could restore grasping motor coordination and task-dependent internal model in subjects with upper limb amputations.

#### METHOD

Three subjects with transhumeral amputation were implanted with said osseo-neuromuscular interface. The Pick-and-Lift task with a sensorized object was used to assess motor coordination during routine grasps. We measured the temporal coordination between the grip force (GF) and the load force (LF) applied to the object. Force sensors on the robotic hand provided the subjects with real-time tactile sensory feedback. We employed a hybrid feedback (HYBR), which combines continuous modulation of the current amplitude of pulses delivered at a constant frequency with short bursts of pulses at higher frequency in correspondence with the events of touch and release. The HYBR was compared to the conventional no-feedback control condition (NOFB).

#### **RESULTS**

The HYBR feedback modality allowed faster executions and a more linear relation between GF and LF (Fig.1). This applied to two out of three subjects, while the third one showed highly coordinated control regardless of feedback. The delay between the instants when the GF and the LF reached 50% of the LF at lift-off, significantly shortened (p<0.001) from 226:350 ms (median:IQR) in the NOFB mode to 176:122 ms in HYBR, meaning 22% reduction of the median delay (Fig. 1). Moreover, HYBR compared to NOFB resulted in a reduction of the median load phase duration from 427:445 ms to 320:172 ms (21%, p<0.001), of the median release phase duration from 567:478 ms to 525:440 ms (7%), and of the median trial duration from 2.61:0.92 s to 2.19:0.49 s (16%, p<0.001).

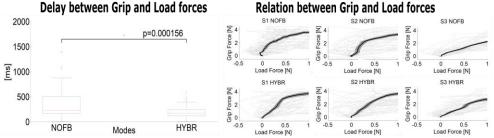


Figure 1. Temporal delay and coordination between grip and load forces.

### **DISCUSSION AND CONCLUSION**

We analyzed the benefit of tactile sensory feedback via direct neural stimulation for grasping motor coordination. The potential of using the proposed HYBR tactile feedback for restoring motor skills and mature grasp behavior in patients with transhumeral amputation was confirmed.

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#### 1.1.5.e

## Cognitive Load and Compensatory Movement in Learning to use a Multi-Function Hand

Helen Lindner<sup>1</sup>, Wendy Hill<sup>2</sup>, Liselotte Norling Hermansson<sup>3,4</sup>, Achim J. Lilienthal<sup>5</sup>

School of Health Sciences, Örebro University, Örebro, Sweden. <sup>2</sup>Institute of Biomedical Engineering, UNB, Fredericton, Canada. <sup>3</sup>University Health Care Research Centre, Faculty of Medicine and Health, Örebro University, Örebro, Sweden. <sup>4</sup>Dept. of Prosthetics and Orthotics, Faculty of Medicine and Health, Örebro University, Örebro, Sweden. <sup>5</sup>School of Science and Techology, Örebro University, Örebro, Sweden

#### **BACKGROUND**

Recent technology provides increased dexterity in multi-function hands with the potential to reduce compensatory body movements. However, it is challenging to learn how to operate a hand that has up to 36 grips. While the cognitive load required to use these hands is unknown, it is clear that if the cognitive load is too high, the user may stop using the multi-functional hand or may not take full advantage of its advanced features.

#### AIM

The aim of this project was to compare cognitive load and compensatory movement in using a multi-function hand versus a conventional myo hand.

#### **METHOD**

An experienced prosthesis user was assessed using his conventional myo hand and an unfamiliar iLimb Ultra hand, with two-site control and the same wrist for both prostheses. He was trained to use power grip, lateral grip and pinch grip and then completed the SHAP test while wearing the Tobii Pro 2 eye-tracking glasses. *Pupil diameter* (normal range: 2-4mm during normal light) was used to indicate the amount of cognitive load.[1] The *number of eye fixations* on the prosthesis indicate the need of visual feedback during operation. *Dartfish motion capture* was used to track the *maximum angles* for **shoulder abduction** and **elbow flexion**.

#### **RESULTS**

Larger pupils were found in the use of I-limb ultra (2.6-5.6mm) than in the use of conventional myo hand (2.4-3.5mm) during the SHAP abstract light tests. The pupils dilated most often during changing grips, e.g. switching to pinch grip for the tripod task (from 2.7 to 5.6mm). After training of using power grip and pinch grip repeatedly, the maximum pupil diameter decreased from 5.6 to 3.3mm. The number of eye fixations on the I-limb ultra (295 fixations) were also higher than on the conventional myo-hand (139 fixations). Smaller **shoulder** 

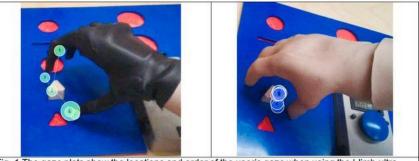


Fig. 1. The gaze plots show the locations and order of the user's gaze when using the I-limb ultra and the conventional myo hand. When using the I-limb ultra, the user looked at the index finger → the tripod wood object → the thumb before grasping (green circles). When using his own conventional myo hand, he looked mainly at the tripod wood object (blue circles).

**abduction** and elbow flexion were observed in the use of I-limb ultra (**16.6**°, 36.1°) than in the use of conventional myo hand (**57**°, 52.7°).

#### **DISCUSSION AND CONCLUSION**

Although it is cognitively demanding to learn to use **a multi-function hand**, it is possible to decrease this demand with adequate prosthetic training. Our results suggest that using a multi-function hand enables reduction of body compensatory movement, however at the cost of a higher cognitive load. Further research with more prosthesis users and other multi-function hands is needed to confirm the study findings.

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#### **ACKNOWLEDGEMENTS**

This project was supported financially by Norrbacka-Eugenia Foundation, Promobilia Foundation and Örebro University.



## 1.1.5.f

## Myoelectric Implant Records Low Noise EMG for Control of Prostheses

<u>Daniel McDonnall</u>, Charla Howard, Brian Crofts, Isaac Myers, Scott Hiatt Sync Bionics, Salt Lake City, USA

#### **BACKGROUND**

Despite the increased availability of advanced myoelectric prosthetic arms, poor control signals limit widespread adoption of advanced prostheses. We are developing a myoelectric implant to provide a high number of reliable, low-noise channels to improve the control of prostheses. The system comprises a hermetic implanted module with multiple intramuscular leads with a total of 32 electrodes. The design allows for independent placement of each lead, providing access to both deep and superficial muscles.

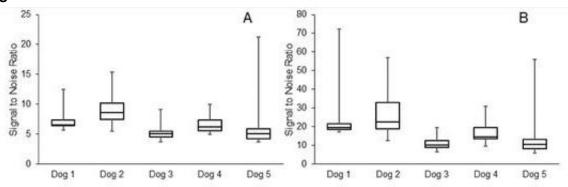
#### AIM

The safety and function of the implanted system was tested in a 6-month animal study to confirm the device successfully transmits high-quality, low-noise EMG signals that can be used to control a prosthetic device.

#### METHOD

Five adult canines were implanted unilaterally in the forelimb. Electrode leads were inserted into triceps and deltoideus muscles, and the electronics package was implanted subcutaneously near the scapula. After 6-months, EMG was collected from each animal. The signal-to-noise ratio (SNR) of the EMG signal was evaluated for each device using a double threshold (time and amplitude) method.[1] The start of a muscle activation event was identified when the signal was greater than 2.0 times the noise of that channel for 100 ms. The average, including the low amplitude onset and relaxation periods, and peak SNR values for each device are reported.

#### **RESULTS**



At the end of the 6-month trial all channels on all implants were still functional. We found that each device had a high, dynamic SNR across all channels. When calculated with low amplitude onset and relaxation periods, the average device SNR was between 5 and 9 (Figure 1A). However, when the SNR was calculated from the peak of each event the SNR was much larger (Figure 1B), illustrating the dynamic range of the signal.

## **DISCUSSION AND CONCLUSION**

These findings demonstrate the implant can record low-noise EMG suitable for control of a prosthetic limb. The low noise and high relative amplitude of the signal (high SNR) measured with the implanted device will allow decode algorithms to rapidly detect the start of muscle activation events and convey this information to the prosthetic limb. The high-quality EMG signal was due to the implantation of the sensors which eliminated many of the physiological factors that reduce the quality of surface EMG.

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#### **ACKNOWLEDGEMENTS**

Funding from NIH and DARPA SBIR grants and the DARPA HAPTIX project.



## 1.1.5.g

## User-Tunable Gain and Mapping Selection for Myoelectric Prostheses to Optimize Cost of Effort, Time, and Reliability

Anjana Gayathri Arunachalam, Kevin Englehart, <u>Jon Sensinger</u> University of New Brunswick, Fredericton, Canada

#### **BACKGROUND**

When calibrating myoelectric prostheses, clinicians must choose the control paradigm (position or velocity control) and gain. These choices balance trade-offs between the things the end-user cares about, such as time, effort, and reliability. For example, choosing a high gain requires lower effort and faster time, but at the expense of reliability. Some alternative control paradigms, such as squared velocity control, can improve all three things at once, but there may be even better solutions, and the choice is likely user-dependent.

#### AIM

The aim of this study is to demonstrate that within a range of control paradigms, there exist optimum solutions that may be tuned by the clinician based on the things the end-user cares about, such as effort, time, or reliability.

#### **METHOD**

The relationship between costs such as time, effort, and reliability and how much people care about them is well quantified across a series of studies by ourselves and others by inductively mapping cost-functions. In this study, we use those functions to calculate the total cost for a particular set of gains and mappings. Our total cost includes a hyperbolic cost of time and quadratic costs for effort and reliability, along for penalties for not reaching the desired trajectories or for finishing while still moving. Mappings of velocity =  $a_1$ \*position<sup>b1</sup>+ $a_2$ \*control-signal were optimized using global-optimization of control-signal splines with free-time to reach two targets, across a discrete range of mapping coefficients.

### **RESULTS**

Four sample conditions were evaluated: equal weights for effort, time, and reliability, along with prioritizing each one more than the others. User's control signals and resulting trajectories are shown for two different targets in Figure 1. Note that depending on what users prioritized, the resulting optimal control signals and prostheses movements were different. Also note that optimal solutions often involved multiple movements — something commonly observed in practice.

#### Target 1: Optimal Control Signal Target 1: Optimal trajectory 300 Device trajectory 200 control 100 400 600 800 1000 800 1000 Time (in ms) Target 2: Optimal Control Signal Target 2: Optimal trajectory 500 를 400 다 300 10 200 5 100 1500 2000 Time (in ms) Risk Time (in ms) -Effort Equal Time

Figure 1. Optimal control signals and resulting trajectory, for virtual-dynamics optimized for four different priorities: equal weighting, prioritizing low effort, prioritizing low time, and prioritizing low-risk.

#### **DISCUSSION AND CONCLUSION**

This study has demonstrated that different priorities of individuals produce

different optimal virtual dynamics. Clinicians currently iteratively tune gains to try to balance competing needs of effort vs reliability. Our method could be used to create an onboard database, allowing clinicians to simply slide a triangular scale prioritizing effort vs reliability vs time, and allowing the settings to be automatically tuned to achieve the best blend of these preferences.

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#### **ACKNOWLEDGEMENTS**

This work was funded by the New Brunswick Innovation Foundation and the Natural Sciences and Engineering Research Council of Canada.



# Free Paper Session Outcome Measurements – Population

#### 1.1.6.a

## On the Use of Health Economic Instruments to Evaluate Prosthetic Services

Andreas Hahn<sup>1</sup>, Arne Schlausch<sup>2</sup>, Pawel Maciejasz<sup>2</sup>

Otto Bock Healthcare Products GmbH, Vienna, Austria. Otto Bock Healthcare GmbH, Duderstadt, Germany

## **BACKGROUND**

Health technology assessment and health economic (HE) value proposition play increasingly important roles in modern health care systems. Demographic change forces public health care to allocate resources where most value is being created. Health economic arguments shall become increasingly vital. The recent inquiry of the AHRQ with respect to lower limb prosthetics is a manifestation of this trend. Despite common perception is the application of specific HE instruments such as EQ-5D-5L very simple, of very reasonable costs and well valuated.

### AIM

We investigate the suitability of EQ-5D-5L to characterize and quantify services provided in CPO practice.

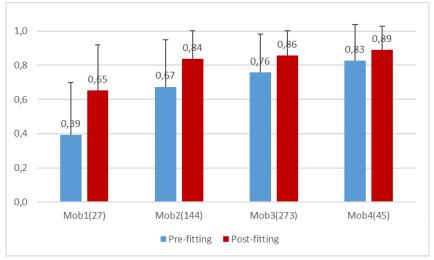
#### **METHOD**

Data were retrieved from 20 prosthetic workshops in Europe and India during routine visits. EQ-5D-5L was applied at subjects first visit and post intervention. If the subject returned within the observation period for any reason, the status was retrieved also. Interventions were stratified for regarding interventions on the socket and as applicable, prosthetic knee or foot components as well as their combinations.

#### **RESULTS**

Data were retrieved from 489 subjects, 77% male, average age 44.8 +/- 20.2. Amputation levels were hip disarticulated (8), transtibial (235), transfemoral (211), knee disarticulated (21) and partial foot (6) 38 subjects

had double amputations. Etiologies were trauma (55%), v.d. (20%), tumor (9%), congenital (4%), osteomyelitis (3%), others (7%), not stated (1%). Mobility ratings (MOBIS grading) were MG1: 27 subjects, MG2: 144 subjects, MG3: 273 subjects and MG 4: 45 subjects. Significant changes can be observed in all five dimensions of EQ-5D-5L. The changes remain significant for a large number of interventions. We also stratified for mobility grading, yielding an over-proportional and sustained improvement for lower mobility grades (Fig 1).



### **DISCUSSION AND CONCLUSION**

QALYs have been used with advanced hydraulic microprocessor-controlled prosthetic components for the quantification of the value added [1,2,3]. Now this concept is extended to assessing P&O services. We find high sensitivity in all dimensions. The instrument qualifies for stratification. Absolute values are comparable to those derived in [1,2,3]. It is easy to induce that P&O services are cost efficient. Further investigations are required to fully explore the potential of the technique.

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#### **ACKNOWLEDGEMENTS**

All authors are employees of Otto Bock Healthcare GmbH.



#### 1.1.6.b

## Development of a Multi-Criteria Decision Analysis Model for O&P

Sarah Chang, David Boone
Orthocare Innovations, LLC, Edmonds, USA

#### **BACKGROUND**

There is a critical need to help clinicians improve decision-making when matching patients with appropriate devices for each patient's activities of daily living (ADLs). Patients' needs are multifactorial, and a single measure will not adequately reflect the complexity of rehabilitation outcomes. Clinicians ultimately aim to optimize patients' function for real-world use, yet have minimal contact with patients' real-world environments.

Beside clinician expertise, the orthotics and prosthetics (O&P) field does not regularly employ quantitative analyses to assist in decision-making.

#### AIM

The purpose of this study was to develop a clinically useful methodology that assesses patients' real-world function, integrates a wide range of outcome measures, and automates processing of this patient-centered information to inform clinicians about patients' function in ADLs.

	Domain			Weight	Score	Score	Score	Score
Patient		General Satisfaction	40%	12%	67	8.0	85	10.2
Perception	30%	Utility	30%	9%	42	3.8	89	8.0
Perception		Social Burden	30%	9%	70	6.3	90	8.1
Bio- mechanical Efficiency		Temporal Symmetry	35%	7.7%	30	2.3	75	5.8
	22%	Prosthesis Dynamics	35%	7.7%	55	4.2	81	6.2
	Same :	Socket Moment/ Load	30%	6.6%	80	5.3	84	5.5
Real-World Activity	23%	Ave Steps per Day	20%	4.6%	45	2.1	60	2.8
		Medium Step Rate	40%	9.2%	85	7.8	85	7.8
		Peak-20	40%	9.2%	50	4.6	50	4.6
Clinical Expertise	25%	Patient Capabilities	50%	12.5%	40	5.0	75	9.4
		Goals for Patient	50%	12.5%	63	7.9	70	8.8
Total	100%	Total Weig	hted Score	100.0%	Score 1	57.3	Score 2	77.2

Weight of

Table 1. Example clinical MCDA for two prosthetic devices

#### **METHOD**

A methodology called multi-criteria decision analysis (MCDA) has been

successfully applied in business and government settings and recently applied in healthcare to aid decision-making in diagnosis, treatment, and health technology assessment.[1] While MCDA is not new methodology, applying MCDA in the O&P field for automating and providing information in one consolidated visualization to the clinician that allows for actionable patient care is novel. To create a holistic decision-making tool, we incorporate four distinct criteria, or domains of outcomes into MCDA: (1) patient perception, (2) "biomechanical efficiency", (3) real-world activity, and (4) clinical expertise.[2] Together, these fundamental domains constitute a very complete picture of patient function in ADLs.

## **RESULTS**

The four domains' data come from validated questionnaires, multiple wireless sensors, and clinician input. Each domain has several parameters that are measured, fused into a single analysis of the patient's function, and normalized to 100 to simplify clinician and patient interpretations. MCDA attributes specific weights to each domain and related parameter. The sensors and surveys result in a parameter score that is multiplied by the weighted-parameter, resulting in a weighted-parameter score. Weighted-parameter scores are then summed to determine the single global score. A higher score suggests better function based on the four domains. A comparison of the single global score between different devices can inform which device may allow optimal function for that patient. Table 1 illustrates an example using the weighted MCDA fusion model, adapted from [3].

## **DISCUSSION AND CONCLUSION**

MCDA has many families of methods [4] and the approach discussed here is only one version. However, once we establish feasibility of a simple MCDA in the O&P field, we can explore alternative methodology options, if necessary, to create stronger and more robust decision-making analyses. Implementing MCDA in the O&P field can help clinicians comprehensively quantify patient performance with different devices, enable evidence-based decisions in device prescription, and engage patients in their clinical care.

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### **ACKNOWLEDGEMENTS**

The authors are employees of Orthocare Innovations, and the completed work was supported by internal research and development funds.



#### 1.1.6.c

## Initial Steps Toward a National Limb Loss and Preservation Registry

Kenton Kaufman<sup>1</sup>, Kathie Bernhardt<sup>1</sup>, Hilal Maradit Kremers<sup>1</sup>, Kristina Finney<sup>2</sup>, Shawn Murphy<sup>3</sup>, Fred Cecere<sup>3</sup>

Mayo Clinic, Rochester, MN, USA. <sup>2</sup>American Academy of Orthopedic Surgeons, Rosemont, IL, USA. <sup>3</sup>Thought Leaderrship U& Innovation Foundation, McLean, VA, USA

#### **BACKGROUND**

Despite the significant burden associated with limb loss, there is paucity of evidence on effective practices and technologies in this population. Published research studies typically rely on administrative data sources, hospital discharge statistics, or small single-center studies with limited longitudinal follow-up. Although limb loss is a common outcome measure in studies that evaluate the effectiveness of diabetes and peripheral arterial disease care, little is known about the effectiveness of practices and technologies following limb loss.

#### AIM

Establish a national Limb Loss and Preservation Registry (LLPR) in the USA which is designed to standardize, measure, and report patient outcomes data, support evidence-based decision making, enhance health care delivery, and establish and disseminate best practices.

#### **METHOD**

In order to include a complete and demographically diverse data set, the LLPR is designed (Figure 1) to obtain and link data from hospitals, clinicians, and patients to assess the effectiveness of different care approaches and timing of specific care procedures to enhance patient-centered clinical decision-making. Data elements have been selected. The data elements reflect characteristics of the individuals, interventions, and outcomes. Pilot data collection has begun from hospitals. The knowledge gained from the pilot phase will inform decisions for the full scale production version.

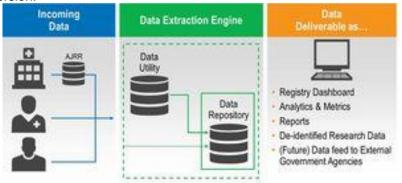


Figure 1. Notional Data Flow Diagram

#### **RESULTS**

The LLPR is an organized system designed to make critical data on Limb Loss and Preservation available to scientists, clinical researchers, hospitals, clinics and individual providers, academia, patients, health-related industries, and the federal government. The comprehensive national registry will allow the capture of critical information related to the causes, processes of care, and outcomes of more than 500 amputations per day occurring in the United States. It provides the capability to evaluate disparities in access to care, care processes, and care delivery across geographic, demographic, etiological, and economic sectors.

#### **DISCUSSION AND CONCLUSION**

Data collection from individuals with limb loss and preservation of all ages, ranging from pediatrics to geriatrics, treated throughout the nation will afford an opportunity to fill data gaps for patient subgroups. Registry data will enrich research and education opportunities, have a positive impact on patient outcomes, and potentially reduce long-term care costs across all geographic, demographic, and economic sectors. With appropriate research questions and data acquired through the continuum of care, marked improvement in outcomes can be achieved.

## **ACKNOWLEDGEMENTS**

Funding provided by National Institute of Child Health and Human Development contract no. HHSN275201800005I.



#### 1.1.6.d

## Health Economic Evaluation in Prosthetics: A Systematic Review

Leigh Clarke<sup>1,2</sup>, Michael Dillon<sup>1</sup>, Alan Shiell<sup>3</sup>

<sup>1</sup>Discipline of Prosthetics and Orthotics, Department of Physiotherapy, Podiatry, Prosthetics and Orthotics, School of Allied Health, La Trobe University, Melbourne, Australia. <sup>2</sup>The Australian Orthotic Prosthetic Association, Melbourne, Australia. <sup>3</sup>Department of Public Health, School of Psychology and Public Health, La Trobe University, Melbourne, Australia

#### **BACKGROUND**

Health economic evaluations are essential to support health care policy and investment decisions. To date, orthotic/prosthetic health economic evaluations have focused on discrete components (e.g., prosthetic knee joints) rather than the broader service. Therefore, the contribution to orthotic/prosthetic policy and investment decisions is unclear. There are opportunities to conduct more informative health economic evaluations of the complete orthotic/prosthetic service, informed by a systematic review that can illuminate common biases and method design challenges.

#### **AIM**

To critically appraise the prosthetic health economic evaluation literature to determine evidence gaps, and illuminate method design issues to inform the design of subsequent research.

#### **METHOD**

Search strings related to the intervention (e.g., prosthesis) and health economic evaluations were developed and tested. A comprehensive range of databases were searched. hand-searching and a forward citation search were also conducted. The *Checklist for Health Economic Evaluation Reporting Standards (CHEERS)* and *Consolidated Health Economic Checklist (CHEC) – Extended* were used to appraise the methodological quality and identify sources of bias. Data extraction and appraisal was conducted by two reviewers. Given the heterogeneity of the published literature, a narrative review was conducted to examine factors that most introduce bias.

#### **RESULTS**

The systematic search yielded eight studies pertaining to prosthetics. This included six studies of prosthetic knee units - of which five compared microprocessor controlled- and mechanical- knees, one compared two types of microprocessor

controlled knees and two compared osseointegration prostheses and socket prostheses. Table 1 summarises key features of the studies. Critical appraisal of the literature identified common issues

with the method

Author	Year	Type of HEE	Study design	Research area	Policy or investment decision to be informed
Brodtkorb et.al	2008	Cost-utility	Model	Trans-femoral prosthetic components	C-Leg vs Non-microprocessor controlled knees
Chen et.al	2018	Cost-utility	Model	Trans-femoral prosthetic components	Microprocessor controlled knees vs Non-microprocessor controlled knees
Cutti et al	2017	Cost-utility	Trial	Trans-femoral prosthetic components	C-Leg vs Non-microprocessor controlled knees
Frossard et.al	2018	Cost-utility	Model	Trans-femoral prosthetic socket design	Bone-anchored prosthesis vs socket prosthesis
Gerzeli et.al	2009	Cost-utility	Trial	Trans-femoral prosthetic components	C-Leg vs Non-microprocessor controlled knees
Hansson et.al	2018	Cost-utility	Model	Trans-femoral prosthetic socket design	Bone-achored prosthesis vs socket prosthesis
Highsmith et.al	2016	Cost-effectiveness	Trial	Trans-femoral prosthetic components	Genium knee vs C-Leg
Seelen et.al	2009	Cost-consequence	Trial	Trans-femoral prosthetic components	C-Leg vs Non-microprocessor controlled knees

Table 1: Summary of prosthetic health economic evaluation literature

designs including: selection bias, recall bias, and measurement error, such as inaccuracies in the identification and measurement of costs and benefits, as illustrative examples.

### **DISCUSSION AND CONCLUSION**

The body of prosthetic health economic evaluation literature is small and focussed on high-cost components or interventions for people with transfemoral amputation. A critical examination of common method design issues can assist the design of future prosthetic health economic evaluations to better inform policy and investment decisions requiring cost-effectiveness evidence.



#### 1.1.6.e

## A Core Set For People Following Lower Limb Amputation Based on the International Classification of Functioning, Disability and Health

<u>Jim Xu</u>, Friedbert Kohler, Hugh Dickson Liverpool Hospital, Liverpool, Australia

#### **BACKGROUND**

The International Classification of Functioning, Disability and Health (ICF) was endorsed by WHO in 2001 as a supplement to the International Classification of Diseases (ICD). Due to its large volume, it is difficult to use ICF in its entirety on daily prosthetic care. To facilitate its daily use, ICF Core Set is required. There are many core sets for different health conditions. A core set for lower limb amputation will assist clinician for its application in prosthetic rehabilitation and care.

#### AIM

This research aims to develop an ICF Core Set for persons with lower limb amputation which is simple but comprehensive enough to cover most of the essential aspects of the function and health of persons with lower limb amputation.

#### **METHOD**

The research consists of four components: 1. A systematic literature review the measures used in clinical trial and study. 2. A qualitative study utilizing focus group and individual interview with persons with amputation in two different countries to explore the person's functions and disabilities. 3. A survey of experts around the world exploring the functional themes related to the functioning and health of the person with amputation. 4. A cross sectional empirical study using a validated patient experience questionnaire in two different countries examining functioning and disability allowing verification of the content validity of the ICF categories relevant to the participants

### **RESULTS**

By linking the functional and health to ICF categories using published standardized ICF linking rules we have selected the most common ICF categories from the four components of the research to two lists. There are two different versions of lists of ICF categories from the research. The short list has 24 ICF categories. The longer list has 48 ICF categories.

## **DISCUSSION AND CONCLUSION**

This multi-centers international cooperative study has generated several common themes and a list of common ICF categories. With analysis of this data lists, we had developed two version of the lists of the ICF categories for the cor set. Both have good face and content validity. The final step of the development of the core set for person with lower limb amputation is to present the two lists for the international expert consensus.



#### 1.1.6.f

## The Economic Value of Mobility Provided by Prostheses and Orthoses

#### <u>David Boone</u>

Orthocare Innovations, Seattle, USA. American Orthotic and Prosthetic Associtation, Alexandria, USA

#### **BACKGROUND**

The primary purpose for creation of a prosthesis or orthosis of the lower limb is to enable mobility, including standing, transferring, and walking. It is proposed that to adequately assess the health economic ramifications of alternatives in prosthetic/orthotic care, one should consider the economic value of mobility itself.

#### ΔIM

This research explores some key constructs of the value of mobility: 1) quality impacts; 2) overall direct health care costs affected by P&O care; 3) burden of disease; and 4) indirect value provided by enabling more physical activity.

#### **METHOD**

Three different constructs of valuing mobility were evaluated for the economic benefit derived. Model data were obtained from previously published research on prosthetic outcomes but the methods are applicable to orthotics too. Detailed description of the methods has been published.[1]

The value of **avoidance of negative outcomes** was estimated by an incremental cost effectiveness ratio sue to reduced falls on overall health costs in transfemoral amputees using microprocessor knee control.[2] The **reduction in burden of disease** was evaluated for economic impact transtibial amputees receiving a prosthesis by applying the Disability Adjusted Life Year model. Health Benefits of Increased Physical Activity were valued based on additional metabolic activity from slow walking.

#### **RESULTS**

**Avoidance of Negative Outcomes:** Over a 10-year analysis, compared with non-microprocessor knees, those with microprocessor controls increased quality-adjusted life years (QALYs) by 0.91 for additional costs of \$10,604, or and incremental cost-effectiveness ratio of \$11,606 per QALY.

**Reduction in Burden of Disease:** The accepted WHO disability weighting for a lower-limb amputation is 0.3. It can be interpreted as a 30% reduction in "healthy life years" for every year lived with limb loss. Using standard criterion of the value per QALY gained, a perfect quality prosthesis would have value of \$15,000 per year for the life of the user.

**Value of Increase Physical Activity:** Using published estimates for the value of metabolic activity of slow walking, a transtibial prosthesis adds value in avoidance of negative metabolic disease costs of \$13,797 over three years.

## **DISCUSSION AND CONCLUSION**

Coupled with direct health impacts from being more physically active and participatory in community, provision of prostheses and orthoses can provide large positive economic impacts. The primary purpose of the lower-limb prosthesis or orthosis is to provide mobility. Logic follows then that the key impact (returning mobility) should be central to analyses of the value of provision of prosthetic care. These analyses indicate that the economic value of the intervention is in excess of the cost of care.

### **REFERENCES**

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#### **ACKNOWLEDGEMENTS**

This work was supported jointly by the American Orthotic and Prosthetic Association and the American Academy of Orthotists and Prosthetists.



# Advanced IC Paediatrics

#### 1.1.7

## Management of Congenital Lower Limb Deficiency - Changes in Practice Secondary to Developments in Prosthetic Technology

Rajiv Hanspal<sup>1</sup>, Morven Mcalinden<sup>1</sup>, Imad Sedki<sup>1</sup>, Iris van Wijk<sup>2,3</sup>, Michiel van der Sande<sup>4,5</sup>, Anka Michielsen<sup>2</sup>
RNOH Stanmore, London, United Kingdom. Rehabilitation Center De Hoogstraat, Utrecht, Netherlands. Wilhelmina Children's Hospital/ University Medical Centre, Utrecht, Netherlands. University Medical Centre, Leiden, Netherlands. Princess Maxima Oncological Centre, Utrecht, Netherlands

#### **Abstract**

Congenital Lower Limb Deficiency is uncommon and management requires a multi-disciplinary approach involving surgeons, physiatrists, prosthetists and therapists. The overall approach involves surgical intervention or prosthetic replacement, often both in varying degrees. Increasingly amputation surgery is being considered as the preferred option to allow benefits from advances in prosthetic technology.

The last 2 decades has seen various developments in prosthetic technology. This includes newer materials with introduction of silicon liners for improved comfort/suspension. Customisable finishing on sockets has made prosthetic limbs more acceptable and appealing. This is accompanied by greater acceptability of disability in our society. New Structural components has made endoskeletal build possible, like in adults. This includes ease of alignment alterations and height adjustment. We recognise newer componentry with more advanced knees units with hydraulic control, energy storage feet and increasing popularity of special prosthesis for sports and leisure.

Clinical management and rehabilitation plans were generally to avoid surgery unless necessary and use basic extension prosthesis when required. Earlier studies showed greater satisfaction with extension prosthesis but with improvement is technology and acceptance of disability in society, limb ablation surgery has allowed improved function. Decision making is more complex and specialised intervention prompts the practice of an integrated specialised clinics to achieve best results. These clinics also provide a tertiary role of supporting services nationally.

Family choice and participation is essential and the treatment option must consider all factors when planning the rehabilitation for any specific child. Recent studies support this approach as the preferred treatment option.

### Statement of the objective / learning objectives

Congenital Limb Deficiency is uncommon. Management involves specialised multi-disciplinary rehabilitation. Decision making is complex especially with current changes secondary to advances in prosthetic technology. The course presents current approach and role of tertiary centres.



# Symposium Seating & Wheelchair

## 1.1.8

Current Status, Challenges & Suggestions to Develop Wheelchair Services in Developing Countries in Asia (Concerning Sri Lanka, India & Myanmar).

<u>Uthpala Mihiran</u><sup>1</sup>, <u>Samitha Samnmali</u><sup>2</sup>
<sup>1</sup>Exceed Worldwide, Mandalay, Myanmar. <sup>2</sup>Ministry Of Health, Colombo, Sri Lanka

#### **Abstract**

Looking in to the WHO guidelines on personnel mobility and wheelchair service, compare the available wheelchair services in Asian countries concerning Sri Lanka, India and Myanmar.

Explain the current situation with the experience of a wheelchair user and what feels with the global situation already experienced.

An overview to the Asia's wheelchair services concerning above mentioned countries. Discuss Wheelchair demand, available challenges, barriers and available support. Suggestions to overcome challenges, barriers and to have services according to WHO guidelines.

## Statement of the objective / learning objectives

Discuss the model or suggest model that over come the barriers and the challenges to achieve the Wheelchair services according to the WHO guidelines.



# Symposium Orthotics: Lower Limb Neurological

### 1.2.1

## Can Orthoses Play a Therapeutic Role in Early Post-Stroke Management?

Stefania Fatone<sup>1</sup>, Nerrolyn Ramstrand<sup>2</sup>, Cleveland Barnett<sup>3</sup>, Paul Charlton<sup>4</sup>

Northwestern University, Chicago, USA. <sup>2</sup>Jonkoping University, Jonkoping, Sweden. <sup>3</sup>Nottingham Trent University, Nottingham, United Kingdom. <sup>4</sup>Peacocks Medical Group, Newcastle Upon Tyne, United Kingdom

#### **Abstract**

Motor control deficits are common and a major contributor to mobility problems post-stroke, with walking limitations present in 75% of persons post-stroke. Research regarding orthotic intervention post-stroke during the acute phase is limited. This is despite the idea that a "window of opportunity" exists for optimal rehabilitation after stroke.

The most common feature of motor impairment early post-stroke is a reduction in the force generating capacity of lower extremity muscles. Of particular relevance to gait re-training, is the idea that the nervous system responds best to interventions that provide an appropriate dynamic stimulus to drive recovery. These ideas have led to development of "assist-as-needed strategies" in lower-limb assisted robotic gait training that guide the leg by applying a force rather than imposing a trajectory. Similar principles may be harnessed when using orthoses to facilitate gait re-training. The major demand on the lower-limbs during standing and walking is gravity, which applies moments across the joints that need to be controlled by the neuromuscular system. An ankle-foot orthosis (AFO) may be used to re-adjust and manipulate the neuromuscular demands placed upon the individual by positioning the foot in relation to the lower leg to provide optimal alignment of the lower-limb to the ground during walking.

We hypothesize that an AFO can facilitate re-learning of the skilled coordination required for walking in early post-stroke gait re-training by influencing both biomechanical and neurophysiological variables.

#### Statement of the objective / learning objectives

To discuss theoretical concepts and research evidence that may support a hypothesis regarding the therapeutic role of orthoses in early post-stroke gait re-training.



# Free Paper Session Orthotics: Lower Limb Orthopaedic - Osteoarthritis

#### 1.2.2.a

Non Operative Treatment of Uni-compartmental Osteoarthritis of the Knee – A Prospective Randomized Controlled Trial: Ankle-Foot-Orthosis versus Knee Unloader Brace

Andreas Hahn<sup>1</sup>, on behalf of the AF Investigator Group Wolf Petersen MD<sup>2</sup>

Otto Bock Healthcare Products GmbH, Vienna, Austria. Martin-Luther-Krankenhaus, Berlin, Germany

#### **BACKGROUND**

Osteoarthritis (OA) is the most common form of joint disease and leads to pain and to a restricted range of motion. In patients with knee OA, the medial compartment is affected more often than the lateral joint.[2]. The load-shifting Agilium Freestep Ankle Foot Orthosis reduces the pathological varus moment at the knee by limiting excessive eversion in the subtalar joint as opposed to applying a direct corrective force as knee.

#### AIM

The present prospective clinical randomized study was conducted to compare the effect of a common unloader (KUB) brace design and Agilium Freestep (AF). The equivalence of the two different orthosis was tested.

#### METHOR

This prospective clinical randomized study enrolled 160 patients with unicompartmental knee OA grade 1-4 in a real-life out-patient clinical setting. Following the baseline assessment during the enrollment, the patients were interviewed after 8 weeks and after 6 months. Primary outcome was pain reduction measured by a numerical analog scale (NAS). Mobility was assessed with the Knee Injury and Osteoarthritis Outcome Score (KOOS), compliance was evaluated and the patients were asked to evaluate the product and report any other kind of intervention or treatment that was performed during the evaluated timeframe.

#### **RESULTS**

160 patients were enrolled, 79 randomized in the KUB and 81 in the AF group. Eighty-nine subjects were mal; mean age of 57,3 ± 10,1 years. Osteoarthritis grading: Grade 1: 13,1%; Grade 2: 46,3%; Grade 3: 31,1%; Grad 4: 7,5%. No significant differences were found between groups. The NAS demonstrated a significant pain reduction during dynamic action (walking, sports), but not at rest. Both groups showed equivalence in the dynamic situations. In addition the KOOS assessment, the compliance, the product evaluation and the additional therapy revealed no significant differences between the two groups. The rate of side effect such as bruising was significantly lower in the AF group.

## **DISCUSSION AND CONCLUSION**

Both systems showed equivalent functioning. Understanding that fitting, compliance and comfort is improved in the AF fitting process, AF is a competitive concept in the treatment of unicompartmental knee osteoarthritis.

## **REFERENCES**

- [1] Petersen et al, Arch Orthop Trauma Surg 2019; 139(2):155-166.
- [2] Menger et al, Arch Orthop Trauma Surgery 2016; 136(9):1281-1287.

#### **ACKNOWLEDGEMENTS**

The authors present on behalf of the Agilium Freestep Investigator Group. A research grant was provided by Otto Bock Healthcare. A. Hahn is a full time employee of Otto Bock.



#### 1.2.2.b

## Orthoses for the Treatment of Osteoarthritis of the Knee: Biomechanical Effect of a Combination of AFO and Planovalgus Foot Orthosis

Thomas Schmalz
Ottobock SE & Co. KGaA, Goettingen, Germany

#### **BACKGROUND**

The use of a specific AFO represents an innovative fitting strategy in knee osteoarthritis (OA).[1] A specific challenge is that many OA patients also suffer from a planovalgus deformity that has to be fitted with a planovalgus foot orthosis (PO). The inevitably increased medial thickness of the PO raises the question whether the combination with the AFO may result in an reduced unloading effect on the knee Joint.

#### AIN

The purpose of the present study is to objectify if the combination of AFO and PO reduces the knee unloading validated for the AFO as a stand-alone device.[1]

#### METHOD

Level walking of 10 healthy subjects was analysed in four situations in randomized order: without orthosis (WO), AFO (Agilium Freestep, Ottobock, Germany) (AFO), planovalgus foot orthosis (Ergopad Work, Bauerfeind, Germany) (PO), and the combination of AFO and PO (AFO-PO). For the measurements, an optoelectronic camera system (27 passive markers, 12 Bonita cameras, VICONPEAK, GB), coupled to two force plates (9287A, KISTLER, CH), was used. The 3D kinematics of the upper ankle joint and the knee joint and the external joint moments were used as specific assessment parameters.

#### **RESULTS**

Between all four situations, no significant differences were found regarding the spatiotemporal parameters (mean gait speed 1.44±0.10 m/s). The mean first peak of the knee adduction moment (KAM) was significantly reduced (p≤0.01) with AFO (0.41 Nm/kg) and AFO-PO (0.39 Nm/kg) compared to WO (0.51 Nm/kg). The mean value for PO (0.52 Nm/kg) shows a tendency of slight increase. The use of both AFO and AFO-PO results in a significant shift of the COP (9.8 and 9.5 mm) during an interval around loading response compared to WO. The transversal knee angle at loading response shows that both AFO and AFO-PO reduce the internal knee rotation significantly by 2°. PO causes no alterations in COP shift and internal knee rotation. In the sagittal plane, no differences between all situations evaluated were seen.

#### **DISCUSSION AND CONCLUSION**

The results of the present study indicate that the orthotic combination AFO-PO leads to a similar unloading of the medial knee compartment of approximately 20% as reported for the AFO as a stand-alone device. Because of the validated correlation between biomechanical and clinical results for the AFO,[1] the results show that AFO-PO is be an interesting and relevant new option for patients suffering from knee OA and planovalgus deformity.

#### **REFERENCES**

[1] Menger et al, Arch Orthop Trauma Surg 2016; 136:1281-1287.



#### 1.2.2.c

## Finding Factors about Orthosis Application for Knee Osteoarthritis Treatment

Shoko Nireki<sup>1</sup>, Yasunobu Kino<sup>2</sup>
<sup>1</sup>OSSUR, Tokyo, Japan. <sup>2</sup>University of Tsukuba, Tokyo, Japan

#### **BACKGROUND**

The Knee Osteoarthritis (OA) is a global leading cause of disability, it is associated with a large social and economic burden, in addition to the physical and psychological affect. Once knee OA is onset, it is important to slow down the progress. There are many treatment options available to manage pain and keep people staying active. Initial treatment is non-surgical which include physiotherapy, medication and orthosis (braces). Recently, focus is shifting to non-surgical treatment.

#### AIM

Knee Orthosis application is included within conservative treatment but it is not commonly applied. This research is aiming to find the facts around knee OA treatment in Japan, to have better understanding of how orthosis treatment are applied.

#### **METHOD**

Research was conducted with text analysis from interview. I conducted Interview to 6 Japanese Orthopedic doctors. They have over 20 years of experience as Orthopedic Surgeon. Transcripted interview into text format for text analysis by KH Coder. Within Text Analysis, it included Frequency List "Top 150" type and "By POS Tags" type, Co-Occurrence Network, Detecting Word Association, and KWIC Concordance. Those allowed to analyze to identify key words to define the concepts. The concepts were installed to create Concept Model.

#### **RESULTS**

By Co-Occurrence analysis, 24 concepts were found. From the summary of concepts, those concepts are considered to be placed at certain locations in a diagram to show the relationship each other and follow the time line. Drawing the Concept Model Diagram, it requires not only text analysis but also actual fitting experiences.

## **DISCUSSION AND CONCLUSION**

It is importance to understand Knee OA as a whole picture, for patient and medical staff. Patient life style is the core of treatment. Clear goal setting for pain relief will bring higher patient satisfaction. Orthosis/Brace treatment is the only external

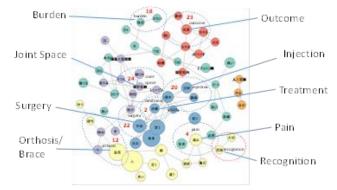


Figure 1. Co-Occurrence Network Diagram

Biomechanical Intervention. Compliance by patient follow up is critical. Trusted relationship between doctor and orthotist is intangible.

#### **REFERENCES**

[1] Noriko Y, Modern Rheumatology 2017; 27(1):1–7.

[2] McAlindon et al, Osteoarth Cartilage 2014; 22:363-388.



#### 1.2.2.d

## Effects of Sharing Information of Orthotic Therapy for Early Knee Osteoarthritis

Shunsuke Ichikawa<sup>1</sup>, Hiroshi Hashimoto<sup>2</sup>, Yasuto Iida<sup>3</sup>, Shigeru Komai<sup>4</sup>
<sup>1</sup>Kawamura gishi Co.Ltd., Osaka, Japan. <sup>2</sup> Pacific Supply Co. Ltd., Osaka, Japan. <sup>3</sup>Iida Orthopedic & Anesthetic Clinic, Nagano, Japan. <sup>4</sup>Shimoyama Prosthetics Manufacturing Co., Ltd., Gunma, Japan

#### **BACKGROUND**

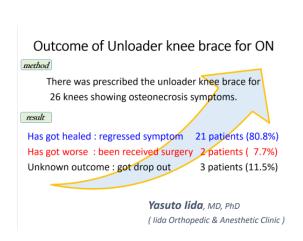
It is reported that knee osteonecrosis (ON) may develop to knee osteoarthritis (OA), that is recently defined as early knee OA. Though we have several case studies that the prescription of unloader knee braces was effective for regressed symptoms of ON, most CPOs were not aware of this. Therefore, some type of information sharing may be needed for better conservative treatment of knee ON.

#### AIM

The aim of this study is to investigate the effects of sharing information in some successful case studies unloader knee braces prescribed ON.

#### METHOD

We designed a brochure consisting 26 case studies of ON with unloader knee braces and provided it to 128 CPOs to share the effectiveness of knee braces on ON. We also collected questionnaires from CPOs who dealt with unloader knee braces in order to build a database. It included age, sex, affliction (OA, ON, among others). It was comparatively classified as before and after the provision of the brochure. Chi-square tests were performed for statistical analysis (p<0.05).



	JulDec. 6mo Y2017	JanJun. 6mo Y2018	JulDec. 6 mo Y2018
	(n = 61)	(n=52)	(n=64)
Median age (range),y	68(13-84)	67(42-90)	66(5-96)
Sex (%)			
Male	15 (24.6)	18 (34.6)	28 (43.8)
Female	46 (75.4)	34 (65.4)	36 (56.2)
Diagnosis ( % )			
Osteoarthritis (OA)	43 (70.5)	37 (71.2)	22 (34.3)
Osteonecrosis (ON)	12 (19.7)	11 (21.1)	34 (53.1)
Meniscus injury	6 (9.8)	4 (7.7)	5 (7.9)
else	0	0	3 (4.7)

	Focus on OA and ON s	ince sharing information.	
	Pre	Post	
	(JanJun. 6mo Y2018)	( JulDec. 6 mo Y2018)	
Diagnosis			X <sup>2</sup> value = 15.05
Osteoarthritis (OA)	37	22	df = 1
Osteonecrosis (ON)	11	34	p < 0.01

## **RESULTS**

We started the collection of questionnaires in 2016. The brochure was provided in July, 2018. The ratio of prescription for ON increased from 20% to over 50% after sharing this information. The prescription ratios for knee OA and for females were reduced. There was no big difference in age. The ratio of prescription of knee braces to ON significantly increased after information sharing (p<0.01).

## **DISCUSSION AND CONCLUSION**

The effects of unloader knee braces to OA have been reported by several researchers.[2-5] Unloading is also needed for ON, however unloader knee braces had seldom been prescribed due to lack of information. The CPOs may have introduced the concept and effectiveness of unloader knee braces to medical doctors that lead to the increase in prescription. Moreover, some reports said that the risk of disuse syndrome may be reduced with the usage of the unloader knee braces.

#### **REFERENCES**

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- [2] Matsuno et al, Arch Phys Med Rehabil 1997.
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- [5] Katsuragawa et al, Int Orthop 2005.



# Symposium Developing Coutries

#### 1.2.3

## Identifying Appropriate Technologies for P&O Services Worldwide: Balancing Bio-Psychosocial Issues and User-Needs Assessment with Engineering Analysis

Kheng Sisary<sup>1</sup>, Maggie Donovan-Hall<sup>2</sup>, Alex Dickinson<sup>2</sup>
Exceed Worldwide, Phnom Penh, Cambodia. <sup>2</sup>University of Southampton, Southampton, United Kingdom

#### Abstract

P&O services are a means to enable individual and state benefits, by improving independence, reducing care responsibilities and enabling people to return to work. Basics or bionics, a challenge to researchers, clinicians and healthcare providers is to identify Appropriate Technologies. As well as enhancements to P&O devices, many technologies have the potential of increasing access to services, such as:

- · more efficient clinic and workshop processes,
- measurements,
- disseminating information to educate clinicians and service users, and
- systems to enable community-based service.

To optimise any technology's use in low resource countries it is essential to understand the social, cultural and historical context of the environment (AHRC, 2016). We cannot assume how these technologies will be received by the societies they are intended to benefit, even if they are clinically successful in other cultures, and we must plan for sustainable implementation.

Our symposium will present interdisciplinary collaborative approaches addressing these issues: Cambodian state-of-the-art:

- clinical service provision;
- clinician training;
- scope for improvement in service access, information dissemination efficiency, follow-up and education;
   and
- which technologies could help with local resources?

Psychosocial co-research tools and principles:

- the importance of assessing needs from user perspectives;
- · co-development of research aims;
- adopting and utilising a co-researcher ethos;
- innovative semi-structured interview methods around technology; and
- · results from clinician, service user and family-member interviews

Potential technologies to enhance P&O access:

- · benchmarking 3D scanning for residuum and device shape monitoring;
- physical activity assessment, and the need to cross-reference with PROMs; and
- digital casenotes for community-based assessment, and synchronisation.

## Statement of the objective / learning objectives

This session will provide insights into methods of assessing user needs of P&O technologies, identifying Appropriate Technologies and planning for sustainable implementation, through a lens of Cambodia-UK collaborations.



## **Basic IC**

## **Prosthetics: Lower Limb Transfemoral**

## 1.2.4

## Prosthetic Alignment: Biomechanical Basics and Clinical Approach for Lower Limb Prostheses

Malte Bellmann<sup>1</sup>, Siegmar Blumentritt<sup>2</sup>

Ottobock SE & Co. KGaA, Göttingen, Germany. <sup>2</sup>Private University Göttingen, Göttingen, Germany

#### **Abstract**

The targets of this course are imparting biomechanical knowledge, deriving of alignment guidelines and practical proceedings in fitting lower limb amputation levels from TT to HD.

At first, short information about the history of prosthetic alignment and important results of various studies will be given. Then (a) present biomechanical aspects and (b) the practical procedure for prosthetic alignment that has been repeatedly proved by the speakers will be demonstrated.

Biomechanics as well as the practical procedure are very different for the individual amputation levels. Both contents will be explained for each amputation level separately (1. Alignment of lower limb prostheses: Biomechanics and guidelines, 2. Alignment of lower limb prostheses: How to do in clinical practice).

## Statement of the objective / learning objectives

Learn about current biomechanical knowledge for prosthetic alignment in TT, TF and HD amputees, learn objective biomechanically based alignment guidelines and how to apply that knowledge in everyday clinical practice.



## **Free Paper Session**

## **Prosthetics: Lower Limb Transfemoral - Socket**

## 1.2.5.a

## **SOCKETMASTER - Optimising the Design and Fit of Prosthetic Sockets for Above Knee Amputees**

Abdo Haidar<sup>1</sup>, Jianxin Gao<sup>2</sup>, Wei Xu<sup>3</sup>

<sup>1</sup>The London Prosthetic Centre, Kingston Upon Thames, United Kingdom. <sup>2</sup>TWI Ltd, Cambridge, United Kingdom. <sup>3</sup>University of Surrey, London, United Kingdom

#### **BACKGROUND**

The functional outcome of lower-limb prosthesis is highly dependent upon the characteristics and anatomical profile of the residual limb and the fit of the socket. A poorly fitted socket can cause discomfort, pain and in even prosthetic rejection. The techniques available to design a comfortable socket have not progressed in the last century. The current approach to socket production is time-consuming and dependent on the prosthetists skills. Often sockets are made without access to comprehensive information related to the comfort.

#### AIM

To develop a new technique for rapid design of prosthetic sockets for above knee amputees with enhanced comfort.

#### **METHOD**

To integrate various micro sensors into a mechanical Master Socket. A gait loading apparatus was also developed. Combined will form a SocketMaster medical tool which can help prosthetists achieve fast and customised design of prosthetic sockets for lower-limb amputees. The Master Socket can be adjusted mechanically and electronically by the prosthetist at different gait positions while the residual limb is positioned inside it. Dynamic pressure and friction between the Master Socket and the residual limb will be collected. The data will be used to optimise the socket design to maximise the user's comfort. The final 3D solid model will be fed into a rapid prototyping machine for fast fabrication.

#### **RESULTS**

Dedicated micro sensors and their electronic readouts were designed, fabricated and evaluated. The mechanical structure of a Master Socket and its integration with the sensors were designed and assembled. A gait loading apparatus was also produced. During the test, biomechanical data of a residual leg under various loading conditions were collected. These data were then used for socket design, and a CAD model was formulated. A physical model was finally fabricated by 3D printing.

## **DISCUSSION AND CONCLUSION**

During 14 clinical tests, biomechanical data of above knee amputees in three postures (mid-stance, push off and heel strike) were collected for socket optimisation. The tests showed positive results for fast design of comfortable sockets. With further optimisation of both hardware and software systems, a comfortable solution for socket design and fabrication with enhanced comfort will be presented in the near future.

## **ACKNOWLEDGEMENTS**

The project received funding from the European Union's Horizon 2020 for research and innovation programme under grant agreement no.645239.



#### 1.2.5.b

## Innovative prosthetic socket system for increasing prosthesis acceptance in hip disarticulation

<u>Tim Baumeister</u><sup>1</sup>, Olaf Gawron<sup>2</sup>, Michael Schäfer<sup>1</sup>
<sup>1</sup>Pohlig GmbH, Traunstein, Germany. <sup>2</sup>Pohlig GmbH, Heidelberg, Germany

#### **BACKGROUND**

People with amputations in the hip area represent a special group of prosthetic users. The concentration and energy required to operate a pelvic socket prosthesis in everyday life is significantly higher than in any other amputation level. According to this, the prosthetic socket plays a central role.

This article describes a practice-proven socket-concept that has already been fittet to 50+ patients with hip disarticulation.

#### **AIM**

A two-part prepreg-style socket technique in combination with a HTV silicone pant improves the upper comfort and the prosthesis control. This leads to a better outcome and an increased prosthesis acceptance

#### **METHOD**

For goal-oriented implementation of this socket-concept, the individual production steps such as casting, modeling, production are defined.

The casting procedure is done either by a classic plaster cast or by a 3D scanner in a designated device called "Simbrace". Subsequently, further processing takes place by means of CAD technology. This is followed by the fitting of the volume-socket with initial informations on the fit. Optimized in it's shape the CPO can create a basis for further processing in order to produce the silicone-interface. Now, the two-part outer Socket in PrePreg technology is produced by autoclaving. The next step is the test and adaptation phase in cooperation with the user.

### **RESULTS**

The implementation of this socket methodology leads to significant improvements in the areas of socket functionality and wearing comfort for the user.

The contoured-elastic imbedding of the stump is the most important part of this concept. The precompression caused by the silicone Interface creates a viable, compact stump condition. The relative movement of the tissue to the pelvic structures of the pelvis is significantly reduced. The socket adaptation by positive locking shows another advantage. The silicone interface contains functional wedges, which represents a fixation unit and also serve as a tightening control.

The dorsal closure technique allows a controlled volume control. In addition to that a partial flexibility in the ventral area allows the better absorption of food.

The stump hygiene and skin protection are significantly improved by the use of HTV silicone.

## **DISCUSSION AND CONCLUSION**

The successfull implementation of this socket system requires a very good planning, especially in system changings of experienced users. In primary care, there is no reason for an alternative socket system without silicone interface from the authors point of view.

The training by the certified prosthetist is mandatory and must be given a corresponding window. Supportive physiotherapy contributes to the successful treatment for safely control the two large prosthetic joints, hip joint and knee joint, via the prosthetic socket.

#### **REFERENCES**

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#### 1.2.5.c

## **Versatility of NU Flex Socket**

#### Taketo Kawamura

Kobe College of Medical Welfare, Sanda Campus Orthotist and Prosthetist 4-year Course, Sanda, Japan

#### **BACKGROUND**

Currently, general transfemoral prosthesis socket such as the Quadrilateral (QL) socket and Ischial containment (IC) socket have problems which is making these sockets requires complex skills while casting and modification. The new trans femoral prosthesis socket called NU Flex SIV (NU) Socket has a lower proximal trimline than the ischial tuberosity. It can be assumed the NU socket doesn't have a significant difference in the result between experts and non-experts because the socket doesn't need complex skills.

#### ΔIM

In order to clarify the versatility of the NU socket, we will make comparisons by creating the socket (measurement, casting and modification) between experts and non-experts.

#### METHOD

We will set 10 students who have experience making either QL or IC sockets, as well as creating both as non-expert subjects (C1-C10). Additionally, we will have 1 teacher as an expert subject (A) in this experience. The model is a trans femoral amputation patient. The tasks in the experiment is to measure circumference, M-L width, length and volume of the stump and the time it takes for casting and modification. A further focus will be on the casting model's stump, and modification of `positive models`. We will also conduct qualitative research to allow a subjective approach for the non-experts after the experiment.

#### **RESULTS**

First, the results show no statistical difference between each subject's casting and modification of the positive model (Table.1).

Secondly, the average time of casting is approximately 9 minutes, the average time of modification of the 'positive model' is exactly 47 minutes and 59 seconds. Regarding the results of the survey, we found that all the non-expert subjects feel that making NU sockets are easier than QL and IC sockets respectively.

	A	Average of C1~C10	A-C	t-radio
M-L width [cm]	14.18	14.562	0.382	0.441697
Length of stump [cm]	20.26	20.578	0.458	0.296002
volume [cm²]	2,881	2,889.40	63.6	0.041389
circumference [cm] 1	42.5	43.687	1.187	0.570804
2	43.35	43.3	0.548	-0.03296
3	43.44	43.227	0.567	-0.14058
4	43.24	42.483	0.757	-0.35284
5	41.61	40.567	1.043	-0.5584
6	35.16	34.955	0.563	-0.15423

Table.1 Result of Measurement by using the 3D scanner

## **DISCUSSION AND CONCLUSION**

As for the trans femoral prosthesis, we understood that creating the NU socket isn't dependant on experience and is easier to create in comparison to other types of sockets. Thus, meaning the NU socket has versatility. However, this study doesn't compare other sockets. Future prospects of this study is to research further comparative socket data. Additionally, we will also consider that casting and modification of NU sockets can work on a computer, as sockets do not require any special techniques.

## **REFERENCES**

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# 1.2.5.d

# **Evaluation of Socket Comfort and Functional Performance for Persons with Transfemoral Amputation: Interim Analysis**

Stefania Fatone<sup>1</sup>, Ryan Caldwell<sup>1,2</sup>, John Angelico<sup>2</sup>, Rebecca Stine<sup>3</sup>, Vasanth Subramanian<sup>1</sup>

Northwestern University, Chicago, USA. <sup>2</sup>Scheck and Siress, Chicago, USA. <sup>3</sup>Jesse Brown VA Medical Center, Chicago, USA

#### **BACKGROUND**

Ischial containment (IC) sockets for transfemoral amputees (TFA) fit intimately with the ischium, limiting hip motion and contributing to socket discomfort.[1,2] Sub-ischial sockets, such as the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket,[3] do not interact with the ischium, potentially increasing comfort. While case studies demonstrate that the NU-FlexSIV Socket potentially improves comfort with comparable functional outcomes to the IC socket,[4,5] further evaluation is needed.

#### ΔIM

The purpose of this prospective, assessor-blinded randomized cross-over clinical trial was primarily to compare comfort, and secondarily functional performance, with the NU-FlexSIV and IC sockets in persons with unilateral TFA.

# **METHOD**

Interim analysis was conducted on the first 20 subjects of a trial that aims to recruit 30 subjects with unilateral TFA who wear IC sockets. For the trial, new sockets were fabricated with prosthetic components standardized within subjects. Patient-reported and performance-based measures collected for each socket included: Socket Comfort Score; Orthotic and Prosthetic User's Survey (OPUS); 5-time Rapid Sit-to-Stand Test (RSTS); Four-Square-Step Test (FSST); and T-Test of Agility. Participants used each socket for 7 weeks with differences in outcomes assessed using published Minimal Detectable Change (MDC) values. As the primary outcome, socket comfort was assessed using the Wilcoxon Sign Rank Test with significance set at 0.05.

# **RESULTS**

Seven subjects withdrew at different stages of participation, leaving 12 subjects with complete data, 5 with partial data, and 3 without data. Subjects with data comprised 14 males/3 females with a mean age of 50.1±12.6, mean years post-amputation of 27.3±17.3, mean height of 177.1±11.7cm and mean weight of 89.4±21.0kg, all with K3 and K4 mobility level. Amputation etiology included 10 trauma, 5 cancer and 2 vascular. There was a statistically significant difference between sockets in terms of comfort at 7 weeks, although only one subject's change in comfort exceeded the published MDC.[6] There were no consistent differences in the other outcome measures between sockets that exceeded published MDCs.

# **DISCUSSION AND CONCLUSION**

Two subjects (11 and 19) did not complete IC socket testing beyond baseline and 3 weeks, respectively, due to back pain, so data were compared at these times. Eleven subjects chose to continue using the NILL FloySIV Socket upon study completion.

No difference

No difference

No difference

No difference

Difference Favors IC Socket

Difference Favors NU-FlexSIV Socket

Difference in Socket Comfort Score at 7 weeks

Figure 1. Difference in Socket Comfort at 7 Weeks (except subjects 11 and 19 who were compared at baseline and 3 weeks, respectively).

continue using the NU-FlexSIV Socket upon study completion. Interim analysis suggests comfort may be better in the NU-FlexSIV Socket with comparable function based on the assessed outcomes. These results are supported by the high proportion of subjects choosing to continue wear of the NU-FlexSIV Socket upon study completion.

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## **ACKNOWLEDGEMENTS**

Funded by the US Department of Defense award #W81XWH-10-1-0744.



# 1.2.5.e

# Diffusion of NU-FlexSIV Socket in Japan 2017-2019

Shin Sasaki, Kenta Tonai

Kobe College of Medical Welfare Sanda Campus, Kobe, Japan

#### **BACKGROUND**

Northwestern University Flexible Sub-Ischial Vacuum Socket (NU-FlexSIV socket) is the trans-femoral prosthetic socket (TF socket) firstly introduced in 2012 by Dr. Stefania Fatone at Northwestern University. Though it was believed for decades that TF socket cannot be fit without ischial weight bearing, NU-FlexSIV socket is radical socket which does not contact pelvis including ischial tuberosity at all. In Japan several NU-FlexSIV socket seminars were held between 2017-2019.

#### ΔIM

This paper will describe how many NU-FlexSIV sockets were fit within 2017-2019 over the country and shows success/ unsuccessl rate including potential causes of failure. The types of liners fit with NU-FlexSIV sockets.

#### METHOD

By asking all participants attended to NU-FlexSIV socket seminars held in Japan in 2017-2019 to fill questionnaire containing questions below.

- 1) How many NU-Flex Socket have you experienced (delivered, fitting, failure) since your attendance to the seminar (there are difference of period, e.g. attendees in 2017 would have 2 years of experience and attendees in 2018 would have 1 year experience only)?
- 2) If there was any failure, what was the potential cause?
- 3) What kind of liner you used for your NU-FlexSIV socket fittings?
- 1) is based on numeric inputs, and 2), 3) are free answers.

# **RESULTS**

- 1) How many NU-Flex Socket have you experienced (delivered, fitting, failure) since your attendance to the seminar?
- 2) If there was any failure, what was the potential cause?
- 1. There was no problem at all during fitting stage with hard check socket, yet it was unstable when it turned to definitive socket with flexible inner socket & hard outer socket.
- 2. Patient did not like liner fitting.
- 3. Because of the age of patient 82 y/o, it was difficult to manage liner fitting.
- 4. There was soft tissue roll at proximal brim which was difficult to manage by socket adjustment.
- 5. Patient was not able to change from current IRC socket to Nu-FlexSIV socket.
- 6. Very short stump.

There was problem about fitting, but patient fears about suction fitting.

# | Niguta | Delivered | Fitting | Failure | Niguta | Delivered | Fitting | Failure | Technology | Tech

Diffusion of NU-FlexSIV socket in Japan 2017-2018

# **DISCUSSION AND CONCLUSION**

This is the report about diffusion of NU-FlexSIV socket in Japan in 2017-2019 during 2 years since 1<sup>st</sup> seminar held in August 2017. I believe that this data is precious as investigating diffusion of 1 type of transfemoral socket from zero in the country. This result would indicate what kind of stump/patients might be suitable or unsuitable for NU-FlexSIV socket fitting, including selection of liners.



# 1.2.5.f

# Comparison the Interface Pressure Inside Socket With and Without Liner During Walking

<u>Van-Thuc Tran</u><sup>1</sup>, Kenta Takizawa<sup>1</sup>, Akihiko Hanafusa<sup>1</sup>, Shin-Ichiroh Yamamoto<sup>1</sup>, Kengo Ohnishi<sup>2</sup>, Hiroshi Otsuka<sup>3</sup>, Yukio Agarie<sup>4</sup>

<sup>1</sup>Shibaura Institute of Technology, Tokyo, Japan. <sup>2</sup>Tokyo Denki University, Tokyo, Japan. <sup>3</sup>University of Human Arts and Science, Saitama, Japan. <sup>4</sup>Niigata University of Health and Welfare, Niigata, Japan

#### **BACKGROUND**

Understanding the pressure and shear stress of the contact interface is important for improvement of the design of the socket. Laszczak et al. measured the interface pressure and shear stress of the trans-femoral socket.[1] The measurement was conducted with only three positions which may not provide enough information about the distribution of pressure and shear stress inside the socket. Moreover, the appearance of the liner would affect the distribution of the interface pressure and shear stress.

#### $\Delta IM$

This research aimed to investigate the differences of the interface pressure while wearing trans-femoral socket with and without liner during walking.

#### **METHOD**

One amputee subject (Female, right amputation, 34 years old, 166 cm) volunteers to conduct this experiment. In this study, two Ischial ramus containment (IRC) sockets, which made by Manual Compression Casting Technique (MCCT), were used: one for fitting without the liner and one for fitting with liner. Subject conducted two experiments: walking while wearing the socket without the liner and walking while wearing socket with liner. The interface pressures were recorded with seven sensitive transducers located on the trans-femoral socket. The data were extracted to every single gait cycle before analyzing. The data were extracted to every single gait cycle for comparison.

# **RESULTS**

From Figure 1 and Figure 2, the gait cycle begins the stance phase on the prosthetic leg and ended with the swing phase of the prosthetic leg. During the middle stance phase, the pressures at AP, PP, MP, MD, and PD by wearing liner are significantly higher than without wearing liner. During the swing phase, the pressure profiles are significantly reducing. The pressure values at all proximal locations and PD by wearing liner are significantly higher than without wearing liner. The pressure while wearing socket without liner at AP, PP, LP, and PD was negative while the case of wearing liner was positive.

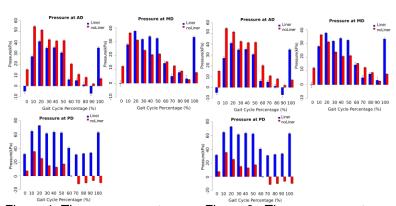


Figure 1. The pressures at anterior proximal (AP), posterior proximal (PP), medial proximal (MP) and lateral proximal (LP).

Figure 2. The pressures at anterior distal (AD), medial distal (MD) and posterior distal (PD).

## **DISCUSSION AND CONCLUSION**

The results represent that the existence of the liner between socket surface and skin increased the pressure at almost location (not all) for our MCCT socket prototype. The appearance of the liner would change the suspension system of the prosthetic leg by applied more pressure at most locations. In conclusion, the appearance of the liner increased the pressure of the contact interface during walking in comparison with the case not wearing liner.

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# **ACKNOWLEDGEMENTS**

This work was supported by KAKENHI: Grant-in-Aid for Early-Career Scientists 18K18423.



# Free Paper Session Outcome Measurements – Mobility

# 1.2.6.a

# Impact of Medical Comorbidities Clinical and Patient-Reported Outcome Measures on Functional Mobility in People with Limb Loss

Christopher Wong<sup>1</sup>, Stanford Chihuri<sup>2</sup>
<sup>1</sup>Columbia University, New York, USA. <sup>2</sup>Columbia University Medical Center, New York, USA

# **BACKGROUND**

For millions of people with limb loss, community integration depends on prosthetic functional mobility. Prosthetic function has been assessed with numerous subjective patient-reported outcome measures. However, perceived function and objective performance-based clinical measures yield different results.[1] Various modifiable and non-modifiable factors affect functional mobility,[2] but subjective patient-reported outcomes and objective clinical measures are rarely combined in explanatory analyses of functional mobility in people with limb loss.

#### AIM

To assess the impact of medical history, patient-reported outcome and clinical measures on 1) patient-reported function using the Prosthetic Evaluation Questionnaire mobility subscale (PEQ-MS), and 2) performance-based 2-Minute Walk Test (2MWT).

#### **METHOD**

Retrospective cross-sectional analysis from 305 community-dwelling volunteers with lower limb loss of any cause and surgical level, recruited from a wellness-walking program held in six states. Participants were 68.8% men; aged 55.9±15.1 years, and 6.3±12.1 years since amputation. 52.4% had vascular amputation causes, 42.4% had surgical levels above the knee, and 81.7% had ≥1 medical comorbidity. Walking levels ranged from limited household (21.1%), limited community (29.6%), and independent community (49.3%), with 60.7% using walking aids. Multiple linear regression models were built using demographics, medical comorbidities by system;

patient-reported outcomes including the PEQ-MS, Activitiesspecific Balance Confidence (ABC) and Houghton scale; and clinical measures of balance and walking ability.

# **RESULTS**

The 2MWT distance model (adjusted  $R^2$ =0.685) included non-modifiable factors (sex, p=0.02; amputation cause, p=0.021; surgical level, p<0.001) and modifiable factors (balance ability, p<0.001; ABC, p<0.001; Houghton, p=0.016). The PEQ-MS model (adjusted  $R^2$ =0.660) included Houghton (p<0001), 2MWT (p<0.001), and integument (p=0.022) and cardiopulmonary (p<0.001) comorbidities. A nested model demonstrated that comorbidities explained >4% of the PEQ-MS variance with amputation cause and surgical level not associated with PEQ-MS score (p>0.05).

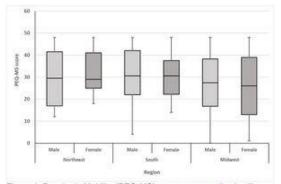


Figure 1: Prosthetic Mobility (PEQ-MS) among community-dwelling males and females with lower limb loss by U.S. region.

# **DISCUSSION AND CONCLUSION**

In this sample recruited from multiple American regions, non-modifiable factors that characterize people with limb loss by amputation cause and level were not consistently associated with outcomes. Clinical measure of walking (2MWT) was associated with balance, ABC, assistive device use, and non-modifiable factors such as amputation cause and surgical level. Amputation cause and level were not associated with patient-reported outcome (PEQ-MS), however, which was more influenced by modifiable factors including medical comorbidities.

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# **ACKNOWLEDGEMENTS**

Grant 1 R49 CE002096, National Center for Injury Prevention & Control, Centers for Disease Control & Prevention



# 1.2.6.b

# National Survey of SIGAM / WAP Mobility Scores in the Netherlands

G.M.(Clemens) Rommers<sup>1</sup>, A (Bert) Kap<sup>2</sup>, M.A. (Marieke) Paping<sup>3</sup>

<sup>1</sup>Maastricht University Medical Center, Maastricht, Netherlands. <sup>2</sup>De Hoogstraat Rehabilitation, Utrecht, Netherlands. <sup>3</sup>Riindam Rehabilitation, Rotterdam, Netherlands

# **BACKGROUND**

In the Netherlands in a population of 17,6 million people there are annually app. 3000 new major lower limb amputations. 50% of these new patients receive a prosthesis during rehabilitation treatment. 95% of amputations are due to vascular pathology. 80% of patients are over 65 years of age. Results of lower limb amputation rehabilitation concerning mobility is of interest to society, healthcare system, insurance companies and to justify healthcare costs to the public.

#### AIM

To investigate on a national basis results of mobility scores after a lower limb amputation in specialized rehabilitation treatment.

# **METHOD**

In a national survey 17 of 23 Rehabilitation Centers and joint hospitals participated in the study. All amputee patients seen by the Consultant in Rehabilitation Medicine were identified. On discharge from the hospital or after in - and outpatient specialized rehabilitation treatment the SIGAM/WAP score was taken. This score measured by 21 yes/no questions and an algorithm gives mobility scores in 6 classes (A-F) [1-2]. These classes include prosthetic use; use of walking aids and covered walking distance. Scoring was done by consultant or treating physiotherapist. Results were anonymously entered in a database and basic statistics were applied concerning patient characteristics, amputation level and prosthetic mobility score.

#### **RESULTS**

In the period of 2006-2015 1200 cases were identified. Not all datasets were complete. This was due to hospital death, quick discharge or loss to follow up. 645 patients after in-patient rehabilitation were scored; 569 patients after outpatient rehabilitation were identified. 56% of patients had a Transtibial amputation; Inpatient rehabilitation: M age 60,6 y; 70% male; Mobility score B-F: 51%.

Outpatient rehabilitation: M age 58,6 y; 69% male; Mobility score B-F: 87%. Prosthetic use by amputation level: Transfemoral: 80%; Knee disarticulation 95%; Transtibial 88%.

# Prosthetic use after outpatient rehabilitation (N=569)

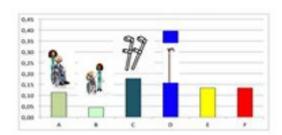


Figure 1. SIGAM/WAP score

# **DISCUSSION AND CONCLUSION**

National data collection gives a good overview of treatment results. National data collection is however complex and not always complete. It overviews the results of an in and outpatient rehabilitation program with good comparable results. The SIGAM / WAP score is easy to administer and shows good test-retest capabilities [3]. After specialized rehabilitation treatment 87% of patients with a major lower limb amputation are mobile with a prosthesis.

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# **ACKNOWLEDGEMENTS**

We like to thank all members of the Dutch Special Interest Group on Amputation and Prosthetics for their support.



# 1.2.6.c

Assessing Mobility for Persons with Lower Limb Amputation: The Figure-of-8-Walk-Test with Inclusion of Two Novel Conditions. Preliminary Results.

<u>Jette Schack</u>, Harald Steen, Peyman Mirtaheri, Terje Gjøvaag Oslo Metropolitan University, Oslo, Norway

# **BACKGROUND**

It is important to have outcome measures reflecting the complexity of mobility in daily life. The Figure-of-8-Walk-Test developed by Hess et al.[1] is a test of curved-path walking designed to simulate the complexity of walking in daily life and has not yet been used in persons with lower limb amputation (LLA). We propose two novel conditions of the Figure-of-8-Walk-Test with the purpose of capturing more of the environmental and cognitive challenges persons with LLA face in daily living.

## AIM

Investigate construct and known-groups validity of the Figure-of-8-Walk-Test with two novel conditions in persons with LLA.

# **METHOD**

50 adult persons, age (SD) 54 (13) years, participated. 56 % had a transtibial amputation and 44% a transfemoral amputation or knee disarticulation. Three Figure-of-8-Walk-Tests were investigated: 1) walking with self-selected walking speed, 2): carrying a tray with two cups of water and 3) walking on uneven terrain. Construct validity was examined by the relationships between Figure-of-8-Walk-Test parameters and other measures of mobility. Comparison of Figure-of-8-Walk-Test parameters based on anatomical level of amputation was used to assess known-groups validity. In addition, to reduce the complexity of the analysis we formed a composite score of both the performance based tests (a *Composite mobility performance score*) and the F8WT (a *Composite F8W score*) and examined the associations between these scores.

# **RESULTS**

Figure-of-8-Walk-Test time and steps demonstrated good to excellent correlation (r = -.50 to -.77) with performance-based mobility measures, while the correlation was fair to good (r = -.41 to -.57) with the self-report mobility measures. Most Figure-of-8-Walk-Test parameters when carrying a tray with two cups of water were different (p < .05) between transtibial and transfemoral amputation/ knee disarticulation. The *Composite Figure-of-8-Walk-Test score* showed a strong negative association with the *Composite mobility performance score* for all three walking conditions (r<sup>2</sup> = .51 to .69; p < .001).

# **DISCUSSION AND CONCLUSION**

The Figure-of-8-Walk-Test and the novel conditions demonstrated good convergent construct validity and evidence of known-groups validity. Strong correlations between the *Composite mobility performance score* and the *Composite Figure-of-8-Walk-Test score* indicate that functional mobility of prosthetic users can be predicted with good accuracy by the composite Figure-of 8-Walk-Test score. Further development of the smoothness score is recommended and future studies should assess responsiveness and reliability of the Figure-of-8-Walk-Test and the novel conditions, while investigations on the known-groups validity should include persons with a wider mobility range.

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# **ACKNOWLEDGEMENTS**

This work was supported by the foundation "Stiftelsen Sophies Minde" Oslo, Norway.



# 1.2.6.d

# The Amputee Mobility Predictor - Translation into Norwegian and Inter-rater reliability

<u>Øyvind Bernhardsen</u><sup>1</sup>, Ole Andreas Nilsen<sup>2</sup>

Trøndelag Orthopedic Workshop, Trondheim, Norway. <sup>2</sup>The Artic University of Norway, Tromso, Norway

#### **BACKGROUND**

The Amputee Mobility Predictor is an instrument designed to measure ambulatory potential of lower-limb amputees with (AmpPro) and without (AmpNoPro) the use of a prosthesis. The instrument has never before been translated into Norwegian and interrater reliability of the Norwegian version has therefore not yet been examined.

#### AIM

The aim of this study was to assess the between raters' (inter-rater) reliability of the Norwegian version of the Amputee Mobility Predictor.

# **METHOD**

24 adult lower-limb amputees were recruited and classified according to ability to ambulate. The Amputee Mobility Predictor performance of participants was filmed. All participants were tested with and without prosthesis. The exception was two subjects that only were tested without prosthesis since they did not use one, and two bilateral amputees that only were tested with their prosthesis since testing without was not possible. Seven raters then scored the film once. For total scores on The AMP, relative reliability was investigated for by calculating Intraclass correlation coefficients. For individual items, Cohen's kappa (k) and percentages agreement were calculated. BlandAltman Plot was used to verify the consistency of measurements graphically

#### **RESULTS**

For inter-rater assessments very high relative reliability (ICCs $\geq$ .98) for AmpNoPro and ICC $\geq$ 0.94 for AmpPro were shown. Kappa values for the individual items ranged between 0.11-1.00. The majority of items, 77.2 %, showed very good or good agreement ( $k\geq$ 0.61). Only one item (inter-rater=3.5 %) showed slight agreement ( $k\leq$ 0.20).

## **DISCUSSION AND CONCLUSION**

This study showed a very high inter-rater reliability of The Amputee Mobility Predictor on lower limb amputees tested both with and without prosthesis. The majority of the individual items showed very good or good agreement, some moderate and one item slight agreement.

Limitations: Results should not be generalized to individuals with cognitive impairments, as they were not included in this study.



# 1.2.6.e

# An Extended L-Test with Multiple Challenging Walking Situations - A Pilot Study

Inger Marie Starholm, Siri Eidnes, Kristine Ottersland, <u>Terje Gjøvaag</u> Oslo Metropolitan University, Oslo, Norway

#### **BACKGROUND**

Current functional tests for evaluating the mobility of prosthetic users, do not sufficiently measure mobility during activities of daily life (ADL). Yet there is a high demand for outcome measures in rehabilitation research that reflect the challenges prosthetic users face on a daily basis.

## **AIM**

The main aims are: 1) Conduct pilot-testing of an extended version of the L-test (L-EXT), incorporating several mobility obstacles identified as challenging by focus groups interviews of prosthetic users. 2) Consider the construct validity of the L-EXT.

# **METHOD**

Challenging mobility situations were identified from focus-group interviews of prosthetic users [1] and incorporated into the "standard" L-test [2] (Fig 1). Ten persons with transfemoral amputation (TFA) and ten healthy controls (CON), aged 54(12) and 52(12) years, started the test in a sitting position. On a signal, they grabbed a carrying bag with three 1L containers (1), walked over a soft surface (2), around two cones (3), progressed over a staircase (4), before placing the containers into the shelf (5). The participants then returned the containers to the bag, and completed the course in the opposite direction. Time stopped when the participants sat down on the chair.

# **RESULTS**

Mean (SD) time for the TFA and CON to complete the L-EXT test was 51.9 (7.4) and 36.1(4.4) seconds, respectively (p < 0.001). Spearman rank order correlation (p) was used to define the bivariate relationships of the L-EXT results (time) with other functional test used for assessing prosthetic mobility. Correlation coefficients with the Timed-Up-and-Go test (TUG), Two-minute-walk-test (2MWT) and Maximal walk speed (MaxWs) test were: 0.833 (p < 0.001), -0.870 (p < 0.001), -0.817 (p < 0.001), respectively.

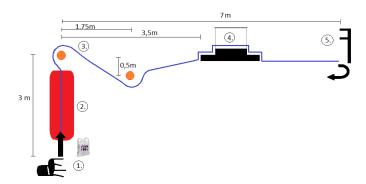


Figure 1. The extended L – test with obstacles (1-5)

# **DISCUSSION AND CONCLUSION**

The TFA performed the L-EXT nearly twice as slow as healthy controls. The TFA in the present study were experienced prosthetic users and their average PLUS-M score was 57.9 (5.0), hence their self-assessed mobility was above average score (50). Comparisons of the L-EXT to other performance tests (Spearman's *rho*) show excellent correlations.[3] In conclusion, we judge the L-EXT test to have good construct validity. Work is in progress to investigate known-groups validity, ceiling effects, and reliability of repeated measurements.

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# 1.2.6.f

# Japanese Translation of the Prosthetic Limb Users Survey of Mobility (PLUS-M)

<u>Geoff Balkman</u>, Soshi Samejima, David Aoki, Brian Hafner University of Washington, Seattle, USA

#### **BACKGROUND**

Patient-reported outcome measures (PROMs) can be used by prosthetists and researchers to evaluate important health outcomes. The Prosthetic Limb Users Survey of Mobility (PLUS-M) is a valid and reliable PROM designed in English to assess perceived mobility of lower limb prosthesis users.[1] Few PROMs specific to prosthesis users exist in Japanese, and translations of existing instruments are needed to facilitate measurement of prosthetic mobility outcomes in Japan.

#### ΔIM

The purpose of this research was to translate PLUS-M from English to Japanese using recommended translation methods in order to maintain the meaning and applicability of items across languages.

#### METHOD

Translation efforts followed recommended processes and best practices.[2] First, PLUS-M items (n=44), response options, and instructions were independently translated from English to Japanese by two investigators. Translators then met with the principal PLUS-M developer to reconcile the forward translations and resolve any discrepancies. Established guidelines [3] were used to code and document decisions. The reconciled translation was next back-translated from Japanese to English by a bilingual collaborator. Investigators compared the back-translation relative to the English instrument, and the developer identified items that required modification. All translations and revisions were recorded in a comprehensive translation document. Four expert reviewers in Japan evaluated the translation and provided additional suggestions for revisions.

## **RESULTS**

Twenty-one items were removed or revised. One item that describes shag (high-pile) carpet was removed because it is not common in Japan. Seventeen items were revised grammatically to maintain the intent of the English items. For example, an item that asks if respondents can "step off an escalator" was translated to "get off an escalator step-over-step" to preserve the intended meaning. Three items were revised to address cultural or environmental differences. For example, the term "block" in, "Are you able to walk a block on flat ground?" does not translate to Japanese. Investigators, therefore, changed "a block" to "from one traffic signal to the next" to revised the scenario and maintain the intended meaning (i.e., walking moderate distances outdoors). The translated items were used to create short forms suited to administration in clinics or research studies (Figure 1).



Figure 1 - Japanese PLUS-M short form

# **DISCUSSION AND CONCLUSION**

The PLUS-M Japanese version is now ready for testing. Cognitive interviews with Japanese prosthesis users will assess the clarity and comprehensiveness of items. Large-scale administration and comparison to US norms will allow comparison between the English and Japanese versions of PLUS-M. International and cross-cultural comparisons of key health outcomes, like mobility, can help to assess the relative effectiveness of prosthetic interventions. Use of standardized outcome measures, like PLUS-M, can facilitate comparisons and improve the standard of care worldwide.

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## **ACKNOWLEDGEMENTS**

The authors thank Kazuhiro Sakai, Toshiki Kobayashi, PhD, Masanori Shimamura CPO, and Noriaki Maeda, PhD for reviewing the translation.



# 1.2.6.g

# Performance Testing in People with Lower Limb Amputation: Interviews with Prosthetists, Physical Therapists, and Physicians

Geoff Balkman<sup>1</sup>, Sara Morgan<sup>1</sup>, Ignacio Gaunaurd<sup>2</sup>, Anat Kristal<sup>2</sup>, Dagmar Amtmann<sup>1</sup>, Robert Gailey<sup>2</sup>, Brian Hafner<sup>1</sup>

<sup>1</sup>University of Washington, Seattle, USA. <sup>2</sup>University of Miami, Coral Gables, USA

# **BACKGROUND**

A variety of performance-based tests can be used to assess mobility in people with lower limb amputation (LLA).[1] Selection of a specific test is likely to be guided by the clinical value of tasks patients perform; the space and equipment available to administrator the test; and/or the time required to set up, administer, score, and interpret the test results.

## AIM

The aim of this study was to collect information from rehabilitation clinicians about factors that facilitate or prohibit use of performance tests in clinical settings. Additionally, we sought to identify tasks that clinicians perceive to be effective indicators of mobility.

# **METHOD**

Semi-structured telephone interviews were conducted to gather information from clinicians about administering performance tests to people with LLA. A convenience sample of prosthetists, physical therapists (PTs), and physiatrists was recruited through investigators' professional contacts. An interview guide [2] was used to ask participants about the clinical environment in which tests may be administered; available resources, including space, equipment, and time; barriers or facilitators to performance testing, and tasks with perceived clinical value. Interviews were audio-recorded and transcribed. Qualitative data were reviewed for themes and quantitative data were tabulated to compare results across and within professional groups.[3]

# **RESULTS**

Prosthetists (n=8), PTs (n=9) and physiatrists (n=8) from 12 states in the USA were interviewed. Physical tasks most frequently identified as useful mobility assessments included walking (n=25/25), sit-to-stand (n=25/25), and

standing (n=20/25). Stair climbing, transfers, and navigating obstacles were also identified as useful by more than half of the participants. All participants had access to a long corridor, a stopwatch, and tape measure. The majority of PTs (n=8/9) had access to therapy gyms, whereas fewer physiatrists (n=5/8) and prosthetists (n=2/8) had access to large spaces. Physiatrists were generally less willing to spend more than 10 minutes administering tests (Figure 1). Most participants (n=18/25) used performance-based tests to document patient progress and nearly half (n=11/25) used them to determine functional level or justify services to payers.

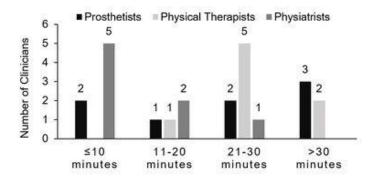


Figure 1. Maximum amount of time clinicians were willing to spend on performance testing per patient appointment.

# **DISCUSSION AND CONCLUSION**

Interviews with clinicians provided insight into factors that inhibit and promote performance testing in clinical practice. Differences in resources across disciplines may inform the pairing of suitable tests to specific environments. Results of this study suggest that performance tests intended for use across disciplines and settings should include tasks with perceived clinical value that require minimal time, equipment, and space.

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## **ACKNOWLEDGEMENTS**

This research was supported by a grant from the National Institutes of Health (R01HD065340).



# Free Paper Session Rehabilitation Medicine & Surgery - Lower Limb Surgery

# 1.2.7.a

# **Examining the Complication and Re-operation Rates After Osseointegrated Reconstruction**

William Lu<sup>1,2,3</sup>, Munjed Al Muderis<sup>3,4,5</sup>

<sup>1</sup>Osseointegration International, Leichhardt, Australia. <sup>2</sup>The University of Sydney, Sydney, Australia. <sup>3</sup>Macquarie University, Sydney, Australia. <sup>4</sup>The University of Notre Dame, Sydney, Australia. <sup>5</sup>Norwest Private Hospital, Sydney, Australia

# **BACKGROUND**

Osseointegration has emerged as a promising alternative to rehabilitating with a traditional socket mounted prosthesis. A major concern of the Osseointegrated approach lies in the risk of infections occurring from the permanent transcutaneous opening often referred to as the stoma. Several systematic reviews have indicated that the occurrence of minor infections can be quite common, serious complications are reported to be rare.

#### **AIM**

The objective of this study is to look into the rate of occurrence of all subsequent complications requiring a reoperation after a patient receives osseointegration surgery.

# **METHOD**

A detailed analysis has been performed on all osseointegration surgeries performed by our group since 2010. The surgeries took place in Sydney Australia at three different hospitals (Norwest Private Hospital, Macquarie University Hospital and Hurstville Private Hospital) and were all performed by a single surgeon. All events leading to a readmission and subsequent re-operation have been identified through hospital operation records and pooled together for meta-analysis. Events identified include: revision of implants, periprosthetic fracture fixation, surgical debridement due to infections, neurectomies and soft-tissue refashioning.

#### **RESULTS**

A total of 261 surgeries have been identified with a minimum 12-month follow-up time (mean follow-up time 33.1±16.14 months) and included in this study. These included 71 tibial, 187 femoral and 3 humeral osseointegration cases. 76 of these were performed using a 2 stage protocol while the remaining 185 were performed in a single stage. Among all cases, there were a total of 130 re-operation events recorded which occurred among 66 patients, indicating a high recurrence rate among the same patients. We recorded a total of 29 debridements, 29 neurectomies, 43 soft tissue refashions, 22 implant revisions and 7 periprosthetic fracture fixations. Interestingly, the rate of debridements and soft-tissue refashions were found to be reduced for patients who were operated using a single stage surgery.

# **DISCUSSION AND CONCLUSION**

Many events leading to readmission after the primary surgery may amount to a significant inconvenience for the patient and financial burden of the healthcare system. We have identified here possible reasons in which an osseointegration patient may need to be re-admitted into hospital for additional surgery. Through the implementation of improved surgical techniques and rehabilitation protocols, the rate of several of these reoperation events can be largely reduced, thus improving the overall outcomes of patients undergoing osseointegration surgery.



# 1.2.7.b

# Pushing the Boundaries of Bone Anchored Prosthetic (Osseointegration) Technology

<u>Munjed Al Muderis</u>, William Lu Osseointegration International, Sydney, Australia

#### **BACKGROUND**

Osseointegration is a surgical approach to eliminate the use of a socket prosthesis which offers amputees a new way to rehabilitate. To date, over 1300 osseointegration surgeries have been performed numbers rapidly increasing each year. Unfortunately, patients who are at high risk of complications are often excluded from these treatments yet are the ones most likely to receive the largest benefit.

#### AIM

The objective of this paper is to summarise the latest clinical knowledge obtained in the development of osseointegration technology and discuss the risk/benefit profiles of possible expansions in indications.

# **METHOD**

This is a meta analysis of the current literature current available on Osseointegration specifically looking into the safety, complications and risk factors associated with this controversial technique. Furthermore, we will also review and report on the mid-to-long term follow-up results based on a multi-centre analysis on the world's largest osseointegration patient cohort.

# **RESULTS**

Our analysis has revealed that similar levels of improvement in function and mobility can be repeated in these patients at very similar risk levels and in some cases perhaps can serve a protective role in controlling the underlying disease conditions.

# **DISCUSSION AND CONCLUSION**

This will allow osseointegration to become an attractive alternative to conventional socket prosthesis for a wider range of amputees. This will assist clinicians in the decision making process of selecting an appropriate treatment strategy for their amputee patients.



# 1.2.7.c

# Osseointegrated Implants in Patients with Diabetes Mellitus: A Case Series of Eight Patients

Shakib Al-Jawazneh<sup>1</sup>, William Lu<sup>1,2</sup>, <u>Munjed Al Muderis</u><sup>2,1</sup>

<sup>1</sup>Macquarie University, Sydney, Australia. <sup>2</sup>Osseointegration International, Sydney, Australia

#### **BACKGROUND**

Osseointegration is a novel approach to eliminate socket related problems experienced by amputees. Over 70% of amputations in developed countries are due to vascular causes with the prevalence of diabetes mellitus reaching pandemic status leading to more amputations. Traditionally, diabetic patients with amputations have been excluded from osseointegrated reconstruction due to higher risks of complications.

#### AIM

The aim of this study is to report on the clinical outcomes of diabetic patients receiving an osseointegrated reconstruction.

# **METHOD**

This is a case series with one-year follow-up in eight diabetic patients with trans-tibial or trans-femoral amputation, and have received osseointegration implants between 2013 and 2016. Clinical and functional outcomes were assessed including pain, prostheses wearing time, mobility, walking ability and quality of life. Adverse events were monitored and recorded, including infection, fractures, implant failure, revision surgery, further amputation and death.

## **RESULTS**

Three trans-tibial and five trans-femoral amputees (aged 48-73 years) were included in this study. All patients were pain-free and still using the osseointegrated prosthesis at 12-months post-surgery. The mobility of all patients improved at follow-up. Notably, five of the eight patients were wheelchair-bound prior to surgery, but all were able to walk and perform daily activities at follow-up. Two patients experienced infection events which were treated by surgical debridement. One patient experienced peri-prosthetic fracture after a fall which was fixated by a lag screw. No other adverse events were recorded.

## **DISCUSSION AND CONCLUSION**

Lower limb amputees with a history of diabetes mellitus have been traditionally excluded from osseointegrated reconstruction. Here we report the initial results of treating diabetic amputees with osseointegration, demonstrating improvements in function, mobility and quality of life. It can be expected that the improved function and mobility can serve a protective role in controlling the underlying diabetic conditions in these patients which makes osseointegration an attractive alternative to conventional socket prosthesis.



# 1.2.7.d

# Osseointegrated Implants for Lower Limb Amputees: Evaluation of Bone Mineral Density

Seamus Thomson<sup>1,2</sup>, William Lu<sup>2</sup>, Munjed Al Muderis<sup>2,3</sup>

<sup>1</sup>The University of Sydney, Sydney, Australia. <sup>2</sup>Osseointegration International, Sydney, Australia. <sup>3</sup>Macquarie University, Sydney, Australia

# **BACKGROUND**

The use of dual-energy X-ray absorptiometry (DXA) is a standard clinical procedure for the evaluation of bone mineral density (BMD). Amputee patients are known to have decreased BMD and an increased risk of osteoporosis in the affected proximal femur and hip region. The major cause of these issues in these patients is the absence adequate loading leading to bone resorption in accordance to Wolff's law.

#### AIM

In this paper, we present a prospective study reporting changes in BMD among amputees who received osseointegrated implants to determine if the loading through the Osseointegrated implant can overcome the bone resorption issues.

# **METHOD**

This is a prospective study of 33 patients, consisting of 24 males and 9 females, aged 22-77 (mean =  $51.0 \pm - 2.0$ ) years with one and two-year follow-up. Selection criteria included age over 18 years, unilateral amputees with socket-related problems. All patients received osseointegrated implants press-fitted into the amputated limb. BMD was assessed using DXA in the femoral neck (operative and contralateral) and lumbar spine (L2-L4) regions, and corresponding Z-scores were generated. DXA scans were taken preoperatively as well as one-year and two-years following osseointegration surgery.

#### **RESULTS**

Mean BMD and Z-scores of spine, and operative and contralateral sides were generated for all patients. Dependent t-tests were used to test for significant differences (P<0.05) preoperative, one-year, and two-years for mean changes in BMD and Z-Scores following surgery. Analysis of the BMD and Z-scores indicated that patients showed improvements at one-year post-surgery.

## **DISCUSSION AND CONCLUSION**

These results suggest that osseointegrated implants are effective at encouraging bone growth and restoring BMD levels for amputees within a short period of time post-surgery. Osseointegrated implants therefore have the potential to address stress distribution issues associated with socket prostheses and restore the normal bone loading regime in lower limb amputees.



# 1.2.7.e

# The Use of Osseointegrated Titanium Implants to Treat Bilateral Amputees

William Lu<sup>1</sup>, Munjed Al Muderis<sup>2,1</sup>

<sup>1</sup>Osseointegration International, Sydney, Australia. <sup>2</sup>Macquarie University, Sydney, Australia

#### **BACKGROUND**

Current socket prostheses remain problematic, resulting in more than 90% of patients with bilateral above-knee amputations being confined to a wheelchair due to the difficulty of mobilizing with prosthetics on both lower limbs. Osseointegration has been regarded as a novel approach to overcome persistent socket prosthetic issues, using a transcutaneous implant directly attached to the residual bone. A number of bilateral amputees have been treated with osseointegration in our center since July 2012.

#### ΔIM

The aim of this paper is to report the early clinical outcomes in this particular group of patients, including the results of functional and quality of life assessments, and safety of the osseointegration procedure.

#### METHOD

This is a prospective pilot study of 13 patients, consisting of 10 males and 3 females, aged 24-62 (mean 38.7) years at surgery, with minimum two-year follow-up. Selection criteria were age over 18 years, bilateral amputees who had socket-related problems or were wheelchair-bound with short stumps and non-reconstructable limb pathology. Principle outcome measures included the Questionnaire for persons with a Trans-Femoral Amputation (Q-TFA), Short Form Health Survey 36 (SF-36), Six Minute Walk Test (6MWT), Timed Up and Go (TUG), and K-levels. Adverse events were recorded including infection, revision surgery, fractures, and implant failures.

#### **RESULTS**

Comparisons were made using differences between the mean pre-operative and mean post-operative values for each outcome measure. Significant improvements in all validated outcome measures were observed. The occurrence levels of adverse events, including the infection rate and revision rate, were similar to other established trans-femoral osseointegration studies.

# **DISCUSSION AND CONCLUSION**

These preliminary results indicate that osseointegration surgery is a safe and effective alternative treatment for bilateral amputees experiencing socket-related discomfort. Compared to the suboptimal outcomes of socket prostheses, osseointegration currently provides one of the best chances for any bilateral amputee to walk again and regain the ability to perform daily activities.



# Advanced IC Sports & Physical Activity

# 1.2.8

Different body, same mind: The collaboration of prosthetic design, fitting and training to maximize athletic performance.

Robert Gailey<sup>1</sup>, Knute Lechler<sup>2</sup>, Peter Harsch<sup>3</sup>

<sup>1</sup>University of Miami Miller School of Medicine, Coral Gables, USA. <sup>2</sup>Ossur, Weinsberg, Germany. <sup>3</sup>Peter Harsch Prosthetics, San Deigo, USA

## **Abstract**

People who have the potential for high-level activities, want to return to the sports and recreational activities they pursued prior to their loss of limb. Although they may have a different body, they have the same mind for sport, general fitness and the same desire to remain healthy by to including regular exercise into their daily lives or just being able to play with their children and friends. Recent innovations in prosthetic materials and designs have enable more people than ever to participate in more diverse sports and recreational activities.

This three-part comprehensive presentation will offer:

- 1) An update on manufacturer's prosthetic materials and design criteria and how they are impacting sports.
- 2) A discussion on socket/suspension designs, sport specific prosthetic alignment and various fabrication techniques to facilitate the return to sports for more people.
- 3) Finally, this presentation will introduce a series of novel training exercises designed to safely maximize athletic performance with a prosthesis. Moreover, selected outcome measures will be introduced to quantify the amputee athlete's improvement while training to reach their goals.

Each speaker will include the most recent scientific evidence. Differences between novice and elite athletes will be described with an emphasis on how an athlete might progress with component selection, prosthetic modifications and training progressions. To facilitate an interactive audience discussion, case studies of known athletes will be presented to provide real-life examples how the information presented may be applied in clinical practice.

# Statement of the objective / learning objectives

Participants will be able to:

- 1) describe the appropriate prosthetic components for specific sports,
- 2) discuss prosthetic fit and alignment concerns for amputee athletes,
- 3) identify training exercises for the enhancement of prosthetic performance.



# Advanced IC Orthotics: Lower Limb Neurological

# 1.3.1

# **Guideline-Based Orthotic Treatment in Neuromuscular Disorders**

Merel Brehm<sup>1</sup>, <u>Fieke Koopman</u><sup>1</sup>, <u>Tom Gort</u><sup>2</sup>, <u>Bart Raijmakers</u><sup>1</sup>

<sup>1</sup>Amsterdam UMC, Academic Medical Center, Amsterdam, Netherlands. <sup>2</sup>OIM orthopedie, Noordwijkerhout, Netherlands

## **Abstract**

Leg orthoses are commonly applied to improve mobility in people with neuromuscular disorders. Yet, the decision-making process leading to orthosis prescription in this patient group is based more on expert opinion and clinical experience (i.e. trial-and-error approach) than on evidence. This results in differences in treatment paradigms both with respect to the indication and construction of leg orthoses. In 2011, a Dutch national guideline on the prescription of leg orthoses in neuromuscular disorders was published, following the Process description of Medical devices.

This guideline provides information that supports the decision-making process leading to orthosis prescription. Hence, understanding of this guideline-based approach, and being able to use it in the decision-making process, including the indication, selection, fabrication, training and evaluation fleg orthoses, will support clinicians and other healthcare professionals in applying orthotic treatment in neuromuscular disorders more effectively.

# Statement of the objective / learning objectives

To provide health professionals with understanding of a *guideline-based orthotic treatment approach* and show how this approach can be used for the indication, selection, fabrication, training and evaluation of leg orthoses *in neuromuscular disorders*.



# Free Paper Session Orthotics & Prosthetics - Digital Technologies

# 1.3.2.a

# Implementation of 3D Technologies to Deliver Transparent Facial Orthoses (TFO) for Burn Patients in a Humanitarian Context

<u>Pierre Moreau</u><sup>1</sup>, Safa Herfat<sup>1,2</sup>

<sup>1</sup>MSF Foundation / Doctors Without Borders, Paris, France. <sup>2</sup>University of California San Francisco (UCSF), San Francisco, USA

## **BACKGROUND**

Conflicts and low resource settings expose populations to challenging living conditions with high risk of severe burns. Deep facial burns require long and specialized treatments with esthetic and functional complications. Among international face burn care standards, application of the TFO is required to limit the appearances of scar complications. TFOs are not always available to patients in humanitarian settings due to lack of access to

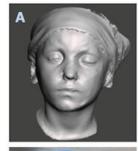
specific materials and trained rehabilitation professionals with specialized training to make these orthoses.

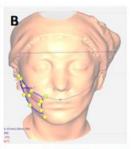
# AIM

To develop a scalable process for creating TFOs using 3D technologies and remote rectification that could increase access to TFOs for facial burn patients in challenging settings, while eliminating patient discomfort due to applying plaster to the face.

# **METHOD**

A 3D surface scan of the patient face is first acquired using a white light scanner (Rodin4D M4D). The surface scan model is then processed on a CAD/CAM software (Rodin4D Neo) to design the TFO through digital rectification to modify pressures on the facial structure. This step can be performed remotely by a trained expert. A negative of the modified face is 3D printed (Ultimaker-3-Extended) using PLA filament, allowing the local team to prepare the positive using plaster and the mask using the conventional thermoformed plastic sheet (PETG). Since Summer 2018, 10 patients at the MSF (Doctors-Without-Borders) Reconstructive Surgery Hospital (Amman, Jordan) have benefited from this new process.









A) Raw 3D Scan Data, B) Rectification using CAD/CAM Software, C) 3D Printed rectified negative, D) Final TFO on patient

# **RESULTS**

This pilot project demonstrated the proof of concept of the 3D workflow for TFO development and the feasibility of remote rectification using the digital process. Among the 10 patients, 6 benefited from digital modifications performed remotely by an MSF expert or Clinical Expert from a French hospital (Leon Berard, Hyeres). For all 10 cases, the local MSF rehabilitation team and the patients did not report any clinical dissatisfaction with this process. The final TFOs were comfortable and safe for the patient as they were made from the same thermoformable PETG material as the conventional TFO.

# **DISCUSSION AND CONCLUSION**

This pilot project demonstrated the feasibility of creating a burn TFO by implementing 3D technologies with remote rectification. A full study is currently underway to to demonstrate the efficiency of this process compared to the conventional process. The use of this method could increase access to specific facial burn care in challenging places where there are currently no solutions available. Furthermore, the use of 3D technologies can simplify the conventional process and provide more comfort to the patient.

# **ACKNOWLEDGEMENTS**

This Project was funded by MSF Foundation donors.



# 1.3.2.b

# Processing 3D-Scans Using Statistical Shape Analysis and Automatic Pose Correction for Subsequent Orthosis Fitting

<u>Benjamin Gröschel</u>, Max Thalmeier Mecuris GmbH, Munich, Germany

#### **BACKGROUND**

In the medical field, 3D-technology enables the creation of individualized medical devices that are tailored to perfectly fit the patient's anatomy. After the acquisition of the patient's 3D-scan, the data needs to be processed before it can be used to design medical devices. Two of the biggest challenges in processing the 3D-data are patient posture and scan quality, where surface information can be distorted by noise.

#### AIM

Two problems will be tackled: A method to automatically correct the posture of lower-limb 3D-scans to acquire a neutral stance and secondly an approach to enhance the quality of patient scans by use of Statistical Shape Models (SSM).

# **METHOD**

The first step to acquire a neutral posture is automatically fitting a generic template model, consisting of a skin and bone model from an average person into the patient's 3D-scan. This is done by rigidly aligning the meshes via the Iterative Closest Point (ICP) algorithm. The mesh of the patient scan is rigged to an armature which can be used to match the posture of the template model.

Overcoming the secondly described issue of low scan quality can be done by using machine learning to register and understand the 3D-data. From a training set containing various shapes of the anatomies of interest, the Statistical Shape Model can be extracted.

# **RESULTS**

The results regarding the automatic pose-correction method are split into three separate rotation angles around the ankle joint. The results for correcting plantar- and dorsiflexion angles are exceedingly good: For all three subjects used, the maximum plantar flexion angle after correction was just above 5° with an overall mean value of 1.7°. Correcting inversion and eversion angles also displayed satisfying results.

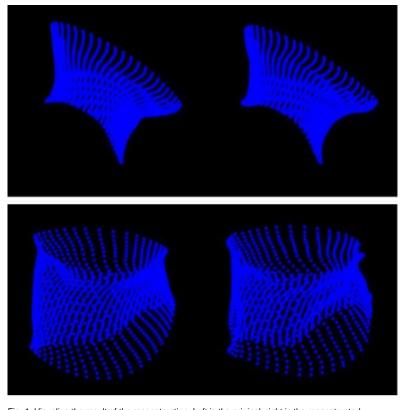


Fig. 1: Visualize the result of the reconstruction. Left is the original, right is the reconstructed.

As for the SSM, the size and diversity of the training set has the biggest influence on the quality of the shape model. Overall the described method is able to reconstruct a new sample from a limited training set, with a sufficient accuracy for orthosis fitting. Figure 1 shows the results of this reconstruction process via usage of the SSM.

# **DISCUSSION AND CONCLUSION**

We have proposed a method to prepare 3D-data for orthosis fitting process. Our method allows for automatically correcting the posture of input data. After obtaining the pose-corrected 3D-data, a model of the patient can be reconstructed using a robust statistical shape model. The result is a model of the patient data that has a correct posture, independent of the quality of the input scan. This reconstructed model is now ready for fitting an orthosis.



# 1.3.2.c

# 3D-SPA, a Novel Method to Determine the Three Dimensional Static Prosthetic Alignment within Conventional Gait Analysis

Daniel W. W. Heitzmann<sup>1</sup>, Rebecca Rack<sup>1,2</sup>, Thomas Kaib<sup>1</sup>, <u>Julia Block</u><sup>1</sup>, Sebastian I. Wolf<sup>1</sup>, Merkur Alimusaj<sup>1</sup> Heidelberg University Hospital, Dept. for Orthopaedics and Trauma Surgery, Heidelberg, Germany. <sup>2</sup>Offenburg University Department of Mechanical and Process Engineering, Biomechanics, Offenburg, Germany

#### **BACKGROUND**

Prosthetic alignment is one influential factor on biomechanics in lower limb prosthetics.[1] Therefore, alignment should be controlled when comparing different prosthetic designs, as differences would be confounding factors and perchance deteriorate results. Conventional 3D gait analysis (CGA) is an established tool to quantity biomechanical effects in lower limb prosthetics. In this study we try to establish a novel method to measure static alignment based on CGA.

#### AIM

The method should quantify the 3D static prosthetic alignment (3D-SPA), by means of CGA. It supposed to be reliable, fast and therefore must not burden the common CGA procedure.

#### METHOD

The retrospective data of twelve participants with an unilateral trans-tibial amputation (PTTA/ 86±12.4kg, 181±7.2cm, 51±12.9years, 2female, 10male) were included.[2] The PTTA used two prostheses either with Variflex or Proflex prosthetic foot (Össur) and stood quietly for 10 seconds on a force platform, with the involved side. They were equipped with markers according to Plugin-Gait. Trajectories were recorded by a motion capture system (Vicon). Euclidean-distances of the ground reaction force vector to Plugin-Gait's hip, knee and ankle joints were calculated, using custom Matlab software (Mathworks, USA).[3] Data is expressed as anterior-posterior and medial-lateral distances of the joints local reference-frame.

# **RESULTS**

The ground reaction force vector runs in the sagittal plane posterior of the hip- and knee- and anterior of the ankle joint centre (Plugin-Gait joint centres) for both feet (see fig.1). In the coronal or frontal plane it runs for both feet medial of the hip, knee and ankle joint centre (see fig.1). Normal distribution of the dataset was confirmed using the Schapiro-Wilk-Test and therefore a two sided Students

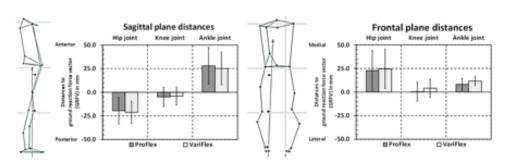


Figure 1: Sagittal and frontal/coronal plane distances of the ground reaction force vector to the the joint centres for the hip knee and ankle of the biomechanical gait analysis model (Plugin-Gait, Vicon, UK)

T-Test was utilized to compare differences between results for each foot. No statistical difference between both feet for all sagittal and coronal distances of the hip knee and ankle were detected (minimum p value >0.14).

# **DISCUSSION AND CONCLUSION**

In this first attempt and analysis of retrospective data we saw no significant differences between both prosthetic feet. To measure interactions between 3D-SPA and its biomechanical effects further studies have to be conducted, with planed alignment changes which could be correlated to biomechanics in gait. The 3D-SPA so far seems to be a promising method to report alignment. It is a true 3D measurement, as no projection onto planes is used to determine distances.

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# **ACKNOWLEDGEMENTS**

We would like to thank the participants with a trans-tibial amputation. We cannot pursue our research without their support.



# 1.3.2.d

# Nominal Accuracy of a Touch-Less Prosthetic Alignment Sensor

Karl Nelson, Caspar Nguyen, Esteban Ruiz, Jack Crowley, <u>Goeran Fiedler</u> APO Technologies, Haddonfield, USA

#### **BACKGROUND**

The success of modular endo-skeletal prosthetics in the last 50 years has come with many advantages for practitioners and patients alike. It has, however, made the documentation and replication of alignment changes more difficult because pyramid adapter angles are not easily measurable. It has recently been proposed to utilize Hall-effect sensors to accurately determine those angles,[1] leading to the development of a customer device for this purpose (APO Technologies, Philadelphia, PA).

#### AIM

This research was conducted to determine the accuracy of the APO device in a simulated use scenario.

# **METHOD**

A pyramid adapter was fixed solidly on a table top and a pylon adapter attached to it in the conventional way by tightening the set screws. The neutral position (90 deg angle to the ground) was confirmed with an electronic protractor. The APO device was calibrated and was subsequently used to facilitate angle changes to 1 degrees, 3 degrees, and 5 degrees in the four general directions, one at a time. At each of these pylon positions the angle was measured with the protractor as well. Agreement between the two measurements was quantified by correlation analysis and TOST equivalence test.[2]

## **RESULTS**

Electronic angle measurements correlated well with the gold standard measurements from a digital protractor (R=0.88). Figure 1 illustrates the correlation (left), as well as the variation between trials and between units of the device (right).

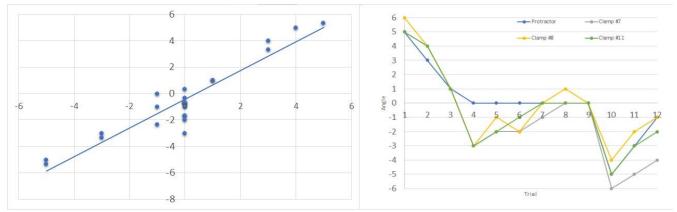


Figure 1: Correlation between gold standard angle measurements and average device angle measurements (left), and comparison of within- and between device deviations (right).

# **DISCUSSION AND CONCLUSION**

The bench tests confirmed an acceptable accuracy of the Hall-effect based angle sensor measurements. Pending further clinical tests, which are currently ongoing, this finding supports the utility of the tested device for the intended purpose of documenting alignment angles in endo-skeletal limb prostheses. Limitations of the study design included the nominal accuracy of the electronic protractor that was used as a comparison standard as well as that one investigator conducted all the tests.

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# **ACKNOWLEDGEMENTS**

This work is supported by a Small Business Innovation Research grant by the National Science Foundation.



# 1.3.2.e

# AmpScan: Open-Source 3D Scan Shape Analysis for Prosthetics and Orthotics

<u>Joshua Steer</u><sup>1</sup>, Peter Worsley<sup>2</sup>, Oliver Stocks<sup>1</sup>, Omar Animashaun<sup>1</sup>, Alexander Dickinson<sup>1</sup> Bioengineering Sciences Research Group, Faculty of Engineering and Physical Sciences, University of Southampton, UK. <sup>2</sup>Clinical Academic Facility, Faculty of Environmental and Life Sciences, Southampton, UK

# **BACKGROUND**

Surface scanners are used to digitise prosthetic or orthotic device-interfacing anatomy. These scans are then imported into rectification software to design the user-specific device. Previous studies have demonstrated the additional information that can be extracted from analysis of single and multiple scans, including benchmarking low-cost scanners by detailed analysis of plaster casting shape consistency,[1] and quantifying limb shape variability across populations.[2] However, this requires tools which are not commonly available to researchers or clinicians.

# AIM

The aim of this study is to develop a software package which provides open-source tools to clinicians and researchers, to capture more information from surface scans of devices and their users' anatomy.

AmpScan is an open-source software package written in Python. It can be used through either a Graphical User Interface (GUI) or directly through Python functions. A common workflow for a pair of shapes involves importing e.g. residual limb and socket design scans, aligning them using manual and automated methods, and calculating the pairwise shape deviation through registration. Further data including volume [3] and variation in cross-

sectional area along the length [4] can also be extracted. Speed performance was quantified relative to a previously reported MATLAB distribution of the code [4], for scans representing typical settings used in the clinic (~3mm vertex distance, 6,500-9,500 vertices) and very high detail (~100,000 vertices,

~1.85mm vertex distance).

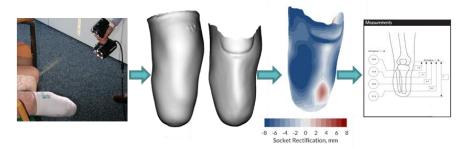


Fig 1: Example AmpScan workflow, from surface scan to quantification of pairwise shape deviation and automated report generation

## **RESULTS**

Detailed documentation of the software can be found online (ampscan.readthedocs.io/), along with community contribution guidelines and examples. Performance improvements were most marked for very fine, detailed meshes. For a ~100,000 vertex mesh, computing speed was increased by 3.86x for automated alignment (1.1s), 11.3x for registration (11.1s), and 19.6x for smoothing of the mesh (1.7s). This enables large sets of scans to be analysed quickly. The visualisation tools enable the surface deviation between scans of the residual limb and a patella bearing socket to be plotted (Fig1), using a standard convention derived from Sanders et al's seminal studies, [5,6] and accessible to users with most colour blindness types (deuteranopia, protanopia and tritanopia).

# **DISCUSSION AND CONCLUSION**

The AmpScan tool will enable researchers and clinicians interested in analysing data from surface scans to access these methods without needing to build them from first principles, or to invest in expensive software. The project's open-source distribution enables the community to contribute to the tool's development, and should allow analysis and results presentation to be benchmarked against a mutually agreed standard. Planned work involves user-experience development, making the GUI available as a web application, and automatic report generation.

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# **ACKNOWLEDGEMENTS**

Funders EPSRC/NIHR (EP/R014213/1, EP/M000303/1), EPSRC (EP/M508147/1) and RAEng (RF/130).



# 1.3.2.f

# Clinical Trial of Digitally Fabricated Ankle & Foot Orthoses

Melissa Fuller<sup>1</sup>, Jessica Fraser<sup>2</sup>, Stefan Czyniewski<sup>2</sup>, <u>Melissa Fuller</u><sup>3</sup>

<sup>1</sup>Mobius Medical, Austinmer, Australia. <sup>2</sup>Mobius Medical, Sydney, Australia. <sup>3</sup>AbilityMade, Sydney, Australia

#### **BACKGROUND**

For children with Cerebral Palsy (and other physical disabilities), ankle-foot orthoses (AFOs) are braces worn to improve posture, movement, and mobility. However custom-made AFOs are traditionally made using a manual plaster-casting process, which is slow and can be distressing for some children.

Digital scanning and 3D printing offer a revolutionary technology and can be used to make custom-made AFOs without plaster-casting or manual fabrication. A digital workflow enables children to access personalised AFOs quickly, easily and simplifies the process.

#### ΔIM

This study had two objectives. First, to determine whether 3D printed AFOs were as safe and effective as traditionally-made AFOs. Second, to compare the psychological impact of digital scanning compared to traditional plaster-casting for children and their parents.

# **METHOD**

27 children with physical disabilities were recruited for an observational study. The effectiveness of the AFO was measured using 2D gait analysis and given a gait score by an Orthotist.

Each participant visited the clinic on four occasions. During the first visit, the child and parent completed a survey about their previous experience with plaster-casting and underwent gait analysis in their traditionally-made AFO. The child's limb was then digitally scanned. They then completed a survey about their experience with digital scanning.

The AFO was then 3D printed and the child returned to be fitted and undergo more gait analysis in their new 3D printed AFO.

# **RESULTS**

Results indicate that 3D printed AFOs perform equally effective as traditionally-made devices but had a superior psychological impact on children and parents.

2D gait analysis revealed that the average gait quality for children in 3D printed AFOs was equivalent to traditionally-fabricated, suggesting that the two types are biomechanically equivalent. There was a slight improvement in gait over the 6 months of wearing 3D printed AFOs, however, this effect did not reach statistical significance.

The questionnaires revealed that both children and parents both found digital scanning to be significantly less distressing and anxiety-inducing compared to the traditional plaster-casting process.

These results suggest that 3D printing and digital scanning could potentially improve the lives of Australian children with disabilities, by helping them access personalised AFOs quickly, easily, and without the stress of plaster-casting.

# **DISCUSSION AND CONCLUSION**

A conclusion can be drawn to confirm that 3D AFOs can be considered as a biomechanically viable alternative to the traditionally manufactured AFOs.

A conclusion can be drawn to confirm that the utilisation of 3D scanners reduced distress experienced by participants when compared to traditional plaster casting methods.

There were no serious AEs noted or unexpected safety problems. It can be concluded from the safety findings the trial's 3D AFO is considered a safe alternative to the traditional manufactured AFOs.



# 1.3.2.g

# Evaluation of Applying Fused Deposition Modeling to 3D Print Lower Limb Orthotics in West-Africa: Preliminary Results of Imp&Acte3D Project

Kris Cuppens<sup>1</sup>, <u>Tom Saey</u><sup>1</sup>, Aude Brus<sup>2</sup>, Veerle Creylman<sup>1</sup>

Mobilab, Thomas More, Geel, Belgium. <sup>2</sup>Humanity & Inclusion, Lyon, France

#### **BACKGROUND**

According to the World Health Organization, only 5% to 15% of the people in low-income countries who need an orthopedic device have access to such a device. New technologies such as 3D printing have the potential to overcome this problem. This study examines whether the production of lower limb orthoses (night splints and (knee) ankle-foot orthoses) with fused deposition modeling (FDM) can help to improve limited access to orthopedic devices in West-Africa.

# AIM

The aim of the study is to check whether 3D-printed orthoses are equally effective compared to conventional ones

# **METHOD**

Patients who required a night splint (ankle joint deformity or genu varum/valgum) or a dynamic (knee) ankle-foot orthosis (knee or ankle instability) were recruited in 4 orthopedic centers in Togo, Mali and Niger. Patients were provided with a conventional and an FDM printed orthosis. Outcome measures were recorded before patients were fitted with a new orthosis and once more after each orthosis was worn for at least 2 weeks. Outcome measures for night splints were knee or ankle angles in sagittal or frontal plane, and 10 meter walk tests for dynamic orthoses. For all patients, the OPUS/CSD scale (Orthotics and Prosthetics Users' Survey - Satisfaction with Devices) was recorded.

# **RESULTS**

To compare the 10 meter walk test (change in improvement of walking with conventional and walking with 3D printed orthosis) and the measured angles (evolution of the angle after both treatments), a paired t-test was performed. To compare the answer values of the OPUS questionnaire, a Wilcoxon signed rank test was used. The preliminary results include data from 15 patients with a dynamic orthosis and 20 patients with a night splint. A 5% significance level was used for all tests. No statistical significant differences were found in improvements of walking speeds between the 3D printed orthoses and conventional ones. Nor a significant difference was found in improvement of the angle. Over all patients, there was one significant difference in answers to the OPUS questionnaire: "My device is comfortable throughout the day" (p = 0.045) in favor of the conventional orthosis.

# **DISCUSSION AND CONCLUSION**

Several causes might explain the differences in comfort between conventional and 3D printed orthoses. First, there is the learning process associated with 3D scanning, which can influence the quality of the orthosis. Also the weight of the orthosis might play a role. The 3D printed orthoses where heavier due to the higher density of the filament, although the questionnaire showed no significant difference on this topic. Lastly, the mechanical properties of the filament play a role in the perceived comfort.

# **ACKNOWLEDGEMENTS**

This research was supported by the Belgian Directorate-General for Development Cooperation and Humanitarian Aid (DGD).



# **Symposium Education**

# 1.3.3

# Physical Disability in Movies and the Media: Prejudices, Patterns and Changing Perceptions

Tina Hittenberger <sup>1,2</sup>, Lauren Selman <sup>3</sup>
<sup>1</sup>Drew Hittenberger and Associates, Petaluma,CA, USA. <sup>2</sup>American Board for Certification, Alexandria, VA, USA. <sup>3</sup>Producer and Activist, Hollywood, CA, USA

#### **Abstract**

Using archival footage and resources from the Academy of Motion Pictures Arts and Sciences, this narrated anthology will survey the history of physical disabilities in movies, illuminating how filmmakers have approached disabilities.

All over the world, people attend movies for entertainment, education and insights into lives other than their own. Using the basic tools of their trade - framing, editing, sound, lighting, set design - filmmakers create powerful experiences that mold perceptions, reinforce stereotypes and create fantasies. Actors, telling stories of people with disabilities, evoke powerful emotions of sympathy, fear, contempt or admiration - but they always remain outside mainstream society.

Prior to the 1960's, being disabled almost always assured social, education and occupational discrimination. Moviemakers' tendency to isolate disabled characters in realistic stories was consistent with the way mainstream society treated its disabled population. However, within the last fifty years, comics, sophisticated cartoons and animation have given rise to SUPERHEROES. In a new bionic world of mechically-enhanced demigods, physical disabilities are transformed into super-powers that can be used for both good and evil. Filmmakers have created high-tech prosthetics, digitally enhanced images, make-up and fantastic special effects that awe audiences. However, these invented characters are eccentric, formidable and certainly not part of the dominant culture. Where does that leave the audience - especially the disabled audience? How does a culture perpetuates itself and it's perspectives? Perhaps the images are so strong and the stereotypes so durable and pervasive that they may have obscured disabled people's perceptions of themselves.

# Statement of the objective / learning objectives

Through a narrated visual anthology attendees will be exposed to ways the movie industry has depicted the physically disabled experience, explore possible reasons for fascination with the topic and examine the attraction of high-tech heroics.



# Free Paper Session Prosthetics: Lower Limb Ankle & Foot - Gait

# 1.3.4.a

# Influence of Different Microprocessor Controlled Prosthetic Foot Concepts on amputees Posture while Standing on Uneven Ground

Michael Ernst, Bjoern Altenburg, Malte Bellmann, Thomas Schmalz Ottobock SE & Co. KGaA, Goettingen, Germany

#### **BACKGROUND**

For lower leg amputees an everyday task like walking and standing on uneven ground is challenging due to the limited adaptability of conventional prosthetic feet. To overcome the poor adaptability, prosthetic manufactures have developed different prosthetic feet with an additional rotational joint, implemented active control of resistance in dorsi-/plantarflexion and inclination-independent control of a dorsiflexion stop, e.g. [1-5].

# **AIM**

The study investigated which concepts implemented in current microprocessor controlled prosthetic feet (MPF) are beneficial for amputees and lead to a natural posture while standing on slopes.

# **METHOD**

We studied 4 transtibial (TT) and 4 transfemoral (TF) amputees. Five different MPF and the everyday prosthesis were used to investigate standing on level ground and on slopes of 10deg and -10deg. For reference, 20 ablebodied subjects (non-Amp) were also investigated. Leg joint angles, external joint torques and vertical ground reaction force (vGRF) distributions between prosthetic and sound side were calculated with the recorded kinematic (Vicon, GB) and kinetic data (2xKistler, CH). Mann-Whitney-U tests with a Bonferroni correction were performed to find differences.

#### **RESULTS**

vGRF distribution, joint angles and torques change in dependence of condition and used prosthetic feet for both ramps. The largest differences caused by the MPF were found on the decline. Other striking results are: almost

symmetrical vGRF distributions for all investigated feet on level ground and for MPF which fully adapt to the inclinations (others p>0.01 to non-Amp, fig.A). Large interindividual parameter variations were also observed (fig.B), except for MPF with full joint adaptation and an autoadaptable dorsiflexing stop.

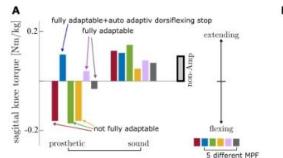




Figure 1. Knee torques and compensatory strategies for TTs on declines

# **DISCUSSION AND CONCLUSION**

The different MPF concepts influence the stance behaviour of amputees while standing on uneven ground. The observed large inter-individual variations in the posture are attributed to user-specific compensation strategies to cope with the lack of adaptability (fig.B). These variations vanish if equipped with an appropriate MPF.[5] The ability of the foot to lock in a dorsal direction once fully adapted to the inclination seems to be the key for a nearly natural posture.[5]

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# 1.3.4.b

Ramp Walking with Abruptly Changing Inclinations: Motion Patterns of TT Amputees Fitted with a Microprocessor-Controlled and a Conventional Prosthetic Foot.

Thomas Schmalz, Bjoern Altenburg, Michael Ernst Ottobock SE & Co. KGaA, Goettingen, Germany

#### **BACKGROUND**

Due to limited neuromuscular control, walking on uneven ground represents a challenge for lower limb amputees. Compared with the limitations of conventional prosthetic feet the new generation of microprocessor-controlled feet should enable a more natural motion pattern especially on uneven ground. Ramp walking was used to investigate parts of those differences, e.g.[1-4]. However, walking on abruptly changing inclinations and possible patient benefits resulting from the new feet technology has not been studied so far.[5]

#### AIM

The study investigated if the advanced adaptability of microprocessor-controlled feet to ground conditions would lead to more natural motion patterns if compared with conventional prosthetic feet for ramp walking with abruptly changing inclinations.

#### **METHOD**

A specific ramp with an abruptly changing incline (10°, Fig.1) was used to investigate walking it down with 10 healthy non-amputees (NA) and 4 unilateral TT amputees. At first, the amputees used their conventional 'everyday' foot (EF). Then they were fitted with a microprocessor-controlled foot (Meridium, Ottobock, "MPF") that enables real time adaptations to different ground surfaces. After an adaptation period of 2 weeks, the test was repeated using the MPF. The kinematic parameters of two gait cycles were determined using a specific marker set (VICON). Ground reaction forces (GRF) were measured with a force plate (KISTLER) during the contact with the abruptly changed incline (Fig.1).

# **RESULTS**

The biomechanical parameters of NA during the gait cycle before the abrupt change of inclination are in accordance with the motion pattern previously published for descending ramps [1]. The change of inclination is predominantly modulated in the ankle joint. The motion pattern of TT amputees is similar to NA for the hip joint whereas the knee joint is excessively extended during the abrupt change of inclination. The mean max dorsiflexion with MPF (16.3°) is

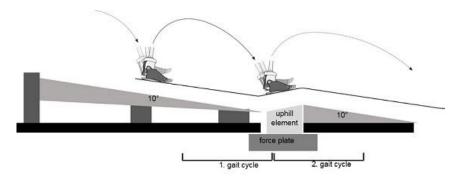


Figure 1. The test ramp with an abruptly changing inclination and analysed gait cycles (prosthetic side).

similar to NA (15.6°); the EF value (10.3°) is significantly decreased (p $\leq$ 0.01). The joint moments during the changing inclination show a pronounced reduction of the knee extension moment for MPF compared with EF (0.42 Nm/kg vs. 0.71 Nm/kg, p $\leq$ 0.01; NA: 0.36 Nm/kg).

# **DISCUSSION AND CONCLUSION**

Compared with the motion pattern of NA, the resulting reaction of TT amputees on the abrupt change of inclination is characterized by a compensation mechanism with an abnormal knee extension. The features of the MPF used lead to a benefit for the patient. Beside the reduced knee loading, the real time adaptation enables an increased dorsiflexion which results in an increased ground clearance and improved safety.

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# 1.3.4.c

# Harvesting and Returning Energy During Prosthesis User Gait

Lucas Lincoln<sup>1,2</sup>, Ben Macomber<sup>1</sup>, Jessica Zistatsis<sup>1</sup>, <u>Sarah Chang</u><sup>1</sup>, David Boone<sup>1</sup>
<sup>1</sup>Orthocare Innovations, LLC, Edmonds, USA. <sup>2</sup>Technical University Munich, Munich, Germany

#### **BACKGROUND**

Ankle joint power absorption and generation is important for gait efficiency, residual limb health, and safety in prosthesis users. The ankle joint attenuates energy transfer caused by collision of the foot with the ground at heel contact, overcomes inertia of the leg as the foot leaves the ground to initiate swing, and dorsiflexes to provide swing toe clearance. An active ankle system that better replicates natural energy transfer and range of motion may significantly improve stability and walking efficiency.[1, 2]

#### ΔIM

The purpose of this study was to validate the function of a prosthetic device to harvest and return energy during transtibial prosthesis user gait.

## **METHOD**

Two transtibial prosthesis users walked with an experimental hydraulic ankle-foot prosthesis over level ground in an IRB-approved study. The prosthesis was designed to harvest energy during stance and return energy for push-off and toe clearance during swing. Study participants walked with the prosthesis in passive mode (locked with the energy harvest and return disabled) and in active mode (energy harvest and return enabled). Applied torque on the prosthetic limb was measured using a Europa+ force transducer (Orthocare Innovations, Edmonds, WA) and ankle rotation angle using an encoder on the prosthesis. The data were processed to calculate energy efficiency of each step and the ankle range of motion.

## **RESULTS**

In passive mode, ankle rotations ranged 1-4 deg, stored energy was 0.9-1.8 J, and returned energy was 0.6-1.2 J. In active mode, ankle rotations ranged 13-20 deg, stored energy was 15.6-19.0 J, and returned energy was 6.3-9.3 J. Energy efficiency ranged between 40-50% during active mode (Figure 1). The participants were excited to feel the energy return that helped

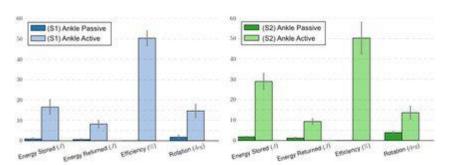


Figure 1. Results for prosthesis user energy harvesting and return.

during push-off and could discern when the ankle was switched into passive mode due to the lack of assistance during walking. One participant commented that the ankle range of motion felt too large, suggesting that the ankle rotation may need to be tuned for each user. The toe clearance function during swing phase appeared sufficient to avoid problems with tripping over the toe.

# **DISCUSSION AND CONCLUSION**

The experimental ankle-foot prosthesis demonstrated the function to store energy during stance and return energy during push-off and swing phases of prosthesis user gait on level ground. Participants responded positively to the provision of energy return. In active mode, the prosthesis returned at least 40% of the stored energy and provided toe clearance that could increase safety during walking. The energy release timing was not the study focus and will be tuned for each prosthesis user in future evaluation studies.

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# **ACKNOWLEDGEMENTS**

We acknowledge National Institutes of Health funding (R43HD080309). Authors are Orthocare Innovations employees (Europa+ manufacturer and experimental prosthesis developer).



# 1.3.4.d Variable Stiffness Prosthetic Foot – Case study

Christophe Lecomte<sup>1,2</sup>, <u>Anna Lára Ármannsdóttir</u><sup>3</sup>, Felix Starker<sup>1</sup>, Sigurdur Brynjolfsson<sup>2</sup>, Kristin Briem<sup>3</sup>
<sup>1</sup>Össur, Reykjavik, Iceland. <sup>2</sup>University of Iceland, Faculty of Industrial Engineering, Mechanical Engineering and Computer Sciences, Reykjavik, Iceland. <sup>3</sup>University of Iceland, Faculty of Medicine, Department of Physical Therapy, Reykjavik, Iceland

# **BACKGROUND**

Current "Energy storing and returning (ESR) feet have specific invariable stiffness categories, matched to each user based on factors such as body weight and activity level. However, during ambulation over different terrains and at different speeds, a fixed stiffness category might induce undesirable compensations in the gait pattern.

## AIM

The aim of this case study is to propose a novel design of a prosthetic foot with adjustable stiffness, and to evaluate the ability of an original questionnaire to capture user perception of prosthetic foot stiffness.

# **METHOD**

The Variable Stiffness Foot (VSF) was constructed using cantilever composites plates with a movable support to adjust stiffness. Two glass fiber beams were used as stiffness elements to control dorsi- plantarflexion. The VSF unit was mounted on a state-of-the-art ESR prosthetic foot. Mechanical testing was done to measure change in stiffness depending on support position.[1]

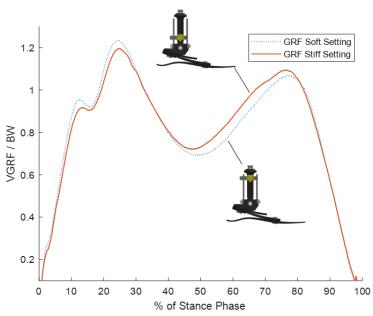
A male participant (age 52, BMI 30) was fitted with a single prosthesis by a certified prosthetist. As a baseline study, motion and force data were collected for level ground walking, for two stiffness settings of the VSF foot. After each stiffness setting, the user answered a questionnaire that evaluated the user's perception.

# **RESULTS**

Mechanical testing of the foot showed a change of 10% of stiffness between each setting. Questionnaire results showed a clear preference for the more compliant setting of the foot, especially safety. Measured ground reaction forces show higher loads at heel strike for the compliant setting and higher loading rate after swing phase of the contralateral side for the stiff setting.

# **DISCUSSION AND CONCLUSION**

User preference for the softer setting is consistent with previous reports on a more compliant foot.[2] Results of the ground reaction forces are like previously reported findings where variations of ground reaction forces can be linked to prosthetic foot stiffness.[3] Further bio-mechanical parameters will be evaluated using the device.



This case study introduced results from a novel design of a prosthetic foot and demonstrated that user questionnaire addressing ankle stiffness can capture a 10% change in dorsi- plantarflexion.

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This research was partly funded by the Technology Development Fund (grant 164061-0611) and the Icelandic Student Innovation Fund (grant 185708-0091).



# 1.3.4.e

# Loading is Symmetrical Between Prosthetic and Sound Sides in Unilateral Transtibial Amputees: a Randomised Controlled Cross-Over Trial

Phoebe Runciman<sup>1,2</sup>, John Cockroft<sup>3</sup>, Wayne Derman<sup>1,2</sup>

<sup>1</sup>Institute of Sport and Exercise Medicine, Stellenbosch University, Cape Town, South Africa. <sup>2</sup>IOC Research Centre, South Africa, Cape Town, South Africa. <sup>3</sup>Central Analytics Facilities, Stellenbosch University, Cape Town, South Africa

#### **BACKGROUND**

Individuals with unilateral transtibial amputation (UTTA) are reported to have higher external ground reaction forces in joints on their sound side. This, and higher peak knee external adduction moments (EAM) result in the over-loading of the sound side during heel strike. These effects have been linked to deficiencies in range of motion (ROM) and power during push off from the prosthesis and increase the risk of osteoarthritis in these individuals.

#### AIM

To describe the biomechanical characteristics and prosthesis user satisfaction of a group of UTTA whilst using a novel, mechanically powered energy storing and returning (ESAR) ankle/foot prosthesis, compared with two control foot prostheses.

# **METHOD**

20 participants performed a standardized self-paced walking gait protocol using three different ankle/foot prostheses (novel ESAR foot (NOVEL), current gold standard ESAR (ESAR) foot and solid-ankle cushioned-heel (SACH) foot), in a randomised cross-over design. Three-dimensional kinematics of the lower body as well as ground reaction forces (GRF) were recorded with an ten-camera stereophotogrammetry motion capture system and three floor-imbedded force plates. User satisfaction was assessed using the Trinity Amputation and Prosthesis Experience Scales Revised (TAPES-R) and Patient-Reported Outcome Measurement Information System (PROMIS) questionnaire (fatigue item). Ethics committee approval number: N16/08/032

# **RESULTS**

Despite similar peak GRFs between feet on the prosthetic side during walking ( $\pm$  108% body weight), there were higher GRFs on the sound side during the load acceptance phase whilst participants used the SACH (126.3  $\pm$  11.5%) and ESAR (116.8  $\pm$  10.5%) feet, but not the NOVEL (108.7  $\pm$  9.3%, p<0.001). EAM observed on the sound side during loading was 0.55  $\pm$  0.3 Nm/kg, 0.6  $\pm$  0.3 Nm/kg and 0.7 $\pm$  0,31 Nm/kg for the NOVEL, ESAR and SACH. The NOVEL had a sagittal ROM of 21.4  $\pm$  3.2°, the ESAR 18.2  $\pm$  3.3° and the SACH 8.4  $\pm$  2.3° (p<0.001). Peak ankle power during push-off from the prosthesis was 2.6  $\pm$  0.5W/kg, 1.9  $\pm$  0.5W/kg and 0.3  $\pm$  0.1W/kg for the NOVEL, ESAR and SACH (p<0.001). The PROMIS and TAPES-R showed that the NOVEL was preferred among the three feet.

# **DISCUSSION AND CONCLUSION**

The use of the NOVEL foot resulted in a similar loading/force pattern between prosthetic and sound sides in UTTA. Furthermore, participants demonstrated a better transition during double support, with improved ROM, power and EAM, whilst using the NOVEL. This improved symmetry indicates a reduced risk of OA on the sound side when using this foot, the three-leaf design of the NOVEL prosthesis should be considered when looking at degenerative conditions in the amputee population.

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# 1.3.4.f

# Comparison of Task Specific Prosthetic Kinematics to Provide Optimized Functional Machine-Based Tests

Felix Starker<sup>1</sup>, Christophe Lecomte<sup>2</sup>, Heimir Tryggvason<sup>3</sup>, Anna-Lára Ármannsdóttir<sup>2</sup>
<sup>1</sup>Össur hf., Reykjavik, Iceland. <sup>2</sup>Össur, Reykjavik, Iceland. <sup>3</sup>University of Iceland, Reykjacik, Iceland

# **BACKGROUND**

Prosthetic feet are designed for the purpose of walking. Daily life activity includes more tasks such as standing, altering gait speed or balancing. Clinical testing is performed under ideal conditions mainly on level ground. Machinebased testing sets focus on the endurance and strength.[1-3] Latest test approaches aim for better insight into foot performance.[4] The input parameters are downscaled from an endurance test.[2] It is unknown how these load profiles represent real life walking.

#### AIM

Aim of this study is to compare and optimize current input curves of a test standard [4] with clinical data from both motion capture and field trials for better

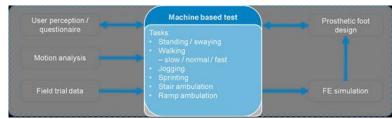
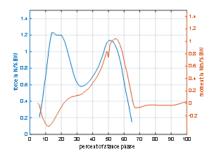


Figure 1. Overview of the task specific tests investigated in relation to the user input and optimization output.



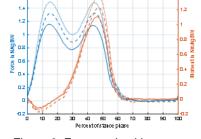


Figure 2. Averaged force and ankle curve from machine-based trial

Figure 3. Force and ankle moment moment curve from user trials

input criteria when optimizing prosthetic foot function.

## METHOD

Central element is a mechanical two-axis test machine to perform the machine-based dynamic tests.[4] The comparison is performed with one state of the art prosthetic foot (Pro-Flex LP, Össur hf., Iceland). For comparison field trial data of one subject walking equipped with a force and torque sensor integrated in the prosthetic leg is performed outdoor through a forest trail.[5] The machine test was done with the same foot. The results were used for FE simulations [6] to optimize prosthetic foot design.

## RESULTS

The direct comparison of the resulting force and sagittal knee moment between motion lab data and machine showed differences both in the input vertical force for mid stance (-20 %) curve as well as the resulting moments compared to the results of the machine based test.[4] Increasing the vertical load (dotted lines) by 14% and 28% with the machine-based test increased the sagittal moment by 14% and 24% but does not represent a step of a user walking trial. These differences are similar for changing the speed (0.6Hz and 1.2Hz) of the machine which does neither represent slow, medium or fast walking speed beside the ground contact time.

# **DISCUSSION AND CONCLUSION**

Comparing motion lab data with the results of the machine based data showed that generic curves from a standard [2,4] to single task curves from a motion lab reveals large differences for all regarded tasks. This can be explained as the input curves for the machine-based test simulate overloading under worst case and not task-based conditions. This calls for adapted input curves to represent task and user group specific loading conditions to allow for better optimization of prosthetic devices.

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# **ACKNOWLEDGEMENTS**

This research was partly funded by the Technology Development Fund (no. 164061-0611) and the Icelandic Student Innovation Fund (no. 185708-0091).



# 1.3.4.g

# Gait Initiation and Termination on Slopes for Transtibial Amputees using Rigid, Hydraulic and Microprocessor Controlled Ankles

<u>Cleveland Barnett</u><sup>1</sup>, Thede Preiser<sup>2,3</sup>, Gerda Strutzenberger<sup>4</sup>, Alan De Asha<sup>5</sup>, Hermann Schwameder<sup>6</sup>

Nottingham Trent University, Nottingham, United Kingdom. <sup>2</sup>University of Salzburg, Salzburg, Austria. <sup>3</sup>German Sport University Cologne, Cologne, Germany. <sup>4</sup>University of Salzburg, Hallein-Rif, Austria. <sup>5</sup>C-Motion, Germantown, USA. <sup>6</sup>University of Salzburg, Salzburg, Austria

## **BACKGROUND**

A stable stance on slopes is essential for a controlled gait initiation and termination for individuals with transtibial (TT) amputation. Hydraulically (HYD) and mikropcrocessor controlled (MPC) articulating joints show positive effects with respect to a better joint load distribution during sloped walking compared to a rigid (RIG) ankle [e.g. 2] and an improved stance control. Articulating ankle joints may result in a more controlled and stable movement due to the better adaptability to a sloped condition than RIG ankle joints.

## **AIM**

The aim of this study is to investigate the effects of a RIG, HYD and MPC articulating ankle on ground reaction force distribution in individuals with TT amputation during gait initiation and terminating in the level and on a slope.

# **METHOD**

Six Individuals with TT will perform 3 trials of gait initiation and termination in the level and on a slope with 5° using a RIG (Esprit), a HYD (Elan with MKP function: off) and a MPC (Elan MKP function: on) ankle component (Chas A Blatchford and Sons, Basingstoke, UK). Additionally 7 healthy control participants (mass: 71±12.1 kg) performed the same gait task. Reflective markers will be placed using a full body marker-set. Kinematic and kinetic data will be collected using a 13-camera motion capture system (Qualisys AB, Gothenburg, SE) and two integrated force plates (AMTI, Watertown, USA). An ANOVA with repeated measures and post-hoc tests will be performed (p=0.05).

## **RESULTS**

Preliminary analysis (n=7) of the CON showed a slight weight distribution towards the right limb using the Symmetry Index (SI) [3] and equal step length for the initiating and following step (Table 1). Data collection of the amputee participants will take place in march and data will be available at the time of conference. It is expected that the SI, step length and kinetic variables are significantly affected by the different ankle settings.

Table 1. Mean±SD of selected variables (symmetry index in stance [%], 1<sup>st</sup> and 2<sup>nd</sup> step length after gait initiation in level and downhill gait of the control group

Variable	unit	0°	-5°	Sign. (p)
IIStance: Symmetry Index 131	% [0: perfect symmetry]	7.0±4.6	12.4±7.9	n.s.
Step length 1 <sup>st</sup> step	m	0.68±0.06	0.64±0.06	n.s.
Step length 2 <sup>nd</sup> step	m	0.73±0.06	0.70±0.06	n.s

# **DISCUSSION AND CONCLUSION**

The data can be used to identify if individuals TT amputation benefit from improved stance control and articulating ankle joint using HYD and MPC settings when commuting on slopes and to identify the difference to a norm situation.

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# **ACKNOWLEDGEMENTS**

We thank Chas A Blatchford and Sons (Basingstoke UK) for providing the Prosthetic devices and orthopedic-technician for testing.



# **Free Paper Session**

**Prosthetics: Lower Limb Transfemoral - Socket** 

# 1.3.5.a

# Impact of Transfemoral Socket Adduction on Pelvic and Trunk Stabilization During Level Walking – A Biomechanical Study

Malte Bellmann, Thomas Maximilian Koehler Ottobock SE & Co. KGaA, Goettingen, Germany

## **BACKGROUND**

As a result of a transfemoral amputation, several muscle insertions of the hip adductors – depending on residual limb length – are lost, while hip abductors remain mostly intact. This leads to a muscle imbalance between these muscle groups. It is known from common practice, that transfemoral prosthetic sockets should be aligned in adduction, to recover physiological pretension of the hip abductors best possible. This contributes to pelvic stabilization in frontal plane and reduces compensatory movements of the pelvis and trunk.

#### AIM

The aim of this interventional biomechanical study was investigating the impact of different socket adduction positions systematically on the pelvic and trunk stabilization during level ground walking.

# **METHOD**

Four adduction conditions were investigated (0°, 3°, 6°, 9°). Six active unilateral transfemoral amputees (K3 and K4 ambulators) with medium stump length (1/3 - 2/3 of the sound side thigh segment) participated in this study. Kinematic and kinetic parameters were recorded in a gait laboratory with a 12-camera optoelectronic system (Vicon, GB) and two piezoelectric force plates (Kistler, CH) embedded in a 12-m walkway. The measurements were performed during level ground walking with self-selected comfortable velocity.

# **RESULTS**

Step width was higher with increasing socket adduction. This is a result of positioning the shank-segment of the prosthesis more laterally, indicated by the slightly more abducted thigh-segment. The medially directed ground reaction force was higher on both sides with increasing socket adduction, while external hip adduction moment was reduced on prosthetic side. Pelvis was raised on the contralateral side over the whole gait cycle with increasing socket adduction (Figure 1 A). During prosthetic side stance phase shoulder obliquity and lateral trunk lean (Figure 1 B) to prosthetic side was reduced with increased socket adduction.

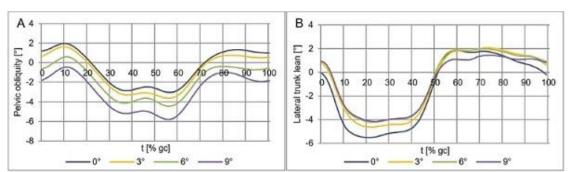


Figure 1. Mean pelvic obliquity (A); Positive value: pelvis is higher on prosthetic side. Negative value: pelvis is higher on contralateral side. Mean lateral trunk lean (B); positive Value: lateral trunk lean to contralateral side. Negative value: lateral trunk lean to prosthetic side

# **DISCUSSION AND CONCLUSION**

The results confirm, that transfemoral socket adduction contributes to pelvic stabilization and reduced compensatory movements of the pelvis and trunk. Socket adduction of 9° turned out to be too high in some cases for the investigated medium stump length. Thus, a socket adduction of 5° to 7° for bench alignment seems adequate for amputees with medium stump length. However, optimum is individual for every amputee and may differ slightly from these values.



# 1.3.5.b

# The Characteristics of the Soft Tissue of the Residual Limb in Persons with Transfemoral Amputation using MRI Analysis

Atsuko Mitsumoto<sup>1</sup>, Takashi Nakamura<sup>1</sup>, Takayuki Maruyama<sup>2</sup>, Masato Maeno<sup>3</sup>, Yoshiko Tobimatsu<sup>1</sup>
<sup>1</sup>Natonal Rehabilitation Center for Persons with Disabilities, Research Institute, Tokorozawa, Japan. <sup>2</sup>Natonal Rehabilitation Center for Persons with Disabilities, College, Tokorozawa, Japan. <sup>3</sup>Natonal Rehabilitation Center for Persons with Disabilities, Hospital, Tokorozawa, Japan

## **BACKGROUND**

The amount of muscle and fat tissue constituting the residual limb would be closely related to the hardness of the soft tissue and the shape of the prosthetic socket. Theses soft tissue composition of the residual limb would be important for the control of a prosthesis. Muscle strength losses and muscle atrophy in patients with amputation are interrelated,[1] while there are few reports of quantifying soft tissue changes of the residual limb after transfemoral amputation.

## **AIM**

This study was to determine the factor of soft tissue changes after amputation and to investigate differences in the muscle tissue between amputated and intact limbs in subjects with transfemoral amputations using Magnetic Resonance Imaging (MRI).

# **METHOD**

11 males, unilateral transfemoral amputees between the ages of 19 and 68 years with a residual limb length of over 20 cm participated in this study. The cross-sectional area (approximately 3 cm distal to the ischial tuberosity) of was calculated using Siemens' MRI (3.0 Tesla). The ratio occupied by each muscle component and total cross-sectional area was compared. The ratio of the muscle occupying the cross section of the residual and intact limbs was defined as the muscle area ratio, and the correlation with years of age and years from amputation was obtained.

# **RESULTS**

In all subjects, the cross-sectional area of their residual limb was small compared to the intact limb (p<0.05, T-test), and the mean value of the ratio of the residual limb area and the intact limb area was 80.0 ± 6.0%. Atrophy of the gluteus maximus and the quadriceps muscle was large in the muscles, whereas atrophy of the adductor muscle group was small, and conversely, the cross-sectional area of the adductor longus muscle was greater in the

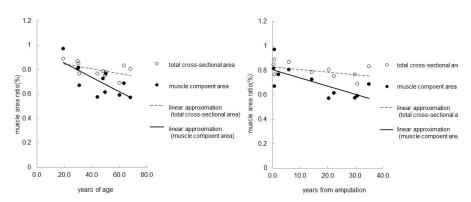


Figure 1: Relationship between years of age and muscle area ratio (left), Relationship between years from amputation and muscle area ratio (right)

residual limb. Muscle area ratio correlated with years of age and years from amputation (p<0.05, Pearson's correlation coefficient: r=-0.787 and r=-0.623).

## **DISCUSSION AND CONCLUSION**

This study showed quantified soft tissue of the residual limb from the MRI image, especially the muscle tissue, and revealed that the atrophy is correlated with years of age and the years from amputation. Muscle atrophy progresses with age in healthy subjects. Therefore, it seems reasonable results that muscle area ratio showed a negative correlation with years from amputation and years of age.

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## **ACKNOWLEDGEMENTS**

This work was supported by JSPS KAKENHI Grant Number JP26350692.



# 1.3.5.c

# The Significance of Socket Motion on Residual Limb Skin Health

Matthew Wernke<sup>1</sup>, Cameron Rink<sup>2</sup>, Surya Gynawali<sup>2</sup>, Alexander Albury<sup>1</sup>, Chris Dearth<sup>3</sup>, Chandan Sen<sup>4</sup>, James Colvin<sup>1</sup>

<sup>1</sup>WillowWood, Mt. Sterling, USA. <sup>2</sup>Ohio State University, Columbus, USA. <sup>3</sup>Walter Reed, Bethesda, USA. <sup>4</sup>Indiana University, Indianapolis, USA

# **BACKGROUND**

Achieving a proper socket fit is critical to the success of the prosthesis and a primary concern for prosthesis users.[1] Despite this concern, there are still high levels of dissatisfaction with prosthesis comfort [2,3] and a high prevalence of skin sores or irritation occurring within the socket, with fit likely being a contributing factor.[4,5] If unresolved, these skin issues can necessitate the disuse of the prosthesis. Research aimed at understanding interface conditions that exacerbate skin issues is warranted.

#### $\Delta IM$

The aim of this study is to quantify skin health in response to in-socket limb motion, an indicator of fit.

# **METHOD**

Ten unilateral lower limb amputees (5 transfemoral and 5 transtibial) participated in the ongoing study. All subjects wore elevated vacuum sockets and the vacuum pump was used to control and quantify motion at the interface. Transepidermal water loss (TEWL), a measure of skin barrier integrity, was measured at each study visit. Following a baseline visit (Visit 1), subjects were randomized to one of three vacuum suspension settings; 1) Low, max of 10 inHg, 2) Med, max of 15 inHg, 3) High, max of 20 inHg. Each setting was worn by the subject for a 4 week period before returning to the research office for health measurements.

#### **RESULTS**

A regression analysis was used to determine the correlation between in-socket limb motion and vacuum pressure setting to limb health values measured by TEWL. TEWL in the residual limb significantly correlated with in-socket motion (p=.0352 transtibial, p=.0442 transfemoral). TEWL in the residual limb did not correlate with vacuum suspension setting (p=.222 transtibial, p=.1816 transfemoral). Compared to vacuum suspension level, in-socket motion is a better predictor of residual limb health outcomes with a higher Pearson correlation coefficient (r square), lower standard deviation of the residuals (Sy.x), and a slope that is significantly non-zero.

# **DISCUSSION AND CONCLUSION**

Early study outcomes suggest that in-socket limb motion is an important factor that affects residual limb health; where reduction of motion improves skin barrier function. That TEWL was not dependent on EVS level points toward individual differences in socket fit across vacuum levels – and suggests that one size does not fit all in this scenario. Additional limb health outcomes remain to be investigated and include: Surface Electrical Capacitance (SEC), hyperspectral imaging, transcutaneous oxygen measurement, and tissue elasticity.

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## **ACKNOWLEDGEMENTS**

This work is funded by the Department of Defense (W81XWH-16-2-0059).



# 1.3.5.d

# Dynamic Finite Element Analysis of the Residual Limb of a Person with a Transfemoral Amputation during the Gait Cycle

<u>Sofía C. Henao</u>, Camila Orozco, Juan Ramírez Universidad Nacional de Colombia, Medellin, Colombia

#### **BACKGROUND**

The design of transfemoral prosthetic systems has not been successful, partially due to the lack of understanding of the interaction between the residual limb and the socket. Therefore, analyses using the Finite Element Method (FEM) can help in improving patients' comfort. Regarding FEM models of people with transfemoral amputation, the information is still insufficient;[1] however, an initial analysis of the donning procedure was already carried out.[2]

# AIM

To model the stress state of the interaction between the residual limb and the socket during the gait cycle of a person with transfemoral amputation.

# **METHOD**

A dynamic FEM analysis of the donning procedure and gait cycle of a person with transfemoral amputation was performed. The subject was healthy and fully active; moreover, he signed off an informed consent in accordance to the Declaration of Helsinki. A hyperelastic material was defined for the soft tissues, the loads at the base of the socket were extrapolated from gait curves, boundary conditions at the femoral head were established and different contact conditions where defined according to the specific circumstances. Furthermore, comfort thresholds were assessed using an algometer and the comfort perception was assessed using a questionnaire.[3]

#### **RESULTS**

The forces and moments curves that represent the conditions of the subject's gait cycle can be observed in Figure 1 (left). These loads were applied at the base of the socket in order to obtain the stress state observed in Figure 1 (right). The maximum normal stress during the gait cycle is  $2.1x10^5 Pa$ , which is located at the pressure tolerant region and is lower than the comfort thresholds assessed at this spot (*i.e.* pressure tolerant region threshold –  $2.68x10^5 Pa$ , pressure release region threshold –  $1.98x10^5 Pa$ , and scar threshold –  $1.58x10^5 Pa$ ) and agrees with the comfort perception expressed by the subject about wearing his prosthetic device.

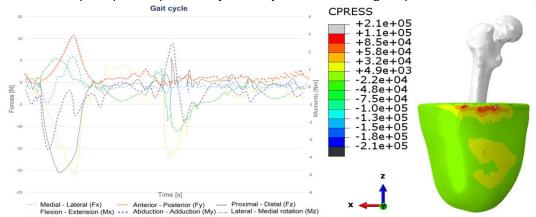


Figure 1. Moments and forces at the socket base during the gait cycle (left) and normal stresses of the residual limb (right).

# **DISCUSSION AND CONCLUSION**

The results of the FEM analysis agrees with the order of magnitude of the reported stresses of previous studies.[1] However, the study was performed on one subject; hence, the results are not generalizable to the rest of the population. Nonetheless, this study can be used to better understand the phenomenon, which can lead to more generalizable results, or for the study of specific pathologies by developing patient specific simulations.

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# 1.3.5.e

# Incidence of Socket Materials and Roughness in Coefficient of Friction Values

<u>Sofia C. Henao</u>, Mauricio Perez, Juan Ramirez Universidad Nacional de Colombia, Medellin, Colombia

#### **BACKGROUND**

Friction plays a critical role in the comfort and functionality of traditional prosthetic systems.[1] Friction helps distributing the load of the amputee's weight between normal and tangential stresses during the support phase of the gait cycle and preventing the prosthesis from slipping off during the swing phase. Hence, the study of the incidence factors can be useful for the selection of appropriate Coefficients of Friction (COF).

#### AIM

The purpose of this study is to identify the incidence of several sockets' materials and different textures in the value of the COF between the skin and the counterpart.

# **METHOD**

In this study, wheel probes of three different materials and three different textures were used to assess the COF against one person's thigh skin. The experiments were executed using a handheld tribometer,[2] and the textures were shaped by applying uniform pressure to the probes after removing them from an oven. As a result, the COF measurements were analysed as a general full factorial design, being the two factors: material (*i.e.* material levels: PVC, PETG, EVA) and textures (*i.e.* texture levels: soft, medium and rough).

#### **RESULTS**

The data is continuous, random and independent, and although the Anderson Darling test defined the distribution as non-normal, with a sample size of 27 the data can be considered normal by the central limit theorem. Moreover, one of the measurements was eliminated from the sample because it was identified as an outlier. From the Analysis of Variance (Table 1) and the Pareto chart can be concluded that both factors and its interactions have a significant effect in the COF, being the material the factor with the greatest effect. Finally, the residuals meet the assumptions.

Table 1. Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Model	8	4.4735	0.55919	27.39	0.000
Linear	4	4.0632	1.01580	49.76	0.000
Material	2	3.8103	1.90514	93.33	0.000
Texture	2	0.2481	0.12405	6.08	0.010
2-Way Interactions	4	0.2954	0.07384	3.62	0.026
Material*Texture	4	0.2954	0.07384	3.62	0.026
Error	17	0.3470	0.02041		
Total	25	4.8206			

# **DISCUSSION AND CONCLUSION**

Previous studies [3] had reported the influence of roughness and the type of material on the COF value. However, it is recommended to conduct experiments with a wider range of materials. Moreover, due to the anisotropic characteristic of the materials, a different manufacturing process to shape the texture should be explored to guarantee that the tested surface is the same that will be in contact with the residual-limb skin.

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### **ACKNOWLEDGEMENTS**

The hand held tribometer was redesign and manufactured thanks to the financial support of the *Universidad Nacional de Colombia*.



# Free Paper Session Outcome Measurements - Gait and Wearables

# 1.3.6.a

# Towards Comprehensive Understanding of Leg Muscle Activity in Gait by a Novel Wearable System with Ultrasound Imaging and Multiple Sensing

<u>Christina Zong-Hao Ma</u><sup>1,2</sup>, Yan To Ling<sup>1</sup>, Queenie Tsung Kwan Shea<sup>1</sup>, Li-Ke Wang<sup>1</sup>, Xiao-Yun Wang<sup>3</sup>, Yong-Ping Zheng<sup>1</sup>

<sup>1</sup>Department of Biomedical Engineering, The Hong Kong Polytechnic University, Hong Kong SAR, China. <sup>2</sup>Department of Rehabilitation, Jönköping University, Jönköping, Sweden. <sup>3</sup>Guangdong Work Injury Rehabilitation Center, Guangzhou, China

#### BACKGROUND

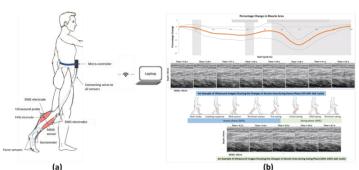
Motion capture and analyzing systems are essential for understanding human locomotion. Specifically, integrating ultrasound imaging technology could further enable the comprehensive understanding of muscle activity. However, the existing devices are too cumbersome and some of them are confined to laboratory settings, limiting their applications to indoor environment only. To our knowledge, none of previous studies have attempted to develop a wearable human motion analyzing system with ultrasound imaging technology.

#### $\Delta IM$

This study aimed to develop and evaluate a wearable motion capture and measurement system, with multiple sensors and ultrasound imaging to enable comprehensive gait analysis.

#### **METHOD**

The developed system contained an ultrasound probe measuring real-time B-mode ultrasound image of muscle, two sets of surface-electromyography (EMG) electrodes measuring muscle activation, a mechanomyography (MMG) sensor measuring muscle vibration, three thin-film force sensors measuring plantar force, & a two-axis goniometer attaching to subject's right leg. The ultrasound probe & sensors captured data simultaneously, and connected to a laptop via



Wi-Fi for data analysis (Figure 1a). The existence of significant changes in muscle activity and joint motion in a gait cycle, comparison of the ankle kinetic data captured by the developed system and Vicon system, and test-retest reliability in each channel's data captured by the developed system were examined.

# **RESULTS**

Ten healthy subjects (7 males & 3 females, aged 26.4±2.4 years, height 169.8±12.2cm, and weight 65.1±14.9kg) participated. Moderate to good test-retest reliability of various channels of the developed system was found (0.512≤ICC≤0.988, P<0.05). Significantly high correlation between the developed system and Vicon system existed in ankle joint angles (0.638≤R≤0.707, P<0.05). This study also identified significant changes (P<0.05) in muscle activity of gastrocnemius during a gait cycle by comprehensively evaluating the muscle activity with the multiple measurement modalities. The trends of the EMG,[1,2] MMG,[1] muscle area,[3] plantar force,[4,5] and ankle angle [4,5] were comparable to previous studies. The muscle area of lateral head of gastrocnemius muscle was found to decrease during the swing phase and reach a trough during mid-swing phase in a gait cycle (Figure 1b).

# **DISCUSSION AND CONCLUSION**

A newly developed wearable motion capture and measurement system with ultrasound imaging that can accurately capture the motion of one leg was evaluated, which paves the way towards real-time comprehensive evaluation of muscles during different activities in both indoor and outdoor environments. Such systems can be applied for diagnosis of skeletal muscle problems, objective evaluation of musculoskeletal disorders, and assessment of balance & gait control pre-/post- prosthetic/orthotic management & rehabilitation.

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# **ACKNOWLEDGEMENT**

This work was partially supported by The Hong Kong Polytechnic University [G-YBRN] and Guangdong Provincial Work Injury Rehabilitation Center [H-ZG4W].



# 1.3.6.b

# Preliminary Results. Is the Duncan Ely Reliable for Measuring Abnormal Activity of the Rectus Fmoris during Gait in Stroke patients?

M Tenniglo<sup>1,2</sup>, M Nederhand<sup>1,2</sup>, L Schaake<sup>1</sup>, E Prinsen<sup>1</sup>, J Buurke<sup>1,3</sup>
<sup>1</sup>Roessingh Research and Development, Enschede, Netherlands. <sup>2</sup>Roessingh Centre for Rehabilitation, Enschede, Netherlands. <sup>3</sup>University of Twente, Enschede, Netherlands

#### **BACKGROUND**

Stiff knee gait (SKG) is characterized by a diminished knee flexion during swing.[1] Abnormal activity of the rectus femoris (RF) is often cited as a main cause.[2] The gold standard for measuring abnormal activity of the RF is electromyography. A clinical tool to assess abnormal activity of the RF is the Duncan Ely test.[3] This test is researched and compared with the gold standard in children with cerebral palsy. However, no research is done in stroke patients.

#### AIM

The aim of this study was to investigate if abnormal activity of the RF measured with surface electromyography (sEMG), corresponds with the Duncan Ely test in stroke patients walking with a SKG.

#### METHOD

The study included 83 chronic stroke patients walking with a SKG.

The sEMG of the RF and vastus lateralis were measured when the patients walked at comfortable speed on a 10-meter walkway. Activity of the RF was analyzed using a computerized algorithm in order to define abnormal sEMG.

Duncan Ely test was performed using a standardized protocol. While the patient laid prone in a relaxed state, the examiner passively flexed the knee rapidly.

The standard matrix was used to investigate if abnormal activity in swingphase of the RF measured with sEMG (Gold standard) corresponds with the Duncan Ely test (Diagnostic test).

# **RESULTS**

Preliminary results showed that the sensitivity of the Duncan Ely test was 72.1 % and the positive predictive value was 59 %. Area under the receiver operating characteristic (ROC) curve of the Duncan Ely test was 0.48 (95% CI = 0.32-0.61, p = 0.85).

This means that there is no relation between the sEMG and the Duncan Ely test.

# **DISCUSSION AND CONCLUSION**

The results indicate that the Duncan Ely test is not a reliable/diagnostic tool to assess abnormal activity of the RF in stroke patients.

For clinical practice: to assess abnormal activity of the RF it is better to use sEMG instead of the Duncan Ely test.

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# 1.3.6.c

# Kinematic Analysis of the Cluster Model when used for Trans-Tibial Amputee Gait Analysis: A Quantitative Comparison with Plug-in Gait Protocol

Manunchaya Samala<sup>1,2</sup>, Philip Rowe<sup>2</sup>, Jutima Rattanakoch<sup>1</sup>

<sup>1</sup>Sirindhorn School of Prosthetics & Orthotics (SSPO), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. <sup>2</sup>Department of Biomedical Engineering, University of Strathclyde, Glasgow, United Kingdom

#### **BACKGROUND**

The describing of the kinematic for trans-tibial amputee (TTA) must take the structure of prosthesis to be account during design marker for the biomechanical model. There are several marker models available for motion analysis. Plug-in Gait (PIG), a clinical gold standard, might not work correctly for TTA gait analysis.[1] The Strathclyde Cluster Model (SCM) was developed based on the cluster marker set proposed by Cappozzo [2] was evaluated and used by Papi with good repeatability.[3]

#### ΔIM

The aims of this study were to compare two available marker models (PiG and SCM) in order to find out appropriate model and marker configuration for used for trans-tibial amputee gait analysis.

#### METHOD

Seven TTA subjects consented to participate in the study. Combining marker sets (SCM and PiG) were attached on each subject. The subjects were then walked at a self-selected speed and recorded by a 3D motion Vicon camera at 100 Hz. The raw marker trajectories of each marker set were processed calculated separately on each data set according to the gait analysis software package for each marker model. The standard deviations, (SD) were used for within- and between-subject variability. Paired t-test with a significance level of  $\alpha$  = 0.05 was used to test the difference between PiG and SCM protocols.

#### **RESULTS**

The within-subject variability for kinematic results was observed and ranged from 0.8° to 4.6° across the two protocols. Although slightly higher values of standard deviation were observed in the SCM protocol showed, but it was considered reasonable and did not exceed 5°.[4]

The between-subject variability on the amputated side for PiG with an average of 17.6° and SCM with an average of 9.3°. For the sound side, PiG showed an average of 15.4° while SCM showed an average of 9.7°. The mean standard deviation for the PiG was larger than SCM on both amputated and sound limb.

Statistic significant differences in joint parameters caused by a change in the protocol were evident more on the amputated side than the sound side in the sagittal plane (p < 0.05).

# **DISCUSSION AND CONCLUSION**

From the comparisons of the kinematic results from the two available protocols (SCM and PiG), it can be concluded that gait kinematics and kinematic parameters are best reported by the Strathclyde Cluster Model. The SCM protocol seems to provide kinematic measurements with a smaller variability than that of the PiG. The results from this study showed that SCM is more practical for measuring amputee gait without losing accuracy when comparing to PiG.

# **REFERENCES**

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- [4] McGinley et al, Gait Posture 2009.



# 1.3.6.d

# Variable Stiffness/Shape Band to enhance Fitting and Comfort in Wearable Devices

Michele Ibrahimi<sup>1</sup>, Linda Paternò<sup>2</sup>, Leonardo Ricotti<sup>2</sup>, Arianna Menciassi<sup>2</sup>

The Biorobotics Institute-Scuola Superiore Sant'Anna, Pisa, Italy. <sup>2</sup>The Biorobotics Institute- Scuola Superiore Sant'Anna, Pontedera, Italy

# **BACKGROUND**

Lower limb orthoses and prostheses accomplish the function they are designed to by interfacing their inner surface (typically made of hard materials) and limb tissues (that are much softer). These devices compress the limbs to guarantee a good fitting. However, such compression can compromise the tissues and quite often leads to skin irritations or even ulcers, which are the major cause of discomfort and device abandonment.[1]

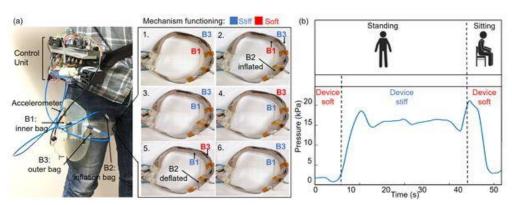
#### AIM

The purpose is the development of a wearable band able to change its shape and stiffness when a subject switches from a standing position to a sitting one, thus allowing shape adaptation and pressure relief when static positions are held.

# **METHOD**

The band is made of two overlapped sealed plastic bags containing sandpaper sheets which can be stiffened independently, by applying vacuum within them [2] (B1 and B3 in Figure 1a). A third plastic bag (B2) is interposed between them for inflation. The band can be wrapped around the limb and it is activated by an

accelerometer detecting the subject position and activating a micro-vacuum pump with solenoid valves, controlled by a micro-controller and pressure sensors. To verify pressure changes at limb interface, a subject worn the band and a pressure sensor was placed between the band and the limb.



# **RESULTS**

Figure 1a shows the working principle. During sitting, the band is kept soft, maintaining the bags at atmospheric pressure. When standing, the outer bag (B3) is firstly stiffened, then the interposed one (B2) is inflated allowing the inner bag (B1) to compress the limb. Subsequently, the inner bag (B1) is stiffened and the outer one (B3) softened. The interposed bag (B2) is deflated and, consequently, the outer bag (B3) adapts to the inner shape. During validation tests, B2 was positioned adjacently to the Scarpa's triangle, which is usually compressed to guarantee high fitting of orthoses and prostheses. As shown in Figure 1b, the mechanism was activated while standing, showing a pressure profile reflecting the device functioning. When the subject sat, the device was deactivated and the pressure dropped. The mechanism can be repeated more than once to compensate volume-shape limb fluctuations.

# **DISCUSSION AND CONCLUSION**

The proposed device is able to increase the comfort of a wearable orthosis/prosthesis, by lowering the pressure profile in static tasks, thanks to a stiffness and shape adaptation mechanism. This may prevent damages due to high pressures acting on tissues for long periods, especially in lower limb amputees.[3] Future work will be focused on the inclusion of additional inflatable chambers, for a better fitting, as well as on the optimization of weight and dimensions of the control unit

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# **ACKNOWLEDGEMENTS**

This work was supported by the project MOTU, funded by INAIL (https://www.repair-lab.it/motu/).



# 1.3.6.e

# Validity and Inter-Rater Reliability of an Inertial Measurement Unit to Assess the Shank-to-Vertical Angle

Lysanne de Jong<sup>1,2</sup>, Yvette Kerkum<sup>3</sup>, Wieneke van Oorschot<sup>1</sup>, Noel Keijsers<sup>1,2</sup>
<sup>1</sup>Sint Maartenskliniek, Nijmegen, Netherlands. <sup>2</sup>Radboud university medical centre, Nijmegen, Netherlands. <sup>3</sup>OIM Orthopedie, Assen, Netherlands

#### **BACKGROUND**

For orthotic alignment the Shank-to-Vertical Angle (SVA) is a commonly used outcome measure.[1] The SVA represents the orientation of the shank relative to the vertical in de sagittal plane. For measuring and adjusting the SVA, a 3D gait analysis (3D-GA) is considered as gold standard. However, this is time consuming and not easy to apply in the outpatient clinic. As an alternative an Inertial Measurement Unit (IMU) attached to the shank can be used to assess the SVA.

#### AIM

Investigate the construct validity and inter-rater reliability of an IMU on the shank to assess the SVA during standing and walking in healthy adults.

# **METHOD**

Thirteen healthy participants (7m/6f, mean age:  $45 \pm 18$  years) were recorded during quiet standing and barefoot walking with 3D-motion capture system and simultaneously with two IMUs anatomically placed at the anterior and lateral side of the shank. Furthermore, the IMUs were placed by two different researchers. The SVA of the

3D-GA was calculated as the angle between two markers on the anterior side of the shank and the vertical in the global sagittal plane (gold standard). Mean difference, intraclass correlation coefficient (ICC), correlation coefficient (r) and repeatability coefficient were calculated for the SVA between the 3D-GA and IMUs during standing and at midstance, and to assess the inter-rater reliability.

# **RESULTS**

The mean (±SD) SVA measured by 3D-GA was 15.6° (±5.7°) for standing and 13.7 (±2.7°) at midstance during walking. Mean differences, ICCs, correlation coefficients and repeatability coefficients are presented in Table 1.

Table 1. Mean differences, ICCs, correlation coefficients and repeatability coefficients for the anterior and lateral IMU, and both raters.

	Anterior IMU	Lateral IMU				
Standing	Rater1	Rater2	Inter- rater	Rater1	Rater2	Inter-rater
Mean difference (SD)	-2.0° (1.9°)	-0.9° (1.9°)	3.1° (3.3°)	6.8° (3.5°)	4.4° (3.4°)	-0.48° (4.4°)
ICC	0.94	0.94	0.76	0.59	0.69	0.73
Correlation	0.94	0.91	0.76	0.79	0.74	0.56
Repeatability coefficient	3.7°	3.8°	6.5°	6.9°	6.7°	8.6°
Walking						
Mean difference (SD)	-0.5° (2.2°)	-0.2° (1.9°)	0.33° (2.6°)	7.7° (2.7°)	5.2° (2.9°)	-2.6° (2.8)°
ICC	0.84	0.88	0.78	0.27	0.29	0.66
Correlation	0.82	0.68	0.64	0.66	0.66	0.63
Repeatability coefficient	4.3°	3.7°	5.0°	5.3°	5.8°	5.4°

# DISCUSSION AND CONCLUSION

A single IMU anatomically aligned at the anterior side of the shank can accurately assess the SVA during standing and walking with an accuracy within 5° compared to 3D-GA. Furthermore, a good inter-rater reliability was found. Although future research should investigate the use of IMUs in orthotic gait, this study indicates that an IMU is a promising method to use for evaluation of orthotic alignment in the outpatient clinic.

# **REFERENCES**

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# **Basic IC Rehabilitation Medicine & Surgery**

# 1.3.7

# Quality Standards in Upper and Lower Limb Prosthetics: A New Way Towards Structured **Fitting Processes**

Merkur Alimusaj<sup>1,2</sup>, Michael Schaefer<sup>3,2</sup>, Olaf Gawron<sup>4</sup>

1 Heidelberg University Hospital, Heidelberg, Germany. Association for Quality Assurance in Arm Prosthetics, Heidelberg, Germany. <sup>3</sup>Pohlig GmbH, Traunstein, Germany. <sup>4</sup>Pohlig GmbH, Heidelberg, Germany

#### **Abstract**

Prosthetic fitting is mostly based on personal experiences and follows therefore empirical knowledge rather than evidence based and structured processes. In 2014 a group of experts published in Germany Quality Standards (QS) in upper limb prosthetics followed in 2018 by a second group publishing QS in lower limb prosthetics. The motivation was to publish acknowledged fitting processes including not only the prosthesis but also educational aspects.

Any recommendation of the QS is given with respect to patient's requirements and uncoupled from prosthetist level of experience or any of the rehab team members. So prosthetic function and construction features as well as socket technique is recommended with respect to patient's needs, and functional deficits. A plenty of ADL's is listed as part of training and educational procedure is described and completes the process. Reason for amputation is also taken into account and has obviously an impact on the technical features of prosthesis, but also to the rehabilitation process itself.

The QS does not only contain fitting recommendations and information about gait education in lower limb or training in upper limb prosthetics, the QS provide additionally the hole documentation structure with respect to the process and regulatory needs, leading to a level of standardization which was not given by now.

The Aim is having a structured fitting process including aforementioned recommendations but also providing a profound quality management and quality assurance in prosthetic fitting allowing for an increased outcome in prosthetic fitting.

# Statement of the objective / learning objectives

A new approach for standardized procedures in fitting and rehab processes in upper and lower extremity prosthetics towards an acknowledged way of Quality Assurance will be introduced to the audience.



# Symposium Seating & Wheelchair

# 1.3.8

# Integrating Wheelchair Service Training in P&O Training Curriculum

<u>David Constantine</u><sup>1</sup>, <u>Ritu Ghosh</u><sup>2</sup>, <u>Perth Rosen</u><sup>3</sup>, <u>Claude Tardif</u><sup>4</sup>

<sup>1</sup>Motivation Charitable Trust, Bristol, United Kingdom. <sup>2</sup>Mobility India, Bangalore, India. <sup>3</sup>UCP Wheels for Humanity, Chatsworth, USA. <sup>4</sup>ISPO, Brussels, Belgium

#### **Abstract**

Articles 20 of the Convention on the Rights of Persons with Disabilities, affirm that States Parties shall take effective measures to ensure personal mobility by facilitating access to good quality mobility aids, devices and assistive technologies at an affordable cost. Wheelchairs are among the most common mobility devices for enhancing mobility. Over 100 million people worldwide require wheelchairs for mobility and function, yet most lack access to appropriate wheelchairs or services to repair them.

Wheelchair services are provided by a wide range of professionals, including prosthetists-orthotists, and effective wheelchair provision requires that personnel have the appropriate knowledge and skills. A lack of properly trained personnel constitutes a major barrier to provision of appropriate wheelchair services. Currently, in most of the P&O training programmes, wheelchair services training is not integrated in the curriculum. Linking with existing P&O training programmes provides an opportunity to develop the appropriate knowledge and skills for prosthetists-orthotists to play an active role in the provision of wheelchair services.

Newly published ISPO Education Standards for Prosthetic/Orthotic Occupations, state that prosthetists/orthotists have the blend of clinical and technical competencies to provide assistive products for people with physical impairments including prosthetic/orthotic devices, postural supports and wheelchairs.

During the symposium, results of the survey conducted by ISPO aiming at gathering information among P&O training institutions on the integration of wheelchair services training within their curriculum, will be presented along with the experience of two organizations integrating wheelchair services training in P&O curriculum.

# Statement of the objective / learning objectives

At the end of the symposium, attendees should have an overview of the integration of wheelchair services training in P&O training curriculum worldwide, challenges and how it can be done professionally.



# Sunday, 6 October

# **Keynote Lecture 2.0**

# Activity Assistive Robotics from the View Point of Rehabilitation Medicine

Eiichi Saitoh<sup>1</sup>
<sup>1</sup>Fujita Health University, Aichi, Japan

#### **Abstract**

In the very near future, robotics is poised to become one of the most helpful tools for disabled people in four domains: They will assist exercise, independence, care givers, and emotional and cognitive activities. We have been engaged in developing assistive robots for 15 years. This presentation will describe our experience in the development of the following robots:

# WPAL (Wearable Power Assist Locomotor): To assist paraplegic people in walking, we developed the Wearable Power Assist Locomotor (WPAL) in collaboration with Aska Co. (Aichi, Japan) since 2005. WPAL incorporates a medial hip joint system composed of medially placed bilateral hip-knee-ankle motor joints without a pelvic component. To date, we have used WPAL with more than 20 patients with spinal cord injury (SCI, including cervical-SCI). Patients were able to don/doff the device by themselves, stand up from / sit down in their wheelchair, keep standing without arm support, and walk around on a flat floor. These results were observed even in patients who could not perform these activities with orthoses.

# Welwalk (Gait Exercise Assist Robot): We developed a Gait Exercise Assist Robot (Welwalk) in collaboration with the Toyota Motor Corporation (Aichi, Japan). Welwalk is for gait exercise in hemiplegia. Use of the robot will be discussed in the context of motor learning.

# STAR (Side Transfer Assist Robot): For elderly care in the community, we propose a Robotic Smart Home (RSH) that consists of a smart home and care assist robots. In the RSH setting, the STAR plays an important role in assisting transfers. STAR consists of an omnidirectional wheel for moving around and a height-adjustable mechanism incorporating a seat, arm rest, and foot rest for lateral transfers. It provides safe and easy lateral transfers even in small spaces such as a standard size toilet within a typical home.



# Advanced IC Prosthetics: Lower Limb Transfemoral

# 2.1.1

# Promoting Life-like Movement Strategies: Bionic Prosthetics, Prosthetists and Physical Therapists Restoring Human Function

Robert Gailey<sup>1</sup>, Michael Corcoran<sup>2</sup>, Carolyn Hirons<sup>3</sup>
<sup>1</sup>University of Miami Miller School of Medicine, Coral Gables, USA. <sup>2</sup>Medical Center Orthotics & Prosthetics, Silver Springs, USA. <sup>3</sup>Pace Rehabilitation, Bredbury, United Kingdom

# **Abstract**

The term "Bionic" was coined in 1958 by Jack Steele and is defined as, "life-like". Advances in microprocessor and other advanced technologies is creating the potential for Bionic lower limb prosthetics to behave more life-like than most could have imagined. While engineering designs and prosthetic fittings have created these opportunities there is still a need for physical therapy to provide the necessary prosthetic training to promote life-like movement strategies for our patients. This presentation will discuss the latest Bionic prosthetic foot and knee components and the therapies required for patients to maximize performance with these state-of-the-art designs.

Prosthetic components will be presented in terms of design characteristics for categories of knees and feet, such as microprocessor, powered or other classes of components. Specific physical therapy exercises designed to prepare patients for the use of sophisticated prosthetic components will be presented and the rationale for each treatment discussed. The team of speakers will describe training strategies for utilizing different prosthetic features during specific functional tasks, including: standing, sitting, walking negotiating inclines, declines, stairs, and curbs.

When appropriate high-level activities such as running will be discussed. Moreover, difference in prosthetic prescription, fitting and training with higher and lower functioning patients will be highlighted with each functional task. The speakers have decades of experience with advanced prosthetic care and physical therapy treatment designs for Bionic prosthetics and have worked with newest technologies.

This presentation will illustrate the need for collaboration between professions to ensure that patients will have prosthetic limbs that appear "life-like".

# Statement of the objective / learning objectives

Participants will be able to: 1) discuss the characteristics of the newest Bionic prosthetics, 2) prescribe preprosthetic exercises, 3) and teach patients how to use the features of Bionic prosthetics when performing functional activities



# Free Paper Session Orthotics: Lower Limb Neurological - Gait

# 2.1.2.a

Long-term use of Ankle-Foot Orthoses does not affect Tibialis Anterior Muscle Electromyography in Patients after Stroke: A Randomized Controlled Trial

<u>Corien Nikamp</u><sup>1,2</sup>, Jaap Buurke<sup>1,2</sup>, Leendert Schaake<sup>1</sup>, Johan Rietman<sup>1,2,3</sup>, Hermie Hermens<sup>1,2</sup>
<sup>1</sup>Roessingh Research and Development, Enschede, Netherlands. <sup>2</sup>University of Twente, Enschede, Netherlands. <sup>3</sup>Roessingh Centre for Rehabilitation, Enschede, Netherlands

# **BACKGROUND**

Foot-clearance in swing is often impaired after stroke. Ankle-foot orthoses (AFOs) are used to improve this, but some clinicians fear that AFO-use after stroke leads to disuse of the tibialis anterior muscle. A randomized controlled trial on the effects of AFO-provision after stroke was performed.

#### AIM

The aim of the current research was to study whether AFO-use after stroke affects tibialis anterior muscleactivity over a period of 26 weeks and whether timing of AFO-provision (early or delayed after stroke) affects the results.

# **METHOD**

Unilateral hemiparetic subjects with indication for AFO-use, maximal six weeks post-stroke were included. Subjects were randomly assigned to AFO-provision early (at inclusion, study week 1) or delayed (eight weeks later, study week 9). Smooth-rectified electromyography of the tibialis anterior was measured in study-week 1, 9, 17 and 26. Paired samples *T*-test compared data with and without AFO within one measurement session. Mixed-model repeated measures analysis within the early and delayed group compared data over the 26-weeks period, including walking speed as confounder. Independent samples T-test were used to compare data of both groups after 26 weeks.

# **RESULTS**

Twenty-six subjects were analysed. Within a single measurement session, walking with AFO significantly lowered tibialis anterior muscle-activity levels during swing (p=0.041) compared to walking without AFO. However, during the 26-weeks follow-up, no changes in tibialis anterior muscle-activity in swing without AFO were found, both for the early (p=0.420) and the delayed group (p=0.282). After 26 weeks, no differences in tibialis anterior activity between the early and delayed group were found in swing, with (p=0.207) or without AFO (p=0.310).

# **DISCUSSION AND CONCLUSION**

AFO-use after stroke lowered tibialis anterior muscle-activity during swing within a single measurement session. However, long-term AFO-use did not affect tibialis anterior activity over 26 weeks. Early or delayed AFO-provision did not affect the findings. The results indicate that there is no need to fear negative consequences on the level of tibialis anterior muscle-activity because of long-term AFO-use (early) after stroke.



# 2.1.2.b

# Effect of Posterior Leaf Spring and Carbon Composite Ankle Foot Orthosis on Gait and Functional Mobility of Hemiparetic Stroke Patients

Zidikheri Msechu, Ahmad Qureshi King Fahad Medical City, Riyadh, Saudi Arabia

#### **BACKGROUND**

Stroke is the most prevalent clinical disease of the cerebral blood vessels leading to death or long-term disability. About 2/3 of survivors achieve independent walking function but continue to have difficulty walking and remain at high risk of fall due to imbalance. Different orthoses are used to treat gait impairment. Ankle Foot Orthoses (AFOs) are among the orthoses commonly used to improve gait in hemiplegic stroke survivors.

#### AIM

The objective of this study was to assess and compare the effect of PLS-AFO and C-AFO on functional mobility, walking speed and satisfaction among hemiplegic stroke survivors

#### METHOD

Twenty-seven hemiplegic ambulatory stroke survivors who had completed a rehabilitation program and who were already using AFO were included in the study. Subjects were randomly assigned either PLS-AFO or C-AFO and assessment was done with and without AFO. Functional mobility, walking speed and satisfaction were assessed using the Timed Up and Go (TUG) test, the 10-meters walking test (10MWT) and Orthotics and Prosthetics users' survey (OPUS) questionnaires, respectively.

#### **RESULTS**

The two types of AFO improved functional mobility. PLS-AFO and C-AFO reduced TUG time by 4.4 seconds (10.5%) and 7 seconds (22.4%), respectively. Walking speed increased during the self-selected walking speed in both AFO users by 0.1m/s (33.4%) and 0.5m/s (40%) for PLS-AFO and C-AFO, respectively. Similarly, increase during fast walking speed were observed on PLS-AFO and C-AFO users by 0.05m/s (12.5%) and 0.01m/s (1.42%) respectively. With both AFOs, participants were satisfied in terms of weight, fit and comfort (>90%). The percentages of those satisfied with the durability of PLS-AFO and C-AFO were 73% and 92%, respectively. Free from irritation and skin abrasion with PLS-AFO and C-AFO were 81.8%, and 85.7% respectively. Pain was reported by 8.1% of PLS-AFO users as compared to 28.6% of C-AFO users.

# **DISCUSSION AND CONCLUSION**

The study showed that both types of AFOs (C-AFO and PLS-AFO) can improve the walking ability of hemiplegic stroke survivors, including walking speed and functional mobility. C-AFO has shown the ability to provide a better self-selected walking speed, while PLS-AFO was slightly better in fast waking speed. Both AFOs provided a high level of user satisfaction. Pain reported with C-AFO suggest the need to redesign. A future study of the AFO users grouped in different level of walking speeds should be considered

### **ACKNOWLEDGEMENTS**

Acknowledgement to King Fahad medical city for providing financial support and facility to perform the study.



# 2.1.2.c

# Relationship between Tibialis Anterior Muscle Activation and Ankle Motion in an Ankle Foot Orthosis-Footwear Combination

<u>Christopher Hovorka</u><sup>1,2</sup>, Geza Kogler<sup>2</sup>, Young-Hui Chang<sup>2</sup>, Robert Gregor<sup>2</sup>

<sup>1</sup>University of Pittsburgh, Pittsburgh, USA. <sup>2</sup>Georgia Institute of Technology, Atlanta, USA

#### **BACKGROUND**

Ankle foot orthoses (AFOs) are commonly used for biomechanical motion control in treating gait disorders due to neuromuscular pathologies. Less common are studies which quantify the relationship between AFO joint constraint and neuromuscular adaptation. We did so by collecting ankle motion and force and EMG data during 15 minutes of continuous treadmill walking, by subjects wearing an articulated, carbon-composite AFO-footwear combination (AFO-FC) system to maximally control joint motion in the sagittal plane.

#### AIM

To test a prediction that an AFO which effectively constrained ankle motion in the AFO STOP condition would result in decreased Tibialis Anterior muscle activation.

# **METHOD**

Healthy subjects (8 females, 6 males) consented to participate in a three-condition protocol approved by the Georgia Tech Institutional Review Board. Ankle motion in the sagittal plane was controlled in an AFO. Conditions were: CONTROL (no AFO), FREE (AFO-FC, no joint constraint) and STOP (AFO-FC in maximal constraint). Each subject walked at their preferred speed for 15 minutes, with continuous sampling of motion, force and EMG [1]. All data were synchronized, filtered and time normalized to 100% of the gait cycle. Mean ground reaction force, moments, and joint angles, for STOP, FREE and CONTROL were calculated. Mean integrated EMG (iEMG) was calculated for each seven gait cycle interval (Figure 1). [Vicon cameras (120 Hz), AMTI force plates (1080 Hz), Noraxon wireless EMG (1500 Hz)].

# **RESULTS**

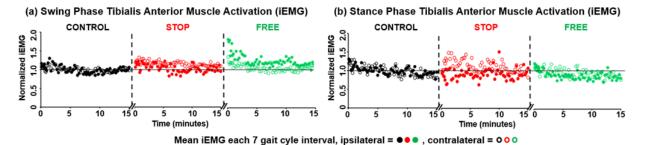


Figure 1. Tibialis Anterior muscle activation data, ipsilateral and contralateral, during swing phase (a) and stance phase (b).

Horizontal line = aggregate mean normalized iEMG of ipsi- and contralateral TA in CONTROL of 15 minute walking period

STOP condition limited ankle motion to iEMG outputs revealed notably different patterns of activation between ipsilateral and contralateral legs. Walking in STOP condition during swing elicited an immediate increase in ipsilateral TA followed by gradual return to baseline, and in stance elicited an immediate decrease followed by a gradual return to baseline. Walking in FREE condition during swing elicited an immediate and substantial increase in ipsilateral TA that remained above baseline throughout the entire 15 minute walking period, and in stance elicited an immediate increase followed by gradual return to baseline. Walking in CONTROL condition elicited immediate increase followed by gradual return to baseline in ipsilateral and contralateral TA muscles

during swing and stance. Walking in STOP and FREE elicited immediate increase followed by gradual decrease

# **DISCUSSION AND CONCLUSION**

These collective findings support a relationship between ankle constraint of motion and decreased Tibialis Anterior muscle activation. Muscle activation is unique to each type of orthotic motion control (maximum or minimum ankle constraint) and each phase of gait (stance or swing).

### **ACKNOWLEDGEMENTS**

and return to baseline.

Funding provided by the American Orthotic and Prosthetic Association (AOPA) and the Orthotic and Prosthetic Education and Research Foundation (OPERF).



# 2.1.2.d

# Effect of the Foot-Plate Length of an Ankle-Foot Orthosis with Plantar Flexion Resistance on the Gait of Stroke Patients

Souji Tanaka<sup>1</sup>, Naoyuki Motojima<sup>2</sup>, Sumiko Yamamoto<sup>3</sup>

Nerima Kenikukai Hospital, Tokyo, Japan. <sup>2</sup>Nakaizu Rehabalitation, Shizuoka, Japan. <sup>3</sup>Guraduate school of International University of Health, Tokyo, Japan

#### **BACKGROUND**

A previous study showed that the ankle-foot orthosis (AFO) with plantarflextion resistance using an oil damper (AFO-OD) affected the first and second rocker functions in the gait of stroke patients.[1] However, the plantarflexion resistance prevents from plantarflexion movement in preswing (Psw) and it inhibits smooth swing of the paretic limb. The foot-plate length also affects the swing movement. We hypothesized if the foot-plate length of the AFO-OD affected the gait parameters related to the swing of the paretic limb.

#### ΔIM

The purpose of this study was to investigate the effect of the foot-plate length of the AFO-OD on kinematic and kinetic variables during gait of stroke patients.

#### **METHOD**

Twenty stroke patients in subacute phase participated in this study. A 3D motion analysis system was used to assess gait in 2 conditions: 1) AFO-OD with full-length foot-plate and 2) the same AFO-OD with  $\frac{3}{4}$  length foot-plate ( $\frac{3}{4}$  AFO-OD). The sagittal plane ankle, knee and hip kinematics and kinetics in stance phase were calculated for the paretic limb. Additional calculated parameters including the top height of heel marker in PSw to evaluate heel rise and step length (nonparetic to paretic) were calculated. A paired t-test was performed to determine whether there was a significant difference between conditions (p<0.05).

#### **RESULTS**

Table 1. Gait parameters in two conditions

	AFO-OD	3/4 AFO-OD	p-value
peak value of hip joint extension angle in PSw (°)	1.48( 9.8 )	2.60( 9.9 )	0.021
peak value of hip joint flex moment in PSw (Nm/kg)	0.48( 0.25 )	0.52( 0.26 )	0.013
top height of heel maker in PSw (m)	0.15( 0.05 )	0.16( 0.05 )	p<0.001
step length (nonparetic to paretic) (%BH)	0.19( 0.08 )	0.21( 0.08 )	0.025

Parametric data: mean (standard deviation).

Table 1 shows the mean, standard deviation, and p-value for each gait parameter in both conditions. There were no significant differences in the ankle and knee kinematics and kinetics between the two conditions (p>0.05). Significant increases were found in the peak values of the hip joint extension angle in PSw (p<0.05) and the hip joint flexion moment in PSw (p<0.05) in the '¾ AFO-OD' condition compared to the 'AFO-OD with full-length footplate'. Significant increases were also found in the top height of the heel marker in PSw (p<0.01) and step length (nonparetic to paretic) in '¾ AFO-OD'.

# **DISCUSSION AND CONCLUSION**

Our results indicated that the ¾ AFO-OD would improve hip flexor moment and step length by enhancing hip extension and heel rise more in PSw than the full-length foot-plate. This study showed that ¾ AFO-OD improved some parameters related to the third rocker, however, ankle kinematics and kinetics in this phase did not improve. Further study is required.

# **REFERENCES**

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# 2.1.2.e

# Effect of a Knee-Ankle-Foot Orthosis with Knee Flexion Control on the Gait of Stroke Patients

Syuntaro Kawaguchi 1,2, Sumiko Yamamoto<sup>2</sup>

<sup>1</sup>Sonoda Rehabilitation Hospital, Tokyo, Japan. <sup>2</sup>Graduate school, International University of Health & Welfare, Tokyo, Japan

#### **BACKGROUND**

The Knee-Ankle-Foot Orthosis (KAFO) are frequently used in gait training of stroke patients in the early recovery stage in Japan. The knee joint of KAFOs is locked and the lack of knee flexion causes some problems during gait, such as circumduction and excessive pelvic obliquity.[1] To solve this problem a KAFO with knee flexion control was developed. This KAFO was specially designed for the gait training run by physiotherapists in gait rehabilitation of stroke patients.

#### ΔIM

The purpose of this study was to compare the gait of stroke patients using KAFOs with locked knee joint and controlled knee joint.

#### METHOD

A newly developed material (Electro-Attractive-Material, EAM) was used at the knee joint of the KAFO. The knee joint is locked in stance phase, and it is released immediately after when a manual switch is pushed by a physiotherapist.

The gait of 7 stroke patients in the recovery phase was measured in two conditions, with a KAFO with a locked knee joint (locked knee) and with a controlled knee joint (EAM-knee). In the gait measurement inertial sensors, foot switches, and EMG sensors were used to measure the pelvic and the hip joint angles and the muscle activities. The Wilcoxon signed rank test was used to compare the results between 2 conditions.

#### **RESULTS**

Table Result of spatio-temporal, kinematic parameters and EMG

	Locked-KAFO	EAM Knee-KAFO
Velocity (m/s)	0.5(0.3 - 0.1)	0.7(0.4 - 1.2)*
Paretic side		
Swing phase duration (s)	0.9(0.6 - 1.2)	0.8(0.1 - 1.1)*
Peak hip abduction (°)	12.4(4.7 - 16.0)	4.2(0.1 - 8.5)*
Peak hip extension (°)	15.0(-3.1 - 21.7)	8.8(6.4 - 16.7)*
Rectus femoris $(\mu V)$ LR	15.3(5.1 - 36.4)	28.0(7.8 - 82.2)*
Longissimus dorsi $(\mu V)$ Sw	19.2(11.9 - 56.2)	15.5(6.9 – 51.8)*

Median values for the gait parameters and EMG in Locked-KAFO and EAM Knee KAFO

(Median(min - max)) (\*:p<0.05)

The gait speed increased and the swing time decreased in the EAM-knee condition compared to the locked knee condition. The abduction, external rotation, and extension of the hip joint were decreased in the EAM-knee condition. The increased activity of the quadriceps in loading response and decreased activity of the longissimus in the swing phase were found in the EAM-knee condition.

# **DISCUSSION AND CONCLUSION**

The decrease of the swing time, the hip abduction and external rotation, and the activity of the longissimus indicate the decrease of compensational movement caused by the locked knee joint. In the EAM-knee condition, the knee joint was slightly flexed at initial contact, and it may induce an increased activity of the quadriceps in loading response. This function prevented the decrease in activity of the quadriceps, which was a disadvantage of traditional KAFO with a locked knee joint.

# **REFERENCES**

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# 2.1.2.f

# The Effects of Ankle-Foot Orthoses on Swing and Stance Phase – A Clinician-Friendly Visualization of the Results of Gait Analysis

Masahiko Mukaino<sup>1</sup>, Kannit Pongpipatpaiboon<sup>2</sup>, Kazuhiro Tsuchiyama<sup>1</sup>, Kei Ohtsuka<sup>1</sup>, Fumihiro Matsuda<sup>1</sup>, Hiroki Tanikawa<sup>1</sup>, Junya Yamada<sup>3</sup>, Eiichi Saitoh<sup>1</sup>

<sup>1</sup>Fujita Health University, Toyoake, Japan. <sup>2</sup>Samitivej Srinakarin Hospital, Bangkok, Thailand. <sup>3</sup>Fujita Health University Hospital, Toyoake, Japan

#### **BACKGROUND**

Ankle—foot orthoses (AFOs) are used to improve gait stability, by increasing toe clearance and stance stability in individuals with hemiparesis. Previous studies have shown that AFOs improve toe clearance and stability during the stance phase. Clinical monitoring via kinematic analysis and deepened understanding of the alterations in biomechanical factors behind the beneficial effect of AFOs should be further clarified.

#### ΔIM

To investigate and visualize the actual impact of AFOs on toe clearance and stance stability.

# **METHOD**

The gait performance of 24 hemiparetic patients due to stroke was evaluated by comparing movement with and without AFOs using a three-dimensional treadmill gait analysis (3DGA) and force plate systems. Kinematic and kinetic analysis was performed to quantify the toe clearance and the movements affecting the toe clearance, such as limb shortening, pelvic obliquity and circumduction, and to quantify the stability in the movement pattern of the centre of gravity during the paretic single stance phase.

#### **RESULTS**

Using AFOs significantly increased toe clearance. The quantified impact of AFOs on limb shortening and pelvic obliquity were significantly different when comparing performance with and without AFOs. Among the movement indices related to toe clearance, limb shortening was increased with the use of AFOs. The elevation of the hip due to pelvic obliquity, representing compensatory strategies, was diminished by using orthoses. On the other hand, the stability of movement of center of gravity during the single stance phase was significantly improved with the use of AFOs.

# **DISCUSSION AND CONCLUSION**

By using 3DGA and force plate analysis, the impact of AFOs on toe clearance and stance stability of hemiparetic patients was quantified and visualized. This approach to visualizing the gait strategy using 3DGA and force plate analysis could contribute to clinical decision making, and thus would facilitate the use of motion analysis in the real clinic.



# Symposium Developing Countries

# 2.1.3

# Providing Resources, Humanitarian Aids and P&O Services in Troubled Areas

Alf Reuter<sup>1</sup>, Klaus-Jürgen Lotz<sup>1</sup>, Hansjörg Strohmeyer<sup>2</sup>, Claude Tardif<sup>3</sup>, Isabelle Urseau<sup>4</sup>
<sup>1</sup>German Association of Orthopaedic Technology, Dortmund, Germany. <sup>2</sup>Office for the Coordination of Humanitarian Affairs (OCHA) | United Nations, New York, USA. <sup>3</sup>ISPO International, Brussels, Belgium, <sup>4</sup>Humanity & Inclusion, Lyon, France

#### **Abstract**

The world faces global crises and disasters that hit rich and poor countries alike. What can be and has already been done to prevent crises and to respond to them by humanitarian activities? The symposium will focus on different approaches/perspectives and will demonstrate which efforts have been made by international organisations to lessen the impacts of crises. The session will showcase successful examples of P&O service deliveries in troubled areas.

#### Lectures:

- Humanitarian aids in troubled areas provided by the United Nations, Hansjörg Strohmeyer (Chief of the Policy Development and Studies Branch, United Nations Office for the Coordination of Humanitarian Affairs)
- P&O demands in troubled areas: an ISPO International perspective, Claude Tardif (ISPO International)
- Answering needs for physical and functional rehabilitation in troubled areas: A continuum approach, Isabelle Urseau (Humanity & Inclusion)

# Statement of the objective / learning objectives

The session will demonstrate different approaches and best practice to tackling challenges faced by crises and disasters. Attendees will get broader insight into international operations and solutions that help to offer access to needed services.



# **Free Paper Session Prosthetics: Lower Limb Transfemoral - Knee**

# 2.1.4.a

# Effect of Prosthetic Alignment on the Biomechanical Characteristics in Transfemoral Amputees

<u>Tengyu Zhang</u><sup>1,2,3</sup>, Fei Liu<sup>1</sup>, Xuefei Bai<sup>1,3</sup>, Run Ji<sup>1,2,3</sup>, Yubo Fan<sup>1,2,4</sup>

<sup>1</sup> National Research Center for Rehabilitation Technical Aids, Beijing, China. <sup>2</sup>School of Biological Science and Medical Engineering, Beihang University, Beijing, China. <sup>3</sup>Key Laboratory of Human Motion Analysis and Rehabilitation Technology of the Ministry of Civil Affairs, Beijing, China. <sup>4</sup>Beijing Key Laboratory of Rehabilitation Technical Aids for Old-Age Disability, Beijing, China

# **BACKGROUND**

The incidence of hip and knee osteoarthritis (OA) in lower-limb amputees is much higher than non-amputees,[1-2] which may be related to inappropriate biomechanical loading after amputation.[3] The prosthetic alignment may be an important affecting factor. However, the effect of alignment on biomechanical characteristics in transfemoral amputees is unclear, and the relationship between malalignment and joint diseases is still undefined.

#### AIM

The aim is to study the effect of prosthetic alignments on the biomechanical characteristics in transfemoral amputees, and analyze the possible adverse effects of abnormal alignments on the lower limb joint.

#### **METHOD**

Gait tests of 10 unilateral transfemoral amputees and 15 non-amputees were performed with an 8-cameras motion capture system and two force platforms, under regularly recommended alignment and eight malalignments, namely 10 mm socket translational alignment (anterior, posterior, medial, and lateral) and 6° socket angular alignment changes (flexion, extension, abduction, and adduction). The differences in biomechanical parameters under different alignments were analyzed, including spatiotemporal gait parameters, ground reaction force (GRF), hip and knee joint reaction force and moment, and compared with those of the nonamputees. Statistical analyses were performed by one-way ANOVA, repeated measure multivariate ANOVA, and paired t tests.

#### **RESULTS**

Alignment had no significant effect on spatiotemporal gait parameters but significantly affected GRF (P<0.00625). The medial GRF of the transfemoral amputee is significantly higher than that of the non-amputees (P<0.0056). The anteroposterior and vertical GRF in the intact side are higher than those in the residual side (P<0.05). The alignment of socket adduction significantly increases medial GRF on both sides (P<0.00625). There was no significant effect of malalignment on joint force and moment of the intact joint, but the residual hip joint force was significantly changed in some malalignments (P<0.00625). The lateral joint force and external rotation moment of hip in both sides, especially in intact side, were significantly higher than those of nonamputees (P<0.0056).

#### **DISCUSSION AND CONCLUSION**

Alignments exert remarkable and complicated effects on the biomechanical characteristics in transfemoral amputees. Alignment changes mainly affect biomechanical characteristics on the plane along which the changes occurs. Socket adduction significantly increases medial GRF which relates to knee OA. The significantly higher medial GRF and lateral hip joint force on intact side may be one of the reasons for the high incidence of intact hip and knee OA.

# **REFERENCES**

[1] Morgenroth DC, PM & R 2012.

[3] Gailey R, J Rehabil Res Devel 2008.

[2] Struyf P, Arch Phys Med Rehab 2009.



# 2.1.4.b

# Level Ground Walking with Three Fundamentally Different Prosthetic Foot Concepts: Effects on Ankle Power and Sound Limb Load

Eva Proebsting<sup>1</sup>, Bjoern Altenburg<sup>1</sup>, Thomas Schmalz<sup>1</sup>, Kerstin Krug<sup>2</sup>, Malte Bellmann<sup>1</sup>
Ottobock SE & Co. KGaA, Goettingen, Germany. <sup>2</sup>University of Applied Sciences, Muenster, Germany

#### **BACKGROUND**

Most prosthetic feet are designed to store and release energy during stance. The performance of them depend on material and construction principles. New powered feet can generate net positive mechanical work in order to provide an active push-off. Caused by this development, the clinical importance of the ankle power is discussed frequently. It is supposed that this parameter affects the load on the sound side of amputees.[1-3]

#### AIN

The biomechanical evaluation of the question whether the ankle power of different prosthetic feet influence the gait of transfemoral amputees particularly the knee load on the sound side.

### **METHOD**

Level walking of 6 transfemoral amputees (age: 46±10 years; weight: 86.3±20.0; height: 1.83±0.10m) with 3 different feet (Solid Ankle Cushion Heel foot (SACH), Energy Storing and Returning foot (ESR) and an active foot (AF)) was biomechanically analysed. In all prostheses a microprocessor knee joint was used. For the measurements, the amputees walked with two different velocities (normal and fast). An optoelectronic camera system with twelve Bonita cameras (VICON, GB) was used to record the kinematics and two linked force plates (KISTLER AG, CH) recorded the kinetics.

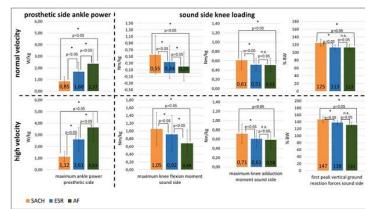


Figure 1. Maximum ankle power of the prosthetic side and load parameters on the sound side

#### **RESULTS**

For both velocities tested, no significant differences were found between the studied

feet (mean velocity normal: 1.27±0.19m/s, fast: 1.62±0.22m/s)

Furthermore, the food comparison showed the same trend for both velocities.

The SACH showed the smallest ankle power maximum with 0.85±0.37W/kg for the normal and 1.12±0.44W/kg for the high velocity. For both velocities the ankle power maxima with the ESR were nearly twice as high and with the AF it has been nearly tripled in comparison with the SACH.

The maximum external knee adduction moment (EAM), the maximum knee flexion moment and the first peak vertical ground reaction forces were reduced with increased ankle power. By comparing this parameters for the different feet, most showed significant differences (figure 1).

# **DISCUSSION AND CONCLUSION**

The ankle power shows a very clear differentiation respective to the three foot concepts. However, the decreased sound side EAM and first peak vertical ground reaction forces show a matching inverse trend but not that clear differentiation. Particularly when comparing ESR and AF values there seems no strong correlation between ankle power and sound limb load. Other factors affect here which needs more investigation. The overall results prove clear advantages using ESR and AF feet over SACH feet.

# **REFERENCES**

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[2] Grabowski, J Neuro Eng Rehabil 2013.



# 2.1.4.c

# Improvement in Gait Outcomes Following Microprocessor Controlled Knee Provision to Established Unilateral Transfemoral Amputees

<u>Bruce Carse</u>, Helen Scott, Laura Brady, John Colvin WestMARC, NHS Greater Glasgow and Clyde, Glasgow, United Kingdom

#### **BACKGROUND**

In 2014 the Scottish Specialist Prosthetics Service (SSPS) was established to provide advanced equipment to eligible NHS service users. While many previous studies have discussed the benefits of microprocessor controlled knees (MPK) [1,2] sample sizes are often small and participant selection criteria are not always described. Furthermore, there is some uncertainty surrounding the ability of MPK's ability to improve energy efficiency to unilateral transfemoral (UTF) amputees.[3]

# AIM

To evaluate the effect on gait outcomes of the provision of MPKs to established UTF amputees, within a large and diverse group of prosthetic service users.

# **METHOD**

A longitudinal study design study design was used, and out of 60 participants measured at baseline, follow-up data were collected from 32. Consecutive UTF patients who met the SSPS criteria were measured in a gait analysis laboratory. Full-body 3D kinematic and kinetic gait measures, and oxygen cost data were taken at baseline, with follow-up measures taken six months post-MPK provision. Participants were aged 52 (16) years, time since amputation was 18 (15) years. Activity levels were K2 (n=5), K3 (n=17), K4 (n=10), and reasons for amputation were mechanical trauma (n=16), peripheral arterial disease (n=5) and other (n=11).

# **RESULTS**

As shown in Table 1, significant improvements in gait profile score (GPS), velocity, step length, vertical ground reaction force (Fz) symmetry, and centre of mass (CoM) deviation were measured. No changes were observed in step length and step time symmetry ratio (SR), net nondimensional normalised (NNN) oxygen cost and base of support.

Table 1 Pre and post-MPK outcome measure data and p-values (\* Paired t-test, \*\* Wilcoxon signed-rank test)

	Mean (SD)	Mean (SD)	p-value	Mean (SD)
GPS (°)	11.18 (2.19)	10.07 (2.06)	<0.001*	5.4 (0.7)
Walking velocity (m/s)	0.88 (0.26)	1.01 (0.25)	<0.001*	1.41 (0.1)
Step length (m)	0.58 (0.11)	0.64 (0.11)	<0.001**	0.74 (0.06)
Step length SR	0.87 (0.09)	0.88 (0.1)	NS*	0.97 (0.03)
Step time SR	0.84 (0.1)	0.85 (0.1)	NS*	0.96 (0.04)
Fz symmetry index	18.94 (16.32)	14.41 (9.33)	<0.001**	1.32 (1.22)
NNN oxygen cost	0.4 (0.12)	0.42 (0.13)	NS*	0.26 (0.05)
Base of support (mm)	339.87 (63.27)	338.34 (59.28)	NS**	238 (32)
CoM deviation (%)	2.17 (1.18)	1.73 (0.75)	<0.01**	0.8 (0.18)

# **DISCUSSION AND CONCLUSION**

The data presented shows significant improvement across the majority of gait-specific outcome measures, which appear to justify the provision of MPKs. The magnitude of these improvements was perhaps not as large as anticipated, which could reflect the diversity within the participant group. We conclude that MPK provision provided significant gait improvements, but outcomes remain far below target 'normal' values, and those quoted for military UTF amputees.[4]

# **REFERENCES**

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[3] Wong et al, J Prosthet Orthot 2012.

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# **ACKNOWLEDGEMENTS**

Lead author's research time funded by NHS Research Scotland Career Research Fellowship.



# 2.1.4.d

# A Novel Dynamic Knee Testing System for Robotic Low-Limb Prosthetics

Inhyuk Moon

Dong-Eui University, Busan, Republic of Korea

#### **BACKGROUND**

As robotic technology advances, it has been widely applied to mechanism design and motion control of hip, knee or ankle parts of low-limb prosthetics. Because the role of knee part is most important while walking, the functional test of robotic knee prosthetics must be an essential test. However the relevant testing standards, ISO 10328 and ISO 22675, only provide a structural testing except knee flexion of low-limb prosthetics. Therefore there is no dynamic test method for the robotic low-limb prosthetics.

#### ΔIM

In this paper a dynamic test method and system for a robotic low-limb prosthetics capable of controlling knee flexion and extension is proposed.

#### METHOD

The distinguished point of ISO 22675 is to realistically simulate the loading conditions of the complete stance phase of walking from heel strike to toe-off. But it is not suitable for testing the knee flexion and extension. In this study, a test dummy is designed. Robotic low-limb prosthetics with knee flexion control is coupled to the transfemoral part of dummy. A treadmill synchronized to walking speed is set up under the test dummy. While testing, the dummy body is actuated up and down, and the loading force is also controlled by the gait cycle. This is the test system to test the performance of the robotic low-limb prosthetics.

#### **RESULTS**

In experiments the loading force defined in ISO 22675 is set up to the dummy, and range of motion (ROM) and swing speed of the hip joint of the dummy is controlled by walking pattern. The motion status is measured in real-time by 3D motion capture system and an embedded motion sensor and an force sensor into the robotic low-limb prosthetics. By comparing the experimental results, the walking motion was well controlled by the test system. The measured force data loaded on the knee part was also well synchronized to the walking motion. The experimental results showed a possibility of the proposed test system for testing the performance of robotic low-limb prosthetics.

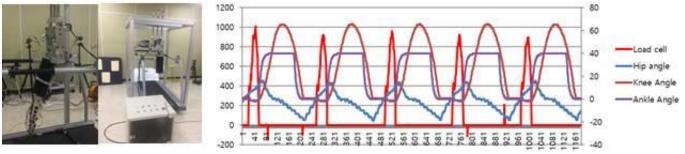


Figure 1. Test system (left) and experimental results (right)

# **DISCUSSION AND CONCLUSION**

The test system was possible to evaluate the gait speed and gait trajectory because the robotic low-limb prosthetics was tested on the treadmill. However it could not perform a quantitative evaluation because simulating a ground reaction force and loading an actual vertical force while walking were not implemented yet. Now our group is trying to design a simulator for ground condition using in testing. This is the future work.

### **REFERENCES**

- [1] ISO 10328:2016 Prosthetics -- Structural testing of lower-limb prostheses -- Requirements and test methods.
- [2] ISO 22675:2016 Prosthetics -- Testing of ankle-foot devices and foot units -- Requirements and test methods.



# 2.1.4.e Gait Data Derived from Bionic Microprocessor Prostheses

<u>Yael Dotan Marom</u><sup>1</sup>, Itzhak Siev-ner<sup>2</sup>, Rachel Tiktinsky<sup>1</sup>, Israel Dudkiewicz<sup>1</sup>, Oren Barzel<sup>1</sup>
<sup>1</sup>Sheba Medical Center, Ramat Gan, Israel. <sup>2</sup>Ministry of Health, Jerusalem, Israel

#### **BACKGROUND**

The advanced technology that has reached prosthetics is the microprocessor integrated and non-integrated knee-ankle microprocessor prosthesis that is synchronized for ambulation. There has not been published information on the data collection derived within the microprocessor knee and foot prosthesis and also from the integrated system. The system has the ability to measure gait parameters and functional activities and generate a report for the user and the therapist.

#### ΔIM

To collect and analyze the reports from the prosthesis for the improvement of patient care and more precise prosthetic alignment.

# **METHOD**

Gait data was collected from two K3 traumatic Transfemoral amputees over one year. The prostheses evaluated were Symbionic leg (by Osssur) subject A and Genium knee + Meridium foot (by Ottobock) Subject B. They were fitted and adjusted according to the proper manufacturer's training protocol. Additionally, training was conducted in a virtual reality systems for advanced gait activities, such as changing speed, walking on a ramp and dual tasking. Data that was saved in the prosthetic software was collected at 4 timeframes, while continuing their rehabilitation as outpatients. The treatment plan utilized data collection from the microprocessor unit in order to improve the gait training process.

#### **RESULTS**

The follow up presented in figure 1. demonstrates improvement of 38% in common walking for subject A and no improvement for subject B. Total steps count improved by 177% for subject A and 58% for subject B. This pattern probably reflects increased daily usage time as measured in subject B. Step distribution is available as presented in figure 2 for subject A. Data regarding usage of advanced options is available in the Genium +

Meridium only: Optimized Physiological Gait (OPG) increased by 100%.

# DISCUSSION AND CONCLUSION

The new technological possibility to derive data from the prosthesis allows a continual concrete follow up of the user's functional level and usage of the specific properties of the microprocessor prosthesis (eg use of reciprocal stairs ascent). The results demonstrate functional improvement and also increase in the use of advanced options. Likewise, there was a need for progressive adjustment of the prosthesis for the amputee to apply the new information and benefit from the new prosthesis.

Subject	A (Symbionic)		B (Genium+Meridium	
Timeframe	1 Month	1 Year	1 Month	1 Year
Average speed (Km/h)	2.6	3.6	2.8	2.8
Steps per day	1564	4342	1432	2267
Common walking speed 2-4 (Km/h) % 2.5-4.5 (Km/h) %	23	41	62	56
Steps with OPG function (%)	N/A	N/A	11	22
Usage time per day (h)	N/A	N/A	4.95	9.9

Figure 1. Follow up data from Symbionic A and Genium+Meridium B

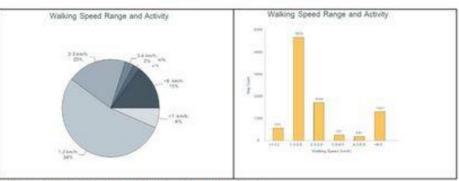


Figure 2. Example of report from Symbionic prosthesis: Distributation of galt speed (left) and step count (right)



# 2.1.4.f

# **Functional Mobility Training for Powered Lower Limb Prostheses**

<u>Suzanne Finucane</u><sup>1</sup>, Ann Simon<sup>1,2</sup>, MG Finco<sup>1</sup>, Levi Hargrove<sup>1,2,3</sup>

Shirley Ryan AbilityLab, Chicago, USA. <sup>2</sup>Northwestern University, Chicago, USA. <sup>3</sup>Department of Biomedical Engineering, Northwestern University, Evanston, USA

# **BACKGROUND**

Lower limb powered prostheses have the capability to provide amputees greater functional mobility within the home and community environment. Providing power at the knee and ankle joint can allow transfemoral amputees to climb stairs with a reciprocal pattern, ascend steep inclines with ease and allow active support for sit-to-stand transitions.[1,2] Clinicians need greater understanding of these powered prostheses and their functions in order to provide appropriate patient training.

#### AIM

The goal of this study was to refine techniques for functional mobility training with powered knee and ankle prostheses for transfemoral amputees.

# **METHOD**

Twenty unilateral transfemoral or knee disarticulation amputees were fitted with a powered knee-ankle prosthesis [2,3] by a certified prosthetist. Ambulation training began with instruction and practice on standing balance and level ground walking. Training progressed to incline walking at various speeds, stair climbing, and sit-to-stand. Training focused on how to utilize cues, refine device settings, and clinician/user feedback to incorporate the power generated from the prosthesis to achieve optimal gait kinematics. Joint angles and prosthesis load measurements provided useful feedback during gait deviation assessments and promoting proper form. Initial training was designed to meet the goals of independent ambulation through all functional mobility modes without clinician support.

# **RESULTS**

Following the development of this training, the majority of users being trained at the Shirley Ryan AbilityLab have been successful in ambulating across all five activity modes within 1-3 sessions of 1-2 hours each. Although a few participants required additional cueing for stair climbing, all participants were successful climbing with a reciprocal gait. Positive reactions were expressed when walking up a large incline since the effect of the ankle power was felt immediately. No trend was shown between the time since amputation, height, or weight on time needed for training.

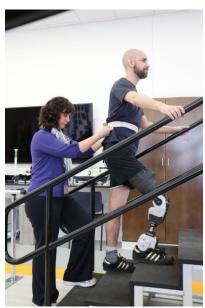


Image 1. Stair ascent with powered knee and ankle prosthesis.

# **DISCUSSION AND CONCLUSION**

Ambulation training was based on users walking as they did prior to amputation. As more powered lower limb devices become commercially available we expect most of these training techniques to carry over to other devices, although additional practices may be necessary for independent ambulation in the home and community. Through this training protocol, clinicians can better instruct amputees on the benefits and limitations of these advanced devices potentially providing improved training and outcomes across multiple modes of ambulation.

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# ACKNOWLEDGEMENTS

Funding was provided by the National Institute of Health 2R01HD079428-05, and the National Institute on Disability, Independent Living and Rehabilitation 90REGE0003-01-00.



# 2.1.4.g

# Differences in Task Completion in K2 and K3 Unilateral Trans-femoral Amputees With and Without Microprocessor Knees and Hydraulic Ankle Technology

<u>Laura Ritchie</u>, Michael McGrath, David Moser, Saeed Zahedi Chas A Blatchford and Sons Ltd, Basingstoke, United Kingdom

#### **BACKGROUND**

Prosthesis Evaluation Questionnaires (PEQs) and focus groups have been used routinely in clinic [1, 2] to score amputees' prostheses as a stand-alone measure of satisfaction. In the UK, NHS funding has been made available for trans-femoral amputees to benefit from advanced technology, to aid and improve mobility. There is a lack of patient reported satisfaction with respect to quantifying efficacy of basic task completion with such components.

#### AIM

The aims were to:

- Establish how K2 and K3 trans-femoral amputees perceived the ease and importance of common everyday movement tasks and activities
- Compare the results within and between each mobility group.

### **METHOD**

Ten unilateral K2 and ten unilateral K3 trans-femoral amputees completed a Prosthesis Evaluation Questionnaire (PEQ). Select PEQ questions about the difficulty and importance of tasks were asked, using one ambulation scale, one function scale and a mixture of transfer, importance and pain questions. For tasks where an importance question was not in the original PEQ, this was added using the same style as the other PEQ importance questions. Scores were coded using a visual analogue scale of 0–100, with 0 and 100 indicating negative and positive responses respectively. Statistical analysis was run comparing within and between groups and was divided into ease of task and importance.

# **RESULTS**

K2 amputees rated standing and moving tasks to be more difficult compared to K3 amputees, however rated the tasks to be as important. Participants using a microprocessor knee reported a statistically significant reduction in difficulty in the ambulation scale than those without, when considering both groups, and it was suggestive that the use of a hydraulic ankle improved the ambulation and transfer question responses.

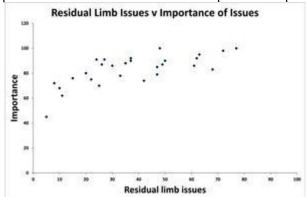


Figure 1. Graph to show residual health scale responses for K2 amputees.

# **DISCUSSION AND CONCLUSION**

It was thought that K2 amputees would find the mobility tasks to be more challenging when compared to K3 amputees, likely due to having reduced balance. This was shown to be the case with significant results comparing slope ascent and descent, carrying objects and performing household chores. The within group task differences could have been due to differences in prosthetic componentry, indicating that the funding available from NHS England is important for improving amputee mobility.

# **REFERENCES**

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[2] Fogelberg et al, Prosthet Orthot Int 2016.



# Basic IC Prosthetics: Upper Limb

# 2.1.5

# **Adaptive Silicone Technology in Developing Countries**

Akouetevi Aduayom-Ahego

Waseda University, Tokorozawa, Japan. Ahelite Brace, Accra, Ghana

#### **Abstract**

The World Health Organization has predicted that the number of people needing assistive devices globally is beyond two billion by 2050 and only one in 10 people in need has access to assistive products. In sub Saharan African, population living with disability represents approximately 78 million. Limited access to rehabilitative services have been observed. Amputations leave subjects to several forms of disability. Distal amputations are commonly due to work related accidents, traffic road accident, and other sort of trauma or diseases. This leaves a lot of stigmatization associated with psychological aspect of the patient. In addition, the appearance and the aesthetic aspect of finger prosthesis play significant role in patient life. However, the rehabilitation of person with finger amputation in developing countries remains very challenging for technicians due to training facilities and lack of appropriate materials. Moreover, the silicone technology has not been introduced in many undergraduate program in the Prosthetics and Orthotics schools in the low resource countries. It is estimated that only 5–15% of people with disabilities can get access to assistive products in the low-resource countries. Previous studies stated that only 5% of the population of people with disabilities could get access to rehabilitation services in Ghana. Recently a study in West Africa reported that graduates wished to introduce silicone technology in their programme. This instructional course will describe in details the rehabilitation of patients in need of silicone prosthesis in sub-Sahara African country Ghana.

# Statement of the objective / learning objectives

Participants, both in rehabilitation and general field will be aware of key challenges and possible sustainable development of silicone technology in developing countries.



# Symposium Education

# 2.1.6

# Growing the Evidence Base in P&O: A Dialogue with the Prosthetics and Orthotics International Editorial Team

Stefania Fatone<sup>1</sup>, Nerrolyn Ramstrand<sup>2</sup>, Michael Dillon<sup>3</sup>, Brian Hafner<sup>4</sup>

Northwestern University, Chicago, USA. <sup>2</sup>Jonkoping University, Jonkoping, Sweden. <sup>3</sup>La Trobe University, Bundoora, Australia. <sup>4</sup>University of Washington, Seattle, USA

#### **Abstract**

The ability to develop a body of knowledge is one of the most important traits of any profession. The evidence contained in the body of knowledge serves as the basis for our clinical, educational, and scientific practices. Our evidence base also helps us to define what is known, what is believed, and what is still yet to be determined.

Peer-reviewed journals, like Prosthetics and Orthotics International (POI), therefore play an important role in the profession by serving as a vehicle for evidence dissemination and a repository of knowledge related to prosthetic and orthotic clinical practice, interventions, and outcomes.

In this symposium we will:

- share our vision for a journal that draws from the collective knowledge, experience, and expertise of our community to create a robust and reliable body of knowledge;
- illuminate some of the challenge we face in achieving this vision, such as ensuring the relevance, accuracy and quality of the information we publish;
- discuss the types of manuscripts we are aiming to attract to POI and present new requirements for manuscript submission;
- engage in a dialogue with those in attendance to contribute their ideas to further developing POI.

The insights gained from this dialogue with clinicians, researchers and educators will help inform the future direction of POI, ensuring that it meets the needs of the profession its serves.

# Statement of the objective / learning objectives

The aim of this symposium is to engage in a dialogue with clinicians, researchers and educators to help POI develop our body of knowledge and create a strong foundation of evident for our field.



# Free Paper Session Education

# 2.1.7.a

# Risk and Hazard Identification of an Out-Patient Prosthetic and Orthotic Clinic and Workshop in Metro Manila

Julio Esteban Tiu, Jannica Nadine Anchores, <u>Edgar Emmanuelle Comandao</u>, Jhonalie Paches, Chas Louis Salvador, Nikolai Santos

University of the East Ramon Magsaysay Memorial Medical Center Inc., Quezon City, Philippines

#### **BACKGROUND**

A hazard is a condition in a workplace that when left uncontrolled, may result to an injury.[1] Hazard identification and assessment is part of the Safety and Health Management Guidelines created by the Occupational Safety and Health Administration (OSHA).[2] Thus, OSHA promotes early detection & prevention of hazards as part of its guidelines.<sup>2</sup> Several studies suggest that hazards exist in Prosthetics and Orthotics (P&O).[3] However, information regarding the hazards in the field of P&O is limited.[3,4]

#### ΔIM

The study aimed to identify the health and safety hazards in the University of the East Ramon Magsaysay

Memorial Medical Center, Inc. – Philippine School of Prosthetics and Orthotics (UERMMMCI – PSPO) Clinic and Workshop areas for P&O practitioners.

# **METHOD**

The study utilized a sequential explanatory method using a walkthrough survey facilitated by a safety professional (SP) and a focus group discussion (FGD) facilitated by an independent moderator. These were analyzed using a descriptive and holistic analysis, respectively. Subjects include all P&O practitioners in the facility excluding foreign clinicians, administration & utility staff, and researchers.

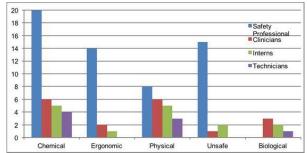


Figure 1. Comparison of hazards identified by the Safety Professional and P&O Practitioners

#### **RESULTS**

Hazards are present in all stages of the P&O work process and were addressed by varying degrees of controls. Finding peaked during the manufacturing stages of the P&O work process starting from rectification until the post-draping stage. Personal protective equipment (PPE) was the most common type of control used. Administrative controls were present in all stages, while engineering controls were mostly used from the rectification to post-draping stages. A synthesis of the FGD and walkthrough shows that the P&O practitioners closely match the hazards identified by the SP. Clinicians were more aware of the hazards found in the workplace, followed by interns. The technicians showed the least knowledge regarding the hazards in the workplace.

### **DISCUSSION AND CONCLUSION**

Hazards are present in the P&O clinic and workshop areas with chemical and ergonomic hazards being the most abundant. Controls of the hazards exist but can still be improved to fully protect the worker from the hazards identified. Hazards and controls perceived by the P&O practitioners closely approximate the assessment of the SP. It is recommended to utilize the results to quantify the risks through a work environment measurement of a workplace.

# **REFERENCES**

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#### **ACKNOWLEDGEMENTS**

University of the East Ramon Magsaysay - Research Institute for Health Sciences.



# 2.1.7.b

# **Embracing Minimal Standard of Educational Strategies for PO Educators-Reflection of Regional Educators**

#### Sisary Kheng

Department of Prosthetics and Orthotics (formerly known as the Cambodian School of Prosthetics and Orthotics), Phnom Penh, Cambodia

#### **BACKGROUND**

Most of PO educators got on job training for teaching training. Some PO training programmes have some sort of teacher training programme for their educators. Exceed Worldwide in Cambodia has a responsibility to coordinate and outsource PO educators to regional projects. Some of regional educators have more experience than others and some had formal education to be qualified educators and some had on job training experience only.

#### AIM

This free paper aims to reflect on the current experience of Cambodian prosthetic and orthotic educators who have been working with schools of Exceed projects in Cambodia, Sri Lanka, Indonesia, Philippines and Myanmar.

# **METHOD**

A 15 questions survey was sent to all educators, both Cambodian Professional and Associate Prosthetists and Orthotists who have been teaching at Exceed's school in the region. The survey was returned either on soft copy or hard copy and it was analysed through excel programme. 25 responses were collected out of 28.

#### **RESULTS**

The PO teaching experience of respondents ranges from one year (their first teaching assignment) to 18 years. Their positive experience in teaching was the starting as an assistant lecturer prior to teaching full teaching responsibilities. All had some sorts of education for being an educator but it was varied from short courses to comprehensive teaching programme. The refresher courses for educators and annual curriculum revision and educators in-house training course were considered of benefit to update skills and opportunities for improvement for them. All faced challenges teaching PO research courses as they have not got a lot of experience in involvement of clinical researches. Though, all expressed the satisfaction over the management support for the capacity development in teaching. The revised Standard of Education for PO Occupations has been said at significant benefits in Outcome Based Education delivery and assessment.

# **DISCUSSION AND CONCLUSION**

There has not been any standard set for PO educators as a minimum training to be qualified PO educators. This would be an initial case for the reflection and refocus exercise for all training programme to design or develop a consensus for minimum standard of teaching training for PO educators, this will ensure that PO programme helps to enable their educators to best deliver the content, knowledge and skills tailored by the programme.



# 2.1.7.c

# Improving the Efficiency of Clinical Management Through Development of Technical Expertise: Prosthetic and Orthotic Technicians Training in Cambodia

#### Sisary Kheng

Department of Prosthetics and Orthotics (formerly known as the Cambodian School of Prosthetics and Orthotics), Phnom Penh, Cambodia

#### **BACKGROUND**

There is an increasing demands of rehabilitation intervention and care provided by associate Prosthetists and orthotists or Professional prosthetists and orthotists as the world population with disabilities is increasing. However, many programmes have been promoted to match other allied health professional enhancement of educational qualifications. However, most of the training programme become more focused on academic skills. New ISPO Education Standards for Prosthetics/Orthotics Occupations, a newly clearly defined guideline on core competencies of Prosthetic and Orthotic Technicians are made.

# **AIM**

This free paper aims to share lesson learned and potential impacts on the training of Prosthetic and Orthotic Technicians in improving the efficiency of clinical management by higher level of professionals

#### **METHOD**

Focus Group discussion with current students on the technicians programme and survey made with previous graduates who completed training programme at Department of Prosthetics and Orthotics (formerly known as the Cambodian School of Prosthetics and Orthotics). The graduates and students had to answer 15 questions related to their experience prior to training, in training and as professional experience after their training for graduates. For the current trainees, the paper based questions were given and they had to return their response anonymously. Then the results were analysed by the use of excel programme.

#### **RESULTS**

Graduates and students expressed their overall satisfaction on the course delivery and core competencies per programme outlines. The supervision and rolling out of academic and technical classes were satisfactory. However, students requested for more exposure on high tech projects where graduates expressed their neutral opinions on this as most of them are practicing polypropylene technologies more than others. The students who had no previous technical experiences stated that they face more challenges to catch up with both theories and hand on activities than those who were technicians prior to their enrolment. Most of the students and graduates expressed the importance of the use of group discussion and peer project as an important learning exercise for them. The case and project presentations were said to be crucial for self-critique and clinical reasoning skills as well as peer learning.

# **DISCUSSION AND CONCLUSION**

This category of profession has potentials to support associate and professional prosthetists/orthotists to serve people requiring prosthetic and orthotic devices well. Their roles in the workshop and manufacturing process are crucial to provide comfortable and functional devices to people with disabilities with an improvement of time allowance for higher level professionals for direct clinical intervention. Though, this professional occupation has not been aware publicly and there is still a minimal interest for enrolment.

# **REFERENCES**

[1] ISPO Education Standars for PO Occupations. ISPO, 2018.



### 2.1.7.d

# Developing National Curriculum Guidelines: An Appropriateness-Based Approach

Sophie Hill<sup>1</sup>, David Rusaw<sup>2</sup>, Tobias Goihl<sup>3,4</sup>, Anne Katrine Hjerman<sup>5</sup>, Linn Reed Schwannborg<sup>1,6</sup>, Krister Bauger<sup>1</sup> Oslo Metropolitan University, Oslo, Norway. <sup>2</sup>Jönköping University, Jönköping, Sweden. <sup>3</sup>Helse Midt-Norge, Trondheim, Norway. <sup>4</sup>Trøndelag Ortopediske Verksted, Trondheim, Norway. <sup>5</sup>Drammen Ortopediskse Institutt, Drammen, Norway. <sup>6</sup>Sophies Minde, Oslo, Norway

#### **BACKGROUND**

In 2017, the Norwegian Ministry of Education and Research began work on a project to develop national curriculum guidelines for all health and social care education programmes at Bachelor level and above. The guidelines will consist of a statement of purpose, learning outcomes and guidance on the structure of the programme. Whilst curriculum guidance exists for many professions and disciplines, there is little written about its development.

#### AIM

To develop national guidelines for prosthetics and orthotics education using an appropriateness-based approach.

#### **METHOD**

A modified RAND/UCLA method was used to gather information and rank appropriateness of developed learning outcomes. Collaboration with stakeholders was important and information was gathered from various professional and user organisations. Programme outlines (if available in English) from ISPO category 1 accredited programmes, together with those from northern European countries were also gathered.

#### **RESULTS**

A total of 23 programmes were invited to provide their programme documents or were accessible online. 11 programme documents were obtained and - without programme level outcomes - were excluded (n=4). Information was obtained via email, online discussion and focus groups from various organisations. The data were collated and organised into different competency areas. From this data 126 learning outcomes were developed and organised into an online questionnaire. All participants who had attended the focus groups and development group members rated the appropriateness of the learning outcome and its competence area. A further focus group and development meeting was held where results were discussed, and the learning outcomes reduced to 51. After drafting of the remaining sections, the document was sent out for consultation. Feedback from the consultation was collated and the guidelines adjusted as necessary.

# **DISCUSSION AND CONCLUSION**

In comparison to existing programme learning outcomes from the documents obtained, there is a considerable difference in the number of learning outcomes. There are country specific differences that need to be accounted for when developing national guidelines. However, the development of national curriculum guidelines using an appropriateness-based approach ensured both a national and international focus.



# 2.1.7.e

# More than Fabrication: Embedding Digital Technologies to Improve Clinical Decision Making and Outcome Reporting in Prosthetic and Orthotic Education

Nathan Collins, Anthony Francis La Trobe University, Melbourne, Australia

#### **BACKGROUND**

In a profession where technology is rapidly changing the way clinicians' practice, educators are faced with the challenge of meeting current clinical expectations whilst simultaneously preparing students to integrate new technologies. Most discussion around technology focuses on improved fabrication techniques, however, we argue the importance of teaching and applying digital technologies to improve the accuracy of assessment, clinical decision making and evaluation of interventions to assist graduates achieve the best client outcome.

#### AIM

This presentation aims to share our experience with curriculum development that embeds and scaffolds clinical technologies across our program with a focus on quantifying and reporting clinical outcomes to inform clinical decision making and improve client outcomes.

#### **METHOD**

The role of Prosthetists and Orthotists in Australia has evolved to extend beyond device provision to that of informed and justifiable clinical decision making, Consequently, our curriculum has developed to address how technology informs our graduates ability to achieve best practice and client outcomes. Iterative development informed by discussions with stakeholders within the clinical, technical, and new technologies areas of Prosthetics and Orthotics have influenced the embedding of digital technologies through all levels of the program curriculum.

#### **RESULTS**

A framework of relating curriculum to clinical context will be addressed including examples such as AFO alignment optimization reporting and pressure distribution management for lower limb Prosthetic and Orthotic clients. Digital and traditional approaches to clinical skills, such as foot casting techniques are completed in parallel to provide students the opportunity to critique and compare approaches.

# **DISCUSSION AND CONCLUSION**

The professional scope of practice and graduate competency standards of the Australian Orthotic and Prosthetic Association (AOPA) provides a foundational framework for curriculum development to meet the needs of both clients and the profession. Consequently, the implementation of technology needs to extend beyond fabrication driven solutions to digital tools which also support and enhance high level clinical decision making and outcome reporting. Further collaboration and dissemination of approaches to support the development of P&O training is recommended.

### **REFERENCES**

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### 2.1.7.f

# Improving the Reliability of Professional Competency Assessment for Orthotist/Prosthetists in Australia

Louise Puli<sup>1</sup>, Emily Ridgewell<sup>1</sup>, Michael Dillon<sup>2</sup>

<sup>1</sup>Australian Orthotic Prosthetic Association, Melbourne, Australia. <sup>2</sup>2 Discipline of Prosthetics and Orthotics, Department of Physiotherapy, Podiatry, Prosthetics and Orthotics, School of Allied Health, La Trobe University, Melbourne, Australia

#### **BACKGROUND**

The Australian Orthotic Prosthetic Association (AOPA) regulates the profession of orthotist/prosthetists in Australia through the establishment, maintenance and application of professional standards, such as competency standards. While portfolios are commonly used to assess professional competency, little research has investigated how reliable these assessments are, or how reliability can be improved.

#### **AIM**

To evaluate how reliable AOPA's competency portfolio assessment is and examine causes of variation to improve reliability.

# **METHOD**

Overseas trained practitioners wishing to have their qualifications and experience recognised by AOPA submitted a portfolio for assessment. Portfolios were randomly assigned to two independent assessors who determined whether the applicant's portfolio demonstrates competency against each of the 68 AOPA Competency Standards (2014) and recorded their determination as "satisfied" or "not satisfied". An administrator collated the independent evaluations and identified any points of disagreement for discussion at a consensus meeting. To quantify interassessor reliability, the Kappa statistic was used for each of the 68 competency standards. To better understand the reasons for disagreement, semi-structured interviews were conducted with each assessor.

#### **RESULTS**

Results from this study show high rates of agreement between assessors upon independent assessment. Points of disagreement were commonly resolved during the consensus meeting between assessors, disagreement was rare. The standards which experienced the highest rates of disagreement were identified.

### **DISCUSSION AND CONCLUSION**

Evidence based standards should be supported by evidence-based processes. Competency assessment via a portfolio of evidence can be conducted and assessed by two assessors with high levels of agreement. Factors that may increase the reliability of the assessment include; appropriate assessor training, the presence of a consensus meeting and clear standards. There are opportunities to further improve the clarity of standards identified as having the lowest level of agreement.

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# Free Paper Session Seating & Wheelchair

# 2.1.8.a

# Using Global Resources to Enhance Wheelchair Education in Prosthetics & Orthotics Curricula

Mary Goldberg<sup>1</sup>, Paula Rushton<sup>2</sup>, Jon Pearlman<sup>1</sup>
<sup>1</sup>University of Pittsburgh, Pittsburgh, USA. <sup>2</sup>University of Montreal, Montreal, Canada

#### **BACKGROUND**

Evidence highlights that a major factor associated with inappropriate wheelchair distribution is the global shortage of wheelchair service provision education and training.[1-4] The World Health Organization Guidelines on the provision of manual wheelchairs in less-resourced settingsrecommend integrating wheelchair service provision content into existing academic rehabilitation programs.[1] However, a 2017 study reported limited training time allocated to wheelchair service provision in some professional rehabilitation programs in low-, middle- and high-income countries.[4]

#### AIM

To develop an evidence-based online Seating and Mobility Academic Resource Toolkit (SMART) through a mixed-methods approach to identify necessary components and investigate preliminary impact.

#### **METHOD**

Data was collected from 3 primary data sources, including an international wheelchair education survey, qualitative interview transcripts with representatives from health care professional university programs and wheelchair education integration 'pilot sites'. Data sources were analyzed using a deductive content analysis approach to produce the Seating and Mobility Academic Resource Toolkit (SMART). Subsequent analyses of SMART analytics and purposive interviews were performed to identify how the toolkit was used in a variety of settings across different types of academic rehabilitation programs and contexts.

#### **RESULTS**

We received 72 responses on our international wheelchair education survey, conducted 14 qualitative interviews with health care professional university program representatives, and hosted 16 presentations from wheelchair education integration 'pilot sites' to identify integration challenges. Themes emerged related to having minimal resources (human, financial, clinical, equipment), unawareness of open-source educational materials, and lack of trained personnel to name a few. Therefore, SMART was developed and includes educational resources (e.g., syllabi, presentations, online modules, evidence-based training packages, labs, evaluations) and strategies to overcome barriers to integrating wheelchair content into curricula. Analytics reveal SMART pages have been accessed 11,703 times globally, and since its launch in April 2018, the average number of pages viewed per session have increased by 7.4%. The interview findings suggest SMART has potential to improve the wheelchair education provided in terms of pedagogic approach, content and resources used.

# **DISCUSSION AND CONCLUSION**

SMART may facilitate the integration of wheelchair content into health care professional university curricula. Ultimately, improved education in this important area of practice may enhance the participation and quality of life of those individuals who use a wheelchair for mobility. Prosthetics and orthotics training programs may consider using globally available resources, such as SMART, to identify strategies to improve wheelchair education and to advocate for their implementation.

# **REFERENCES**

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# **ACKNOWLEDGEMENTS**

This work was supported by the International Society of Wheelchair Professionals.



# 2.1.8.b

# Effect of Active Cast on Residual Muscle during Wheelchair Operation of Cervical Cord Injury Patients

<u>Taku Itami</u><sup>1</sup>, Sakura Ogawa<sup>1</sup>, Ken'ichi Yano<sup>1</sup>, Yasuyuki Kobayashi<sup>2</sup>, Ryo Yamamoto<sup>2</sup>, Takaaki Aoki<sup>3</sup>, Yutaka Nishimoto<sup>3</sup>, Norio Hayashi<sup>4</sup>

<sup>1</sup>Mie University, Tsu, Japan. <sup>2</sup>Luminous Japan Co., Ltd, Murakami, Japan. <sup>3</sup>Gifu University Hospital, Gifu, Japan.

<sup>4</sup>Musculoskeletal Functional Anatomy Research Institute, Gifu, Japan

#### **BACKGROUND**

Most cervical cord injury (CCI) people need to use a wheelchair in daily life.[1] Especially, C5-C6 level of CCI patients can't usually perform the extension movement of elbow joint so that they can't operate the wheelchair strongly. Previously, we have developed the motion assist robot, which is named Active Cast (AC) for the upper limbs to transmit their residual function around shoulder to hand operations.[2]

#### ΔIM

The purpose of this study is to clarify the influence of wearing AC on the musculoskeletal of their residual function during wheelchair operation by people with different symptoms of CCI.

#### METHOD

Two subjects with C6B1(right), C5B(left) and C6B2(both) of the Zancolli classification were participated in this evaluation experiment. The treadmill was set to reproduce the running on a slope. The inclination was set to 3% for the C5 level CCI subject, and 4% for the C6 level CCI subject in order to confirm that the musculoskeletal of their residual functions better. We used the 3D motion analysis system and a myoelectric potentiometer for the analysis during 20 [s] wheelchair operation. From the above, the effect of AC on residual muscles of CCI subjects with different symptoms was analyzed.

#### **RESULTS**

Based on the experimental results without AC, we confirmed that the C5 level subject operated the wheelchair using the elbow flexion force, and the C6 level subject used the force of the pronation of forearm. On the other hand, from the results with AC, in the case of C5 level subject, the scapula elevated greatly due to locking the elbow joint, and the amount of activity of the upper trapezius muscle also increased comparing with the case without AC. In the case of C6 level subject, we confirmed that the amount of scapula abduction increased, and the serratus anterior muscle was also exerted.

# **DISCUSSION AND CONCLUSION**

It was revealed that wearing AC induced motions and residual muscles around the shoulder of CCI subjects with different symptoms. In C5 level CCI, it was confirmed that the elevation movement of the scapula was induced, and in the C6 level CCI, the abduction motion of the scapula was induced. It was confirmed that the effect of AC differs by symptoms with the pronation of forearm.

### **REFERENCES**

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# 2.1.8.c

# Wheelchair Mobility with Commands from Eye Blinking and IoT Capabilities

<u>Carla Gómez-Carrasquilla</u><sup>1</sup>, David Gómez-Carrasquilla<sup>1</sup>, <u>Arys Carrasquilla-Batista</u><sup>1</sup>, Josué Gómez-Pereira<sup>2</sup>, Karol Quirós-Espinoza<sup>2</sup>

<sup>1</sup>Instituto Tecnológico de Costa Rica, Cartago, Costa Rica. <sup>2</sup>ACB Mecatrónica, Cartago, Costa Rica

#### **BACKGROUND**

Nowadays it is well known that voice-activated wheelchairs help the quadriplegic get around, and houses can be equipped with similar systems to operate lights and appliances; but which are the options when besides quadriplegic there is no way to give voice commands to the wheelchair or to communicate our desires to other people. The first approach of this project was presented in the International Workshop on **We**arable **Rob**otics (WeRob 2014) [1] and a new version in WeRob 2017.[2]

#### **AIM**

Provide an alternative to quadriplegic persons in order to give commands from eye blinking and communicate with outside world through Internet of Things (IoT) capabilities incorporated in a wheelchair.

# **METHOD**

To fulfill the aim of the project, the engineering design method was followed which as first step includes the definition of a clear problem statement, then pertinent information was gathered in order to generate multiple solutions. Afterwards, the information was analyzed, a solution was selected, tested and implemented. Two approaches have been generated previously,[1, 2] the first one was developed with a neural signal reading device and a Bluetooth communication board; afterwards a new alternative was evaluated including eye blinking commands. Now, a faster microcontroller with IoT capabilities has been incorporated in the design process to include IoT capabilities.

#### **RESULTS**

Taking a decision considering commands coming from eye blinking, to give mobility to a wheelchair, is not a simple task, bad decisions can end up in moving a person in a wrong direction which will give more difficulties instead of solutions. In the actual study a faster microcontroller with embedded software and hardware for IoT is used, this device can manage multiple sensors as inputs and multiple actuators as outputs. The raspberry Pi 3 was selected because it is single-board computer with wireless LAN and Bluetooth Low Energy (BLE) on board. The developed system discriminates an involuntary blinking from a low motion voluntary blinking and take a decision to move forward a model wheelchair. The position and given commands are sent to an IoT platform to save the wheelchair movement data.

# **DISCUSSION AND CONCLUSION**

A single board computer with on board wireless LAN and Bluetooth gives more possibilities to incorporate IoT capabilities for decision-making about wheelchair movement, and besides that voluntary blinking recognition is detected with precision and faster. The developed system fulfils the aim to provide an alternative to quadriplegic persons in order to give commands from eye blinking and communicate with outside world through IoT capabilities incorporated in a wheelchair.

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# **ACKNOWLEDGEMENTS**

Research and Extension, Student Affairs and Academic Services from ITCR. ACB Mecatronics project engineering department.



# 2.1.8.d

# Pressure Distribution Characteristics Against Human Body and Human Body Model Seated on Various Seat Cushions

#### Hiroki Ishihama

Eisei Hospital Rehabilitation Research and Development Center, Tokyo, Japan

#### **BACKGROUND**

Using a seat cushion, we feel the situation where the protrusion of the ischium hits the bottom of the cushion. At the pressure measuring time, the phenomenon that the peak pressure value gradually increases is observed. In prevention of pressure sores, it is important to elucidate the mechanism of bottoming phenomenon. The pressure distribution response characteristics when continuously using various seat cushions were studied in the human body and human body model.

# AIM

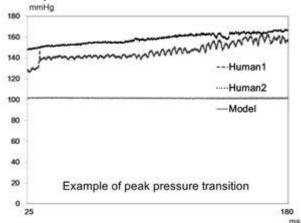
It was aimed to investigate whether the bottom was due to a change in the condition in the seat cushion or a change in the internal pressure in the human body.

# **METHOD**

Seven seat cushions were prepared on the wheelchair. Subjects were two healthy adult male and a biological model. The biological model was made from plastic bone specimens and silicone materials (170 cm, 32 kg). Each cushion was placed on the plate seating surface of a wheelchair (Netti em, Alu Rehab AS) set at a tilt angle of 0° and a reclining angle of 95°, and a pressure distribution measuring device was laid on top(Xsensor X 3 Pro, Xsensor Technology Corp.). Measurements were carried out, with the human body and human body model sitting still at the pelvis intermediate position, randomly on each seat cushion (3 minutes / 4861 frames).

#### **RESULTS**

In each seat cushion, there was a gradual trend of peak pressure after sitting of the human body. On the other hand, this tendency was not observed in the human body model. The difference between the maximum and the minimum value of the peak pressure was significantly higher for each human body than for the human body model. There was no significant difference between the maximum and minimum values of the contact area between human body and human body model.



# **DISCUSSION AND CONCLUSION**

Local concentration of pressure can not be said to be caused by sinking of humans in the seat cushion or compression of the material. Rather, it is presumed that biological changes occur over time.

If compressive stress affects blood flow, in order to distribute body pressure, wheelchair users are required to improve the movement such as push-up and use the wheelchair posture conversion function.

#### **REFERENCES**

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#### 2.1.8.e

# Clinical Assessment of Personal Standing Mobility Qolo for Voluntary Sit-to-Stand Posture Transition of People with Thoracic Level Spinal Cord Injury

<u>Hideki Kadone</u>, Yukiyo Shimizu, Shigeki Kubota, Yosuke Eguchi, Diego Paez, Tomoyuki Ueno, Yasushi Hada, Kenji Suzuki, Masashi Yamazaki University of Tsukuba, Tsukuba, Japan

#### **BACKGROUND**

We are developing Qolo, a new personal mobility device for those with motor disability in their lower limbs. It assists sit-to-stand and stand-to-sit postural transitions as well as navigation in standing posture with hands-free operation. Its mechanism to assist the postural transition is implemented with passive gas springs without using electric actuators, making it compact, light-weight and low cost.

#### AIM

The purpose of this study is to report clinical assessment of the device after modification of its design to realize voluntary sit-to-stand posture transition of people with thoracic level spinal cord injury (SCI).

#### **METHOD**

In the improved design of the device, reviewing our preceding clinical experiments, the assistive force of the knee springs was doubled and lumbar assist was added. Six participants with SCI (age: 30-52y, 4 males and 3 females, neurological level: T4-L3, AIS: A-C, MMT Hip Ext.: 0-1, Knee Ext.: 0-3) were asked to conduct stand-up and sit-down postural transitions using the improved version of the device. Feasibility of the assisted motions were evaluated.

#### **RESULTS**

Six out of the seven participants were able to smoothly conduct voluntary stand-up and sit-down motions using the device by themselves, without additional assistance. Two of the them (T10A, T6A, MMT Knee<=1) achieved voluntary stand-up motion only with the improved version of the device. One participant (T4A, MMT Knee=0) needed additional manual assistance to achieve voluntary stand-up motion using the device.

#### **DISCUSSION AND CONCLUSION**

The improvement of the device extended its capability to assist sit-to-stand and stand-to-sit posture transition of people with lumbar or thoracic level SCI. At the same time, necessity of stronger support for middle to upper thoracic level SCI was investigated. For the next step, we plan to introduce stronger assistive force, and improve of harnessing and attachment and detachment processes to facilitate its daily use.

#### **REFERENCES**

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# Symposium Other

#### 2.2.1

# Assistive Technologies against Ageing Society - WHO Symposium

<u>Chapal Khasnabis</u><sup>1</sup>, <u>Alarcos Cieza</u><sup>1</sup>, <u>Takaaki Chin</u><sup>2,3</sup>, <u>Takenobu Inoue</u><sup>4</sup>, <u>Yutaka Takamine</u><sup>5</sup>

<sup>1</sup>World Health Organization, Geneva, Switzerland. <sup>2</sup>The Hyogo Institute of Assistive Technology, Kobe, Japan. <sup>3</sup>The Hyogo Rehabilitation Centre, Kobe, Japan. <sup>4</sup>Research Institute of National Rehabilitation Center for Persons with Disabilities(NRCPD), Tokorozawa, Japan. <sup>5</sup>Empowerment Okinawa, Okinawa, Japan.

#### **Abstract**

It is very important that people who are in need of assistive products utilise those products in their daily life. In the first part of this symposium a keynote lecture will be made by a Japanese opinion leader who is an AT development director of a national institute, and is recommended by The Rehabilitation Engineering Society of Japan (RESJA). He will talk about the current situation of assistive products development and use in Japan which is the most aged society in the world. In his speech a research project is introduced which focuses relationship of assistive products use and daily activities of older people including nonagenarians and centenarians.

A panel discussion will be held in the second part of the symposium. Remarkable panelists from WHO and Japan make short presentations about the circumstances of people with disabilities or the elders and usage status of assistive products in Southeast Asian and other countries. After the short reports, the organisers from WHO and NRCPD develop discussions with the panelists about better practice of AT use or methods to improve access to high-quality affordable AT.

# Statement of the objective / learning objectives

The aim is to bring deeper understanding among opinion leaders in P&O / Assistive Technology fields. The audience can learn the current situations of AT and be inspired to support AT development and dissemination.

The Symposium 'Assistive Technologies against Ageing Society' on Sunday, 6 October 2019, consists of two sessions with the first one taking place from 13:00 - 14:15 and the second one continuing from 14:30 - 15:45.



# Free Paper Session Orthotics: Lower Limb - Robotics

#### 2.2.2.a

# Effectiveness of Rehabilitation Training with Hybrid Assitive Limb on Walking Ability and Balance in Individuals with Chronic Spinal Cord Injury

Mitsunori Toda<sup>1</sup>, Ikuya Okano<sup>1</sup>, Naoki Yamamoto<sup>2</sup>, Takashi Yasuda<sup>1</sup>, Yoko Fukatsu<sup>1</sup>, Naoya Nobumoto<sup>1</sup>, Nami Hashimoto<sup>1</sup>, Koji Tamura<sup>1</sup>, Yuki Maeno<sup>1</sup>, Masafumi Segawa<sup>1</sup>, Akemi Nishimura<sup>1</sup>, Miki Ohgushi<sup>2</sup>, Takaaki Chin<sup>1</sup> Hyogo Rehabilitation Center, Kobe, Japan

#### **BACKGROUND**

Spinal cord injury (SCI) is an inherently serious condition that have a profound physical, psychological, and socioeconomic impact on affected individuals. Recently, the incidence of incomplete SCIs are increasing, and the central nervous system of incomplete injury has the potential of plastic change. Hybrid assistive limb (HAL) is an exoskeleton robot suit that supports walking of persons with motor dysfunction. The effectiveness of HAL training on walking ability and balance in individuals with chronic SCI is still unlear.

#### **AIM**

To investigate the effctiveness of walking tarining with robot suit HAL for walking ability and balance in individuals with chronic spinal cord injury.

#### **METHOD**

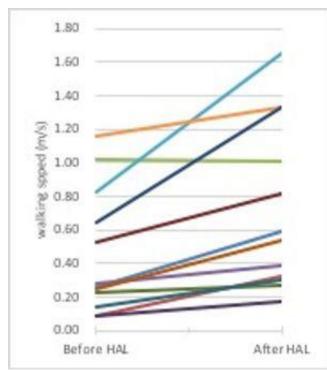
Fifteen patients with chronic SCI (11 men, 4 women) classified by the American Spinal Cord Injury Association (ASIA) D (zone of partial preservation C4-L3), who received full rehabilitation in the acute and subacute phase of SCI were enrolled. A single case experimental A-B(pre-post) design study by repeated assessments of the same patients. The subjects performed 3 to 6 months (30 minutes per session, 2 times per week) HAL training with walker and supported by physical therapists. Functional outcome measures included 10-m walk test(10MWT), 6-minute walk test(6MWT), Berg balance scale(BBS), and the walking index for SCI II (WISCI II), which were evaluated without HAL.

#### **RESULTS**

Twelve patients completed 3 to 6 months HAL training (3 patients dropped out after 6 or 8 sessions). Functional outcome measures were analyzed in those who completed HAL training. The mean walking speed in 10MWT increased from 0.46±0.37 m/s to 0.73±0.50 m/s (p<0.01). The improvement corresponded to a 59% faster walking than in initial evaluation. Walking distance in 6MWT increased from 127.8±112.7m to 217.5±159.1m (p<0.05). Balance evaluated by BBS also improved from 28.1±13.4 to 39.8±11.8 (p<0.01), and WISCI II from 13.8±5.1 to 17.0±2.6 (p<0.05).

#### **DISCUSSION AND CONCLUSION**

Our results suggest that HAL training could improve walking ability and balance in individuals with chronic SCI. In the past, rehabilitation for SCI focused not on functional improvement, but on compensation for impairment. HAL would facilitate motor recovery and improve mobility in chronic SCI, and may play an important role in rehabilitation for SCI in future. Further controlled studies should be needed.





#### 2.2.2.b

# Heterotopic Triggered HAL: Novel Gait Training Methods for Patients with Complete Quadriplegia or Paraplegia due to Chronic Spinal Cord Injury

<u>Yukiyo Shimizu</u><sup>1</sup>, Hideki Kadone<sup>2</sup>, Shigeki Kubota<sup>3</sup>, Tetsuya Abe<sup>3</sup>, Tomoyuki Ueno<sup>1</sup>, Yasushi Hada<sup>1</sup>, Masashi Yamazaki<sup>3</sup>

<sup>1</sup>Department of Rehabilitation Medicine, University of Tsukuba Hospital, Tsukuba, Japan. <sup>2</sup>Center for Innovative Medicine and Engineering, University of Tsukuba Hospital, Tsukuba, Japan. <sup>3</sup>Department of Orthopaedic Surgery, Faculty of Medicine, University of Tsukuba, Tsukuba, Japan

#### **BACKGROUND**

Patients with complete paraplegia after spinal cord injury (SCI) are difficult to walk by themselves. Gait training with conventional orthoses for complete paraplegia requires excessive upper limb usage and is difficult to train knee extensor during ambulation. We developed a new method of HAL using remaining muscle activation as a trigger for paralyzed limb, and we called heterotopic HAL method (T-HAL).

#### **AIM**

This study aims to describe voluntary gait and voluntary knee extension using Heterotopic Triggered HAL method in patients with complete quadri/paraplegia after chronic SCI.

#### **METHOD**

Nine patients, 20-67 years old, C6-T11, AIS A-B, were enrolled in this study. HAL session consisted of two parts: the first session was voluntary ambulation using upper limb triggered HAL (UT-HAL method). In addition, for cases who could contract hip flexor, the second session was done for active knee extension using hip flexor activation. Surface electromyography (EMG) was used to evaluate muscle activity of hip flexor and quadriceps femoris (Quad) in synchronization with a Vicon motion capture system. The modified Ashworth scale (MAS) score was evaluated before and after each session.

#### **RESULTS**

There were not seen severe complications such as hypoautonomic hyperreflexia, or symptomatic venous vein thrombosis, etc. The only observed adverse event was redness caused by contact between the skin and harness in cases 1, 2, and 3 which was avoidable by using a cushion. In three cases, from C6 to T6, MAS score significantly decreased after each session. In all cases, EMG before the intervention showed no activation in either Quad. However, periodic activation of the lower limb muscles was seen during UT-HAL ambulation. In two cases, in T10-11, there was observed active contraction in both Quads and hip flexors after intervention.

#### **DISCUSSION AND CONCLUSION**

We focused on residual upper limb muscle activity and the coordination between the upper limbs and contralateral lower limbs in natural gait. We observed neurological positive changes in two cases after the intervention. Moreover, patients with cervical cord or upper thoracic cord injuries, who have difficulty performing conventional gait training with orthoses, may experience decreased spasticity and activation of paralyzed muscles. These findings suggest that T-HAL method is a feasible option for rehabilitation for complete quadri/paraplegia with chronic SCI.



#### 2.2.2.c

# Gait Rehabilitation using Lower Limbs Robot Assisted Training System on Patients with Burn: A Pilot Study

So Young Joo, Yoon Soo Cho, <u>Cheonghoon Seo</u> Hallym University, Seoul, Republic of Korea

#### **BACKGROUND**

Gait enables human beings to move forward, and most people consider gait to be natural skill. But gait disturbances are very prevalent to the patients with burn injury. A major cause of functional impairment including pain and joint contractures. Contractures at the lower extremities such as the hip, knee and ankle significantly limit gait. Recent attention of the application of artificial intelligence in rehabilitation, in particularly lower limbs robot assisted rehabilitation has become a hot issue of studies.

#### AIM

This study is purposed to find the efficacy and study the mechanism of motor recovery after robot assisted gait training on patients with lower extremity burn.

## **METHOD**

7 patients with lower extremity burn were included. All patients received 4 weeks robot assisted training. Functional scores of functional ambulation category (FAC) and 6-minute walking distances, and pain score of visual analog score (VAS) during robot assisted gait training were measured.

#### **RESULTS**

FAC and VAS scores after training were better than the scores before training. 6-min walking distance after training were significantly increased than the measure before training(p<0.05). Lower limbs robot assisted rehabilitation training improves patient's pain, and increases walking speed on patients with lower extremity burn.

#### **DISCUSSION AND CONCLUSION**

Lower limbs robot assisted rehabilitation improves the walking speed, and prolongs their walking distances. The use of robot assisted rehabilitation may facilitate early recovery from burn injury.



#### 2.2.2.d

# Efficiency of Use of Robotized Systems with Biological Feedback in Rehabilitation of Children with Infant Cerebral Palsy

Antonina Salieieva, Irina Chernysheva, Irina Vasilenko, Galina Logvin, <u>Olena Lutsenko</u> Ukrainian Research Institute for Prosthetics and Rehabilitation, Kharkiv, Ukraine

#### **BACKGROUND**

The infant cerebral palsy is one of the most wide-spread reasons of disability at child's age. The success of rehabilitation depends on intensity of kinesitherapy, quality of movements and motivation of the child that is ensured with modern robotized systems with biological feedback.

#### AIM

to estimate efficiency of use of robotized systems with biological feedback in rehabilitation of children with infant cerebral palsy.

#### **METHOD**

The basic and control groups of children (26 persons in each) with spastic paraparesis, flexion positioning of lower extremities, impairment of supportability and walking, matched in functions, age and gender were formed. The course of rehabilitation included: massage, apparatus physiotherapy, therapeutic exercises. The patients of the basic group additionally had mechanotherapy on a robotized system "Lokomat Pediatric" for training strength of muscle, for increasing of amount of movements in joints. The period of observation - 1 year (3 courses of treatment). Efficiency of the given treatment was evaluated with a method of functional testing (Ashworth, GMFCS, GMFM), program testing of a robotized system (L-FORCE, L-ROM) before and after the course of rehabilitation.

#### **RESULTS**

For the period of observation the spasticity of muscles (Ashworth) of lower extremities in patients of both groups reduced, on the average, for 1 point. The level of limitation of the gross motor functions (GMFCS) in both groups didn't change essentially. Motor possibilities (GMFM) of the patients of the basic group increased, on the average, on  $25 \pm 7$  %, of the control group - on  $12 \pm 7$  %. The isometric strength of muscles - flexors of a knee and a hip (L-FORCE) in the basic group increased, on the average, on 3 Nm, the strength of muscles-extensors of a knee and a hip - on 2 Nm, in the control group – didn't change. The amount of active movements in knee and hip joints (L-ROM) achieved physiological norm in the basic group and in 25 % of children of the control group.

# **DISCUSSION AND CONCLUSION**

The mechanotherapy on a robotized system with biological feedback "Lokomat Pediatric" in rehabilitation of children with infant cerebral palsy allows to increase the strength of muscles trained, amount of movements in joints, results in improvement of indexes of functional testing, to increase motivation of children for performing active exercises in game.

Motor rehabilitation of patients with infant cerebral palsy with the use of mechanotherapy on a robotized system "Lokomat Pediatric" has shown high efficiency in comparison with traditional methods.

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#### 2.2.2.e

# The Use of G-EO-System in the Rehabilitation of Persons with Consequences of Traumas of the Spine and the Spinal Cord

Antonina Salieieva, Irina Kabanenko, Natalie Zaderiy, Michail Zaitsev, <u>Olena Lutsenko</u> Ukrainian Research Institute for Prosthetics and Rehabilitation, Kharkiv, Ukraine

#### **BACKGROUND**

The problem of restoring of motor impairments which are caused by an injury of a spine and a spinal cord, is connected to the limited ability of nervous cells to regeneration, to complexity and duration of forming of compensation mechanisms.

#### AIM

Increasing of efficiency of rehabilitation of patients with consequences of injuries of a spine and a spinal cord by use of robotized systems

#### **METHOD**

G-EO-System is used in rehabilitation of persons with consequences of an injury of a spine and a spinal cord. The number of the patients from 2017 till 2019 consists of 325 persons, 258 patients (79,4 %) used G-EO-System in the program of physical rehabilitation. By results of the performed testing according to Valutazione Fuczionale Mielolesi (VFM) three groups of patients were chosen: a low level of functional abilities – a significant degree of disability (1,2 points); a middle level of functional abilities - a moderate degree of disability (3,4 points); a high level of functional abilities - a mild degree of disability (5 points).

#### **RESULTS**

For each group of patients, depending on the level of functional abilities, rehabilitation measures were performed, an individual program with the use of G-EO-System which includes periods of performing training, safe loads, complexity of performance and duration of each course was developed.

In the first group of patients, in the amount of 67 persons, a course of physical rehabilitation without the use of G-EO-System was carried out, in the second group (258 patients) G-EO-System has been included. For patients of both groups physical rehabilitation promoted increasing of tolerance to physical exercise and stabilization of hemodynamic indexes. However, for patients of the first group the period of adaptation to physical exercise without the use of G-EO-System proceeded longer and more difficult, that increased the time of staying in the clinic for these patients.

# **DISCUSSION AND CONCLUSION**

The experience of using G-EO-System in the set of rehabilitation measures for patients with consequences of an injury of a spine and a spinal cord for restoring motor responses allowed to come to a new level of rehabilitation. The application of the robotized G-EO-System accelerates the process of restoring and forming of standing and walking skills, generates a stereotype of walking, raises motivation to independent walking, reduces terms of rehabilitation.



# **Basic IC Education**

# 2.2.3 Collaboration Leads to ISPO Accreditation

Robin Seabrook<sup>1</sup>, Catherine Carter<sup>2</sup>
<sup>1</sup>NCOPE, Alexandria, USA. <sup>2</sup>ABC, Alexandria, USA

#### **Abstract**

Join the discussion on how an educational accreditor and a certification body have collaborated to achieve ISPO accreditation for their orthotist and prosthetist training program and benefit from the validation by a recognized external body. The goal of reaching accreditation by complying with ISPO Education Standards for Prosthetic/Orthotic Occupations can often be enhanced with two or more organizations working together as partners to identify assets, improve areas of weakness and provide the appropriate information, data and statements required as part of the application process. These two US-based organizations will discuss the opportunities recognized, successes and challenges faced while working toward ISPO accreditation and reaccreditation validating demonstrated compliance to internationally-accepted standards. The details of how this collaboration has been successful and how those details can be applied in other countries will be discussed.

# Statement of the objective / learning objectives

Attendees should expect to gain knowledge on process for pursuing accreditation/recognition by an external body and how collaboration can aid in achieving the goal of accreditation.



# Advanced IC Prosthetics: Lower Limb Transfemoral

# 2.2.4

# **Basics Of Advanced Socket Design In Transfemoral Prosthetics**

Michael Schaefer<sup>1</sup>, Marlo Ortiz<sup>2</sup>, Malte Bellmann<sup>3</sup>

POHLIG GmbH, Traunstein, Germany. <sup>2</sup>Ortiz Internacional, Guadalajara, Mexico. <sup>3</sup>Ottobock, Goettingen, Germany

#### Abstract

The prosthetic Sockettechnique after above knee amputation is currently experiencing many innovative care approaches around the world that raise questions and make even experienced providers think. What are minimum and adequate requirements for the different stump lengths, properties of muscles and tissues, imbedding techniques?

It is undisputed that the performance of the Amputees depends significantly on the design of the prosthetic socket. As the central link between man and technology, it has to fulfill biomechanical aspects as well as specific imbedding characteristics. Some of them can be discussed, others are almost irrefutable, since they are based on clearly comprehensible physical laws.

In addition to an introductory lecture on the biomechanical requirements for walking with above knee prostheses, the different design features of proven modern AK socket systems are considered and critically examined. Experts in this care area report on the latest approaches to high performance socket designs in transfemoral prosthetics. Different methods of shape detection from plaster cast to digital scan are considered as well as the critical debate on the design of the sheep entry level (Ischial containment, Ischio-Ramal containment, subischial technique).

The experienced suppliers also deal with specific imbedding features and technical features in the design of a modern AK-Sockets, which all have the best possible performance of the user's goal. At the same time, concrete approaches for the improvement of the sockets guidance behavior will be shown, as well as measures with influence on the reduction of stump - socket - pseudarthrosis and the painful stump.

# Statement of the objective / learning objectives

This advanced course is designed to teach successful approaches in the design of modern AK sockets, highlighting and commenting on critical content and demonstrating to listeners the path to successful performance in modern socket design.



# Free Paper Session Prosthetics: Upper Limb – 3D Printing

#### 2.2.5.a

# Increasing Access to Upper Limb Prosthetics in a Humanitarian Context by Implementing 3D Technologies

Safa Herfat<sup>1,2</sup>, Pierre Moreau<sup>1</sup>

<sup>1</sup>MSF Foundation / Doctors Without Borders, Paris, France. <sup>2</sup>University of California San Francisco (UCSF), San Francisco, USA

#### **BACKGROUND**

Over 15 years of conflict throughout the Middle East region has led to an increase of people living with disabilities, including upper limb deficiency. Unilateral upper limb deficiency patients commonly seek cosmetic prostheses to help deal with the social stigma and to provide a secondary support limb for bimanual tasks. The lack of prosthetic clinicians and prohibitive cost of prostheses (\$1000-\$3000) has led to patients having limited options. More cost-effective, durable solutions are needed to increase access to these patients.

#### AIM

Evaluate the feasibility of locally designing, manufacturing and fitting patient-specific, 3D printed below elbow prostheses, while also providing comprehensive clinical care, including P&O care and occupational therapy, in a humanitarian context.

#### **METHOD**

Each patient first underwent clinical assessments to identify their specific needs. 3D surface scans of the stump and contralateral limb were acquired and used to design each socket and prosthesis. Components were 3D printed at the Fab Lab (Irbid, Jordan) in various materials (rigid PLA, semi-flex co-polyester, flexible TPU). After

fitting, clinical assessments were performed at various time points to improve the designs and refine the processes. Nine questions from the Orthotic & Prosthetic User Survey (OPUS) were used to determine patient satisfaction. A multi-disciplinary team was involved including local staff and expats from several specialties including P&O, physiotherapy, occupational therapy and biomedical engineering.

### **RESULTS**

By February-2019, 21 patients received 3D passive prostheses (N=17 transradial, 29% female, 48% 3.8/4.0). Early challenges included long-term durability of components and paint coating. Patient availability for long term follow-up is another challenge commonly experienced in humanitarian contexts. The cost of raw materials needed to manufacture the 3D printed prostheses ranged from \$20 to \$50.



Final Fitting of a Fully 3D Printed Patient-Specific Prosthesis with Flexible TPU Hand (Mirror of Sound Right Side)

# **DISCUSSION AND CONCLUSION**

We have demonstrated the feasibility of locally designing, manufacturing and fitting 3D printed prostheses, while providing comprehensive medical care (rehabilitation and occupational therapy in a humanitarian context. The R&D process continues to improve the durability of the prosthesis and design process. Future directions include expansion of the 3D project to other humanitarian contexts with the goal of increasing access to P&O care and further developing other 3D applications related to surgery and burns.

## **ACKNOWLEDGEMENTS**

This project was funded by MSF Foundation donors.



#### 2.2.5.b

# Implementing 3D Technologies to Increase Access to Partial Hand Prosthetics

Safa Herfat<sup>1,2</sup>, Pierre Moreau<sup>1</sup>, Corin Shirley<sup>2</sup>, Alex Hetherington<sup>2</sup>

MSF Foundation / Doctors Without Borders, Paris, France. <sup>2</sup>University of California San Francisco (UCSF), San Francisco, USA

#### **BACKGROUND**

Partial hand amputations are one of the most common upper extremity limb deficiencies. A prosthesis that restores both cosmesis and function is often difficult to create due to irregular anatomy, skin/soft tissue complications, as well as limited prosthetic components for this level of limb loss. Currently available solutions in high resource settings remain cost prohibitive in for humanitarian settings. Implementation of 3D technologies could provide a cost-effective option, particularly for pediatric patients who require frequent replacement of their prostheses.

#### AIM

Determine the feasibility of implementing 3D scanning, digital design and 3D printing to deliver cost-effective partial hand prosthetics in a humanitarian context and measure early patient satisfaction.

#### METHOD

The patient's partial hand and contralateral hand were scanned with a 3D scanner (Rodin4D-M4D/Peel3D). A thin (2mm thickness) test socket was first designed and 3D printed (Lulzbot-Mini-2) using flexible TPU filament. Once the socket fit was validated, the mirrored mesh from the sound side was aligned with the socket mesh. The two meshes were then digitally stitched together to create a final 3D model of the patient-specific prosthesis. The prosthesis was then printed in flexible TPU and post-processed (e.g. painted). All digital design was performed in a free mesh editing software (Autodesk Meshmixer). Nine questions from the O&P User Survey (OPUS) were used to determine patient satisfaction.

#### **RESULTS**

Partial hand prosthetics were successfully designed, 3D printed, and fitted for 3 patients (two adult patients from

the MSF-Doctors-Without-**Borders Reconstructive** Surgery Hospital - Amman, Jordan, and one pediatric patient from UCSF P&O Clinic (San Francisco, CA). The initial test sockets fit successfully (i.e. providing adequate suspension and comfort) for all three patients. Both MSF patients completed the 2 week OPUS satisfaction survey, reporting 98.5% mean satisfaction score and mean 5.5 hours usage/day, with no reported







Left: Flexible Test Socket, Middle & Right: Final Partial Hand Prosthesis

failure or injury due to the prosthesis. A posable finger prototype has been developed for the 3<sup>rd</sup> patient. This model requires additional design and post-processing time. The material cost for each prosthesis is currently under \$30 USD and requires 2-3 hours for design and 1-3 hours for post-processing.

#### **DISCUSSION AND CONCLUSION**

This pilot project has demonstrated the feasibility of using 3D technologies to digitally design and 3D print partial hand prosthetics. A partial hand prosthesis created using 3D technologies offers a cost-effective alternative to expensive patient-specific prosthesis created using conventional approaches. Early outcomes showing high patient satisfaction are encouraging but a full study with more patients and long term follow-up is needed.

#### **ACKNOWLEDGEMENTS**

This Project was funded by MSF Foundation donors.



### 2.2.5.c

# How to Make 3D Printing a Tool and not a Disruptor

<u>Jeffrey Erenstone</u><sup>1,2</sup>, Amit Ratna Bajracharya<sup>3</sup>, Amrita Lama<sup>4</sup>

<sup>1</sup>Operation Namaste, Lake Placid, USA. <sup>2</sup>Mountain Orthotic and Prosthetic Services, Lake Placid, USA. <sup>3</sup>Limb Care Nepal Pvt. Ltd, Kathmandu, Nepal. <sup>4</sup>Limb Care Nepal Pvt.Ltd, Kathmandu, Nepal

#### **BACKGROUND**

The authors have been deeply involved with the implementation of 3D printing in the field of Prosthetics. Jeff has worked around the world and Amit has focused on his home country of Nepal. Together, they hope to help developing world care leapfrog their infrastructure limitations to provide cutting edge care. Amit and Jeff have worked together for years on improving care in Nepal. Amit is assisting Jeff with test cases on a nonprofit internet based global digital collaborative care network.

#### AIM

Provide Background information and show O&P providers around the world, especially in developing countries, ways to use 3D printing as a tool to improve care through case studies and discussion of successful implementation of the technology by certified clinicians.

#### METHOD

The presentation debunks some myths about 3D printing and provides an overview several different 3D printing technologies including SLS, MJF, SLA, and FDM. We demonstrate multiple international case studies of O&P providers using 3D printing and digital technology to improve the care provided. Special attention is used to highlight cases were this technology was successfully used in developing countries, allowing the providers to leapfrog over their infrastructure and supply chain limitations. In all these cases, the care was provided by trained and certified O&P professional. The software tools and education used is explained so the participates can pursue the same methods in their own care.

#### **RESULTS**

The cases in this presentation were hand selected for their successful outcomes and the informative nature of their circumstance. In most cases scientific rigor has not been applied because of their use as anecdotal examples. However a detailed survey was done on patient outcomes in Nepal using OPUS and these results will be presented.

#### **DISCUSSION AND CONCLUSION**

The presentation outlines aspects of the case studies that made implication of 3D printing successful. Tangible recommendation are given to help steer practitioners down the same successful paths. It has been found that practitioners commonly use immersive experimentation to learn more about new technology so suggestions for low cost methods of experimentation are included. Whenever possible, we will focus on utilization of free, open source software which helps remove the barrier of entry for practitioners with limited financial means.

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### **ACKNOWLEDGEMENTS**

Victoria Hand Project, Operation Namaste, Limbforge, Range of Motion Project, Lifenabled, and Create O&P.



## 2.2.5.d

# A Comparison Between Three-Dimensional Printed and Traditional Body-Powered Upper Limb Prostheses

#### Torv Alexander

Ottobock Ireland, Dublin, Ireland. University of Strathclyde, Glasgow, United Kingdom

#### **BACKGROUND**

Upper limb loss or absence can have a major impact on a person's life. Some users have rejected current traditional upper limb devices for reasons including cost, weight, appearance, function and comfort. Manufacture of upper limb prosthetic devices using three-dimensional (3D) printing aims to provide a solution by addressing some of these issues.

#### AIN

The aim of this investigation was to make a comparison between upper limb 3D printed prostheses and traditional upper limb prosthetic devices.

#### **METHOD**

To assess if 3D printed upper limb prosthetic devices are currently suitable for provision, a testing methodology was generated. Different specifications of upper limb prosthetic devices were measured. Measures included cost, manufacture time, weight, size, appearance and functionality. Two of the most commonly used devices from each category were manufactured and tested. Results were used to make comparisons between 3D printed and traditional devices.

#### **RESULTS**

This investigation has found that, when compared to traditional prostheses, 3D printed devices cost considerably less and can provide some functional benefit to patients. However, traditional devices are more functional, more robust, have improved comfort and are less bulky.

#### **DISCUSSION AND CONCLUSION**

This investigation highlights some of the potential issues and limitations of 3D printed body-powered upper limb prostheses. Applications of 3D printed upper limb prosthetics could be as a temporary, secondary or transitionary device. However, provision in these circumstances should be with caution and treatment should always include a prosthetist. These conclusions could have an effect on the future design, manufacture and prescription of prosthetic devices for upper limb amputees.

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#### **ACKNOWLEDGEMENTS**

 $Sarah\ Day,\ Christine\ McMonagle,\ University\ of\ Strathclyde,\ Ottobock\ Ireland.$ 



#### 2.2.5.e

# The Hundred Dollar Hand, a 3D-Printed Prosthesis for Developing Countries

<u>Gerwin Smit</u>, Jan van Frankenhuyzen Delft University of Technology, Delft, Netherlands

#### **BACKGROUND**

A major part of the amputees lives in developing countries and many of them do not have access to prosthetic healthcare. New technology like 3D-printing offers a potential solution to provide these amputees with affordable prostheses. Many 3D-printed hands have been developed recently. Unfortunately, these designs are often fragile and it remains unknown on how well they perform on functionality and durability.[1] Most of them have bright colors and do not look very anthropomorphic.

#### ΔIM

We aim to develop a 3D-printed hand prosthesis that is low-cost, lightweight, durable, functional, requires a low actuation force and has a hand-like appearance.

#### **METHOD**

The design of the hand prosthesis should be low-cost and allow for local production. We used 3D-printed PLA wherever possible and steel (laser-cutting) where necessary (e.g. loaded parts and axes). The hand is Voluntary Closing and can be controlled with a shoulder strap. The mechanism was designed for efficient force transmission. The hand has 1 DOF, similar to conventional prosthetic hands and can be fitted with a cosmetic glove. It has been tested in a mechanical evaluation, a duration test (>200.000 loading cycles) and in functional tests (Box and Block Test or BBT) with able-

bodied subjects (n=20) using a prosthesis-simulator.

#### **RESULTS**

We designed a low-cost hand, that can be produced and sold for a price below \$100, hence its name: 'Hundred Dollar Hand'. The hand can be produced locally, using a standard 3D-printer and a standard laser cutter. The hand, without glove, weighs 220 grams. The mechanical evaluation showed the actuation force to be relatively low (~75 N to pinch 20 N). The hand withstood over 200.000 loading cycles in the duration test, needing only minor repair. The BBT functional test showed a score of 31.9±4.8 blocks/min. When covered with a cosmetic glove, the hand has a hand-like appearance, comparable to standard prosthetic hands.

### **DISCUSSION AND CONCLUSION**

We present a low-cost 3D-printed hand prosthesis, the 'Hundred Dollar Hand' that is durable, functional and requires a low actuation force. It can be covered with a cosmetic glove, to create a hand-like appearance. Unlike many other studies on 3D-printed hands, our study provides data on durability and functionality. The hand was tested using mechanical testing machines and able-bodied subjects with a prosthesis-simulator. The 'Hundred Dollar Hand' illustrates the feasibility of low-cost, functional and durable 3D-printed design.



Figure 1. The 'Hundred Dollar Hand', printed parts and assembled.

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#### **ACKNOWLEDGEMENTS**

We would like to thank all students who contributed to the development of the Hundred Dollar Hand.



### 2.2.5.f

# The Future of Prosthetics: A World-First Clinical Trial of Affordable, 3D-printed, Multi-grip Myoelectric Prostheses for Children in the UK

<u>Joel Gibbard</u> Open Bionics, Bristol, United Kingdom

#### **BACKGROUND**

The adequate provision of upper limb prostheses for children and young people is complex, reflecting the changing size, diversity of activities, as well as early social and psychological development. At present via the NHS (National Health Service), in the UK, multi-grip myoelectric prostheses are not routinely commissioned for children and young people.[1] And with almost half of all upper limb amputees abandon their prostheses, attributed primarily to a lack of functional gain, there was need for an intervention prosthesis.

#### AIM

Open Bionics have embarked on Phase 2 of a world-first clinical trial to investigate the following: does the provision of an affordable, multigrip, myoelectric prosthesis equal and surpass function in children and young people in comparison to standard NHS care?

#### **METHOD**

In 2017, Open Bionics were awarded a development contract from the NHS to conduct Phase 1 (a feasibility study). Phase 2 is a randomised control trial (stratified randomisation, with cross-over design) with 8 transradial participants between the ages of 8 and 17 at 2 NHS Centres. The trial compares Open Bionics' product the Hero Arm; an affordable, 3D-printed multi-grip myoelectric, with a single-grip myoelectric at a similar price-point routinely commissioned by the NHS: the Ottobock Electrohand 2000. Users will spend 3 months with each prosthesis. The primary outcome measure will be an Action Research Arm Test, alongside additional measuring of time in use as well as qualitative, semi-structured interviews.

#### **RESULTS**

Phase 2 is ongoing, but Open Bionics will present initial findings at the ISPO World Congress in October 2019. Myoelectric multi-grip prostheses costs between £25,000 to £80,000, and this is too expensive for routine commissioning on the NHS. The Hero Arm is available to the NHS at a similar pricepoint as the less functional and less aesthetically empowering single-grip prosthesis that is currently routinely prescribed to children with transradial upper limb differences. The authors anticipate the results of this world-first clinical trial will provide a clear pathway for multi-site adoption of affordable multi-grip, myoelectric prosthetics under normal NHS care, moving from basics to bionics.

#### **DISCUSSION AND CONCLUSION**

This clinical trial and overall initiative will bring about a landmark step change in care on the NHS, making myoelectric prosthetics an option for all children and young people that require them. In addition, thanks to Open Bionics' game-changing liscening, the Hero Arm comes with swappable covers in the style of Star Wars, Marvel and Disney Frozen - creating advanced functional prostheses that kids really want to wear. What else could be done to increase prosthesis adoption rates for children?

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#### **ACKNOWLEDGEMENTS**

SBRI Healthcare; Dr Abby Tabor, University of Bath



# **Free Paper Session**

# **Prosthetics: Lower Limb Transtibial - Socket**

#### 2.2.6.a

# Design, Development and Static Tests of an Adjustable Socket for Transtibial Amputation

Nora Sirrs, Carlos Galván-Duque, Jorge Letechipia Applied Research and Technology Institute, Universidad Iberoamericana, Mexico City, Mexico

#### **BACKGROUND**

Daily changes in residual limb volume cause inaccurate fit of the socket.[1] These volume changes are, mainly related to the cause of the amputation and the user's physical activity.[2] The decrease of the prosthesis adjustment, results in lesions of the skin, shear stresses in the stump and loss of contact between socket and residual limb. Sanders reported an average loss of volume of -2.3%/h.[3]

#### AIM

Design, develop and test an adjustable socket prototype for transtibial amputation, which allows the user to adapt it to volume changes, without removing the prosthesis, maintaining a good prosthetic fit throughout the day.

#### **METHOD**

An adjustable socket was developed with an inner polyethylene socket and a carbon fiber reinforcement. The adjustment mechanism was 3D printed in stainless steel using Selective Laser Melting. To adjust the socket to the stump volume, the mechanism increases the pressure in specific areas: anterior and posterior compartments, and tibial medial shaft.

Pressure inside the socket was measured (F-Socket, Tekscan) under two conditions:



Figure 1.
Adjustable
Transtibial
prosthesis.

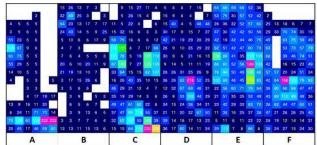


Figure 2. Maximum pressure maps (red square: anterior compartment, green square: tibial medial shaft, yellow square: posterior compartment). A and B: artificial stump -10%, C and D: artificial stump: original, E and F: volunteer.

- Artificial stumps made of silicone: static load 55kg
- Original volume and reduction of 10%

Volunteer: static load 70.6kg.

Socket's total volume adjustment was calculated with truncated cone model.

#### **RESULTS**

A transtibial prosthesis was assembled with the adjustable socket (figure 1). The pressures between the socket and the residual limb were measured with two pressure sensors 9811E (matrix of 16x6 sensors) placed in specific areas of interest (tolerant and intolerant pressure zones). In all cases (artificial stumps and volunteer), the measurement was performed for 60 seconds, in which the mechanism of the socket was increased from minimum to maximum adjustment over time. The obtained pressure maps at maximum adjustment are shown in figure 2. The total volume adjustment achieved inside the socket was 6.67%.

#### **DISCUSSION AND CONCLUSION**

The adjustable socket achieved an increment of pressures in tolerant areas, maintaining low pressures in intolerant areas, mainly in crest of tibia. In addition, the mechanism allows to manually adjust the socket without removing the prosthesis. Higher volume adjustment was achieved compared to the literature. Future work contemplates dynamic tests with patients and redesigning the mechanism to enhance stability, incorporating a security limit to avoid excessive pressures. An automatic system will be developed for the mechanism.

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# **ACKNOWLEDGEMENTS**

This project is funded by the Applied Research and Technology Institute, Universidad Iberoamericana-Mexico City, project F145006-SNI.



### 2.2.6.b

# Investigating the Composition and Tissue Deformation During Simulated Prosthetic Loading of Intact and Trans-Tibial Residual Limbs

<u>Jennifer Bramley</u><sup>1</sup>, Peter Worsley<sup>1</sup>, Luciana Bostan<sup>1</sup>, Angela Darekar<sup>2</sup>, Chris Everitt<sup>2</sup>, Dan Bader<sup>1</sup>, Alex Dickinson<sup>1</sup>

<sup>1</sup>University of Southampton, Southampton, United Kingdom. <sup>2</sup>University Hospital Southampton NHS Foundation Trust, Southampton, United Kingdom

#### **BACKGROUND**

Post-amputation, reconstructed tissues are not conditioned to tolerate loading experienced during activities of daily living, which can cause recurring damage.[1] Studies have examined the relationships between tissue damage and internal tissue strains, indicating that high strains can lead to muscle damage within 10 minutes.[2] To date there is limited understanding of how loading affects vulnerable residuum tissues during early prosthetic rehabilitation. MRI has demonstrated potential to observe morphology [3,4] and the response to simulated static prosthetic loading in participants without amputation.[5]

#### ΔIM

This study aims to compare the morphology and biomechanical response of residual and contralateral limb tissues during representative prosthetic loading in people with trans-tibial amputation.

#### **METHOD**

Pressure was applied to the lower limbs of participants with unilateral trans-tibial amputation using a cuff inflated to 60 mmHg, representing that experienced using the Pneumatic Post-Amputation Mobility (PPAM) Aid.[6] 3D printed indenters were positioned underneath the cuff at three sites relevant to prosthetic load bearing, and the indenter-skin interface pressures were measured (Oxford Pressure Monitor II, Talley, UK). T1-weighted MR images acquired on a 3T MRI scanner (MAGNETOM Skyra, Siemens, Germany) were recorded at baseline and

60 mmHg to characterise direct tissue deformation [5] and visualise morphology.[3,4]

# **RESULTS**

Preliminary MRI data are presented for one female participant aged 46yrs (Figure 1). At 60 mmHg cuff inflation, interface pressures ranged from 47-72 mmHg, representative of static PPAM Aid A B C D D

Figure 1 Corresponding transverse section MR images displaying one participant's intact (A & C) and residual limb (B & D) baseline, Note: red represents the limb outline at baseline (solid) and 60 mmHg cuff pressure (dashed), yellow represents superficial adipose mask and blue represents muscle infiltrating adipose mask

usage during early rehabilitation. The indenters generated gross compressive strains in the contralateral and residual limbs, respectively, of approximately 4% and 5% at the patellar tendon, 14% and 21% at the lateral calf, and 9% and 15% at the posterior calf. The contralateral limb, with a cross-sectional area of ≈40.1 cm², consisted of ≈12% superficial adipose tissue with 2 consisting of ≈8% superficial and ≈7% infiltrated adipose tissue.

### **DISCUSSION AND CONCLUSION**

MRI revealed marked soft tissue deformations at low representative pressures, greater than MRI resolution (0.6 mm). Significant adipose infiltration was observed in residual limb muscle tissue suggesting muscle atrophy post-amputation. The relatively low stiffness of adipose tissue would account for the increased deformation values. Investigation of morphology and deformation measurements in more participants will help to increase knowledge of adaptation post-amputation and inform techniques that could be used with individuals to reduce the risk of soft tissue damage.

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#### **ACKNOWLEDGEMENTS**

Ethics: ERGO41864. Funders: EPSRC (EPN5097471, EPN02723X1), IfLS and RAEng (RF130).



#### 2.2.6.c

# Towards Real-Time Prediction of Transtibial Socket Fit During the Design Process

Joshua Steer<sup>1</sup>, Peter Worsley<sup>2</sup>, Martin Browne<sup>1</sup>, Alexander Dickinson<sup>1</sup>

<sup>1</sup>Bioengineering Sciences Research Group, Faculty of Engineering and Physical Sciences, University of Southampton, Southampton, United Kingdom. <sup>2</sup>Clinical Academic Facility, Faculty of Environmental and Life Sciences, University of Southampton, Southampton, United Kingdom

#### **BACKGROUND**

Finite Element (FE) modelling has long been proposed as a computational tool to support the socket design process by predicting the structural interactions at the residuum-device interface. It has been hypothesised that predicting these interactions will enable a reduction in the number of clinical fitting and adjustment sessions required.[1] However, clinical translation has not been achieved due to need for expertise in model development, lengthy simulations, and lack of corresponding imaging, material and loading data.

#### AIM

This study aimed to develop a workflow and software interface for a tool to support clinicians with real-time pressure predictions during the transtibial socket design process.

#### **METHOD**

A parametric FE model of the transtibial residuum enabled variation of residuum length and profile (according to an established surface scan dataset [2]), tibia length and soft tissue stiffness. This was coupled to a parametric socket design which permitted adjustment of press-fit, patella tendon, fibula head and tibial crest rectifications. 150 random combinations of these variables were generated across the design space. Socket donning and loading to 400N was simulated. Interface pressure predictions were used as training data for a surrogate model, which fitted a continuous function across the design space.[3] A custom software interface was developed that visualised pressure predictions in response to these residuum and design variables (Figure 1).

#### **RESULTS**

Unlike labour-intensive single model generation methods, this parameterised approach enables a wide population of individuals to be studied with no additional effort beyond selecting their appropriate residuum parameters. The surrogate approach also allowed prediction of the pressure distribution for a new socket 100,000x faster than the full FE simulations



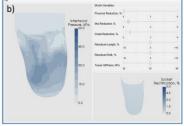


Figure 1: a) FEA model development process from MRI, b) Software environment used to explore how socket design and patient anatomy affects residuum pressure

(2ms vs 30 minutes), with <3kPa deviation between methods. Exploration of the design space demonstrated the competing effects inherent within the socket design process. Sockets with higher press-fit were predicted to reduce distal loading at the expense of increased proximal pressure and shear over the bony prominences of the tibial tuberosity and fibula head. The converse was true for low-press fit sockets, where the removal of peripheral shear allows the residuum to slide further into the socket and increase residuum tip pressure.

# **DISCUSSION AND CONCLUSION**

The developed software platform, driven by the surrogate model, would enable prosthetists to access predictions of a new individual and socket design's pressure and shear distribution in real-time without needing to develop the model themselves. Clinical adoption will require an extensive training database to increase model predictive power, experimental validation, and feedback from prosthetists during software development. This will facilitate clinical feasibility studies to determine the potential improvements to socket fitting services and user experience.

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# **ACKNOWLEDGEMENTS**

Funders EPSRC/NIHR (EP/R014213/1, EP/M000303/1), EPSRC (EP/M508147/1) and RAEng (RF/130).



#### 2.2.6.d

# Influences and trends of Various Shape Capture Methods on Outcomes in Transtibial Prosthetics: A Literature Review

<u>Eddie Yang-Suyi</u>, Navid Aslani, Anthony McGarry Department of Biomedical Engineering, University of Strathclyde, Glasgow, United Kingdom

#### **BACKGROUND**

The socket works as a mechanical coupling between the human body and the prosthetic limb. To allow efficient and comfortable use, it is crucial to attain a good socket fit. The production of a socket occurs over four stages – shape capture, modification, fabrication and alignment. Due to this close relation between processes, errors made may be cumulative. It is important that the residual shape is captured as accurately as possible to obtain the best chance of a good fit.[1-3]

#### AIM

This review examines the influences and trends of shape capture methods on the outcomes of validity, comfort of user and clinical efficiency in the population of trans-tibial prosthesis users

#### **METHOD**

Databases and relevant journals were searched. Participants: trans-tibial prosthetic users/limb models. Intervention: shape capture methods. Outcomes: validity, comfort of user and clinical efficiency.

#### **RESULTS**

Overall, 22 papers were evaluated. 8 papers evaluated hands-on and hands-off methods, 2 evaluated CAD and 12 evaluated measurement systems used with shape capture. No papers relating to clinical efficiency were found.

#### **DISCUSSION AND CONCLUSION**

Overall evidence was weak in suggesting that effects on outcomes were due to the sole influences of shape capture. However, studies suggest that hands-on methods are dependent on a prosthetist's skill. Hands-off methods, although repeatable, might still require experience to attain a good fit. CAD studies were mostly conducted on theoretical models. Shape capture measurements require more consistent "gold standards". The relationship between socket fit and comfort is still unclear. Overall, more research is required in each area.

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#### 2.2.6.e

# Transtibial Prosthetic Socket Design and Suspension-Mechanism: A Literature Review

Nadhira Al Shuaili, Navid Aslani, Anthony McGarry

Department of Biomedical Engineering, University of Strathclyde, Glasgow, United Kingdom

#### **BACKGROUND**

The body-weight of the prosthetic user is supported and distributed by the prosthetic socket during the stance phase of gait. Throughout swing phase, inertial forces (pressure and shear) are exerted by the socket suspension-mechanism onto the residuum to facilitate suspension.

#### ΔIM

To identify and investigate available evidence in Trans-Tibial (TT) socket design and suspension to highlight the most effective weight transfer mechanisms and suspension techniques.

#### METHOD

A literature review was conducted to investigate areas of discrepancy in the present knowledge; with regards to available evidence in both TT socket design and suspension-mechanisms to identify the most effective weight transfer mechanism and suspension techniques where possible.

Boolean search terms and truncation were used using relevant keywords in online search engines to obtain precise results.

In each search engine, the search strategy was refined. A total of 135 papers were retrieved relating to inclusion/exclusion criteria. Further refined by checking title and abstract. Included papers were appraised and graded using the Scottish Intercollegiate Guidelines Network (SIGN) checklists (https://www.sign.ac.uk).

#### **RESULTS**

17 papers which met inclusion criteria were reviewed.

Papers obtained were divided into three sections: reviews, socket design clinical studies and studies investigating suspension techniques. Each table illustrates the main findings (PICO: Patient/Population, Intervention, Comparator and Outcomes), grade of evidence<sup>1</sup> and the presence of commercial bias.

## **DISCUSSION AND CONCLUSION**

A conclusion on whether socket preference is due to the suspension-mechanism or socket design itself cannot be drawn. PTB sockets are still successfully used and in some studies preferred over TSB. Biomechanically, TSB sockets allow for a more even weight-distribution when combined with suction, particularly VASS. Limited evidence supports that such designs may have effect on wound healing and early ambulation. Crossover randomised controlled trials with larger sample sizes are required to establish an evidence base to improve clinical practice.

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## **ACKNOWLEDGEMENTS**

The authors would like to thank Mr. Stephanos Solomindis for the time he devoted and his appreciated input and advice.



#### 2.2.6.f

# Testing the Durability of 3D Printed Prosthetic Sockets

Benjamin Jameson<sup>1</sup>, <u>Goeran Fiedler</u><sup>1</sup>, Prakash Shrivastava<sup>2,3</sup>, Srinivasa Regalla<sup>3,4</sup>, Rory Cooper<sup>1</sup>
<sup>1</sup>University of Pittsburgh, Pittsburgh, USA. <sup>2</sup>University of Southern California, Los Angeles, USA. <sup>3</sup>PSPR 3D Tech, Hyderabad, India. <sup>4</sup>BITS Pilani, Hyderabad, India

#### **BACKGROUND**

It is important to quantify the strength and structural suitability of affordable sockets for underserved world regions, recently made possible through additive manufacturing (3D printing). PSPR 3d Tech Pvt. Ltd. Hyderabad, India, has used additive manufacturing to supplant traditionally produced prosthetics. The standard ISO 10328 is originally tailored to the testing of standardized components, such as pylon adapters, and does not

include provisions for (semi-)customized components

such as the 3D-printed sockets.[1, 2]

### AIM

We describe a standardized testing protocol that has been adapted from established international testing standards for purposes of testing prosthetic sockets. Preliminary results will be presented.

#### **METHOD**

In order to adapt the testing procedures for our purposes, we reduced the number of tests scenarios to the most pertinent load conditions (i.e., early and late stance phase of the simulated step cycle). A method of fixating the test object in the setup [3] was adopted. Each test sample was prepared by suspending a length of pipe in the socket with plaster of Paris. According to test load level A80 (80kg), the socket fixation is tested following ISO10328-3 (Static test, 944 N), followed by a cyclic failure test that calls for application of 1180N over 3M cycles and finally a static failure test where load is increased to 2065N.

Figure 1. Test socket preparation

### **RESULTS**

Tests on three socket samples are currently ongoing (Figure 1). The first tested socket survived the initial

static testing as well as the first 250,000 cycles of the cyclic testing (at 1 Hz).

#### **DISCUSSION AND CONCLUSION**

No universally accepted standards for the testing of prosthesis sockets exist. Adapting ISO standards for other prosthetic components may fill this gap.[1, 2] One such test protocol is applied to quantify the stability of a novel low-cost 3D printed socket design. Preliminary findings show that sockets withstood the static test and did not fail through the first 250,000 cycles of fatigue testing. Final results of this ongoing work may inform the prescription of such sockets in the future.

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#### **ACKNOWLEDGEMENTS**

PSPR 3D Tech, SHARE-INDIA, University of Pittsburgh. Thanks to Garrett Grindle and Ben Gebrosky.



# Free Paper Session Rehabilitation Medicine & Surgery - Epidermiology

#### 2.2.7.a

# Mobilization Status of Diabetics Versus Non-diabetics after Below Knee Amputation: A Comparison

#### **Amit Saraf**

Teerthanker Mahavir Medical College, Moradabad, India

#### **BACKGROUND**

Mobility following below knee amputation has a direct impact on the quality of life. Early and independent mobilization develops confidence in the below knee amputee. This helps the patient to become psychologically, socially and economically independent. In this study we compared mobilization status of diabetics versus non-diabetics amputees. We also prepared a note of type of supports used and duration of prosthetic usage by both the groups postoperatively.

#### AIM

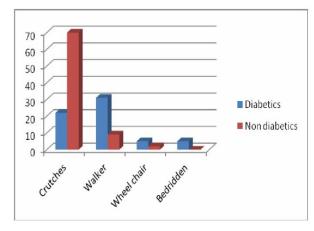
To compare rehabilitative outcome after below knee amputation in diabetics versus non diabetics on the basis of prosthetics and orthotics used by them

#### **METHOD**

This was a 2 years prospective and 10 years retrospective study. A total of 144 below knee amputees using various supports for mobilization were included in this study of which 63 were diabetics and 81 non diabetics. They were followed for a minimum period of 1 year. On follow up they were observed for the type of support used for mobilization.

#### **RESULTS**

92 patients initially used crutches for mobilization. 40 patients used walker, 7 used wheelchair and 5 remained bed ridden before they died. Of 92 patients who were using crutches, 22 were in diabetic group and 70 in non diabetic group. 31 patients of diabetes and 9 patients of non diabetic group used walker. 5 patients in diabetic group and 2 patients in non diabetic group could mobilize only on a wheelchair. All 5 bedridden patients were in diabetic group. 104 patients started using prosthesis for mobilization once their stumps had healed adequately of which 30 were in diabetic group and 74 in non diabetic. Result was statistically significant. 43 were using it for less than 6 hours per day, 55 were using 6-12 hours per day and 6 patients were using it for > 12 hours per day.



Comparison of diabetics versus non diabetics post op rehabilitation after below knee amoutation

# **DISCUSSION AND CONCLUSION**

Non diabetics preferred crutches and prosthesis for mobilization in comparison to diabetics. More diabetics were bedridden or on wheel chair after amputation. Non diabetics were using prosthesis for longer time in comparison to diabetics. Major causes for this difference was preoperative lower ambulatory grading in diabetics, weaker muscle mass, old age, co-morbid conditions, increased incidence of infection and prolonged stump healing time.

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#### 2.2.7.b

# Physical Therapy after Lower Extremity Amputation: Predictors and Outcome Implications

Szu-Ping Lee, <u>Hui-Ting Shih</u>, Gregory Amaya, Rosman Gante, Zachary Meinzer, Abbas Sadrossadat Department of Physical Therapy, University of Nevada Las Vegas, Las Vegas, USA

#### **BACKGROUND**

The number of people with limb loss is growing substantially, partly due to an aging society and the prevalence of diabetes. Physical therapy (PT) has been shown to improve perceived functional outcomes and quality of life in older adults and individuals with diabetes, however it is unclear why certain patients do not receive PT after amputation and whether the beneficial outcomes shown in other populations translate to individuals with limb loss.

#### AIM

To explore characteristics of patients who received physical therapy after amputation and to retrospectively determine perceived function and quality of life in individuals who did and did not receive PT after amputation.

#### METHOD

Forty male and 8 female (57.8±15.1 years) participants were recruited from the local prosthetic and physical therapy clinics, rehabilitation hospitals, and an amputee patient support group. All participants completed the following surveys: Amputee Perception Survey designed to assess participants' medical history and recovery from amputation, Short-Form 36 survey (SF-36), mobility section of the Prosthesis Evaluation Questionnaire (PEQ), and Fear of Falling Avoidance Behavior Questionnaire (FFABQ). SF-36 scores indicate perceived quality of life (QoL); the PEQ measures prosthesis-related changes in mobility; and the FFABQ assesses activity avoidance behaviors associated with fear of falling.

#### **RESULTS**

Of our participants, 38 received physical therapy (YesPT) and 10 did not (NoPT); the mean age for the YesPT

group was 59.5±15.1 years and 51.3±15.2 years for the NoPT group. YesPT group consisted an equal distribution of individuals with unilateral above the knee (AK: 42.1%) and below the knee (BK: 42.1%) amputations, and 15.8% of higher level (i.e. hip disarticulation) or bilateral amputations. The NoPT group consisted of 10% AK and 90% BK amputations. A higher percentage of individuals in the YesPT group lost their limbs due to vascular causes than NoPT (36.8% vs 20%). There were no statistically significant differences in SF-36 Total, PEQ, and FFABQ scores, and perceived

	cs, perceived funct Yes PT (n=38)	No PT (n=10)	p value
Level of Amputation (AK/BK/Other)	16 (42.1)/ 16 (42.1)/ 6 (15.8)	1 (10.0)/9 (90.0)/ 0 (0.0)	
Cause of Amputation	14 (36.8)/ 24 (63.2)	2 (20.0)/ 7 (70.0)	
(Vascular/Nonvascular)			
PEQ Total	86.3±32.1	85.0±29.5	0.907
FFABQ Total	13.2±14.8	7.0±7.5	0.208
SF36 Total	106.2±14.2	108.9±5.8	0.363
Perception of confidence of mobility	7.4±2.4	8.7±1.7	0.128
(0-10)			
Perception of satisfaction of mobility	7.3±2.4	6.9±3.2	0.653
(0-10)			

confidence of mobility with prostheses between the two groups.

## **DISCUSSION AND CONCLUSION**

Presence of more complex amputation (i.e. high level, bilateral) and a vascular etiology were shown to be potential predictors to receiving PT after amputation. While these characteristics have been shown as detrimental to physical function, both the NoPT and YesPT groups in this study exhibited similar levels of perceived function and quality of life. We theorized that physical and perceived limitations in performing activities of daily living shortly after amputation are important determining factors to whether a patient seeks PT.

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#### 2.2.7.c

# Major Lower Limb Amputation in Central Australia: A Retrospective Review of Patient Demographics, Hospital Factors and Outcomes

Laura Stuart<sup>1</sup>, Lara Kimmel<sup>2</sup>, Andrew Jolly<sup>1</sup>
<sup>1</sup>Central Australia Health Service, Alice Springs, Australia. <sup>2</sup>Alfred Health, Melbourne, Australia

#### **BACKGROUND**

The Northern Territory has the highest rate of lower limb amputation when compared to other states and territories in Australia.[1] 26% of persons in the Northern Territory identify as Aboriginal or Torres Strait Islander and evidence exists that this population have reduced health outcomes when compared to non-Aboriginal or Torres Strait Islander cohorts. A region within the Northern Territory, Central Australia, is home to ~44,000 people and covers an area of 872,861km<sup>2</sup>.

#### AIM

The aim of this study was to review the demographic information of those who have undergone major single lower limb amputation in Central Australia and their hospital and longer term outcomes.

#### **METHOD**

Retrospective medical record review of those patients who underwent major single lower limb amputation in a Central Australian hospital from 2012-2017 was undertaken. Demographic, operative and post-operative outcomes were recorded including hospital length of stay, time to prosthetic fitting, time to independent ambulation and mortality. Factors associated with these outcomes were determined using both univariate analysis and multiple logistic regression.

#### **RESULTS**

58 major amputations were performed [female n=26, (45%), Aboriginal or Torres Strait Islander n=48 (83%)]. Mean age at amputation was 52.9 ( $\pm$ 11.80) years for Aboriginal or Torres Strait Islander peoples and 66.2 ( $\pm$ 14.97) years for non-Aboriginal or Torres Strait Islander peoples (p=0.003). 98% of the Aboriginal or Torres Strait Islander peoples had T2DM (p<0.001) and 75% of this population had renal disease (p<0.001). 55% of individuals received a prosthesis, 90% of these went on to become proficient in ambulation. Length of hospital stay, time to prosthetic fitting and time to independent ambulation were not associated with immediate inpatient rehabilitation engagement, Aboriginal or Torres Strait Islander status or remoteness. 32 patients (55%) passed away within a median time period of 460 days (IQR 174, 875.5). Aboriginal or Torres Strait Islander status showed a trend towards mortality but this was non-significant (p=0.097).

# **DISCUSSION AND CONCLUSION**

The majority of amputations in Central Australia were performed on Aboriginal or Torres Strait Islander peoples, with this group being younger than the comparable cohort. This group were more likely to pass away in the follow up period although Aboriginal or Torres Strait Islander status was not significant when gender and Charleson Comorbidtiy Index >7 group were considered. Rehabilitation access and prosthetic management was equitable between groups. Further research should investigate any potentially avoidable causes of mortality post amputation.

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#### **ACKNOWLEDGEMENTS**

We acknowledge the Traditional Owners of the land on which we live and work.



#### 2.2.7.d

# Pattern of Upper Limb Amputation Associated with Lower Limb Amputation Following Blast Injury: The UK Experience from Iraq and Afghanistan

<u>Louise McMenemy</u><sup>1,2</sup>, Valeria Mondini<sup>1</sup>, Darren Roberts<sup>3</sup>, Angela Kedgley<sup>1</sup>, Jon Clasper<sup>1,2</sup>, Sarah Stapley<sup>2,3</sup>
<sup>1</sup>Centre for Blast Injury Studies, Imperial College London, London, United Kingdom. <sup>2</sup>Royal Centre for Defence Medicine, Academic Department for Military Surgery and Trauma, Birmingham, United Kingdom. <sup>3</sup>Queen Alexandra Hospital, Portsmouth, United Kingdom

#### **BACKGROUND**

Developments in prosthetic design have improved outcomes for lower limb (LL) amputees. LL prosthetic donning and doffing can be problematic in combination with an upper limb (UL) amputation. The extent of UL amputation, following the wars in Iraq and Afghanistan, has not been documented. Following polytrauma, injury details are recorded on the Joint Theatre Trauma Registry (JTTR), however, partial hand amputation is often not recorded in the context of multiple injuries. Knowledge of this cohort could aid in prosthetic modification.

#### **AIM**

The aim was to document the frequency and pattern of LL amputation with UL amputation at any level.

#### METHOD

A JTTR search was undertaken for all UK military LL amputees. These records were scrutinised, examining imaging and notes to document any UL amputation. Demographics, level of amputation, and injury profile data were recorded.

#### **RESULTS**

164 LL amputees were identified with full clinical notes available, of which 68 also had an UL amputation. All cases were male with a median age of 24 (range 18-42). Only explosive mechanisms (improvised explosive device (IED) and grenade) resulted in combinations of UL and LL amputations; the majority (73.5%) were bilateral LL amputations. UL amputations were mostly unilateral (85%), and partial hand (72%). Most partial hand amputations excluded the thumb (75.5%), however more bilateral LL amputees sustained partial hand amputations including the thumb (20% vs 11%). No significant difference of side, right or left UL was found (p>0.05). 9 casualties sustained major UL (wrist or above) amputations without a LL amputation, all blast mechanism.

#### **DISCUSSION AND CONCLUSION**

The increased prevalence of partial hand amputation, including thumb loss, in bilateral LL amputees is likely secondary to increased energy transfer required for bilateral LL traumatic amputation compared to unilateral. It also highlights a cohort for whom donning and doffing of LL prostheses is likely to be problematic due to a relative lack in dexterity. Knowledge of these combinations and documentation of this cohort, enables potential modification of prosthetics to help further improve the quality of life of LL amputees.



#### 2.2.7.e

# **Epidemiology of Vestibular Dysfunction in Community Ambulators with Lower Limb Amputation**

<u>Jennifer Lucarevic</u><sup>1,2</sup>, James Moore<sup>1</sup>, Ignacio Gaunaurd<sup>1,3</sup>, Christopher Bennett<sup>1</sup>, Allison Symsack<sup>4</sup>, Paul Pasquina<sup>4</sup>, Robert Gailey<sup>1</sup>, Michael Schubert<sup>5</sup>

<sup>1</sup>University of Miami, Coral Gables, USA. <sup>2</sup>California State Dominguez Hills, Los Alamitos, USA. <sup>3</sup>Miami Veterans Affairs Healthcare System, Miami, USA. <sup>4</sup>Henry M. Jackson Foundation for the Advanccement of Military Medicine, Bethesda, USA. <sup>5</sup>Johns Hopkins University School of Medicine, Baltimore, USA

#### **BACKGROUND**

Individuals with lower limb amputation (LLA) have been shown to have limitations in mobility,[1] balance,[2] and greater rates of falling [3] than the able-bodied population. While it is known that the vestibular system provides critical information for balance and mobility, there is a lack of research to describe the rate and type of vestibular function in the limb loss population.

#### **AIM**

The purpose of this study was to identify the rate of peripheral and central vestibular dysfunction in a cross-section of community ambulators with LLA.

### **METHOD**

A convenience sample of community ambulators with unilateral LLA were recruited from a national conference sponsored by the Amputee Coalition. Eligible participants were required to be more than 1 year post amputation surgery, with a comfortable socket, and > 3 months use of current prosthetic componentry. The EyeSeeCam (Interacoustics, Denmark) and the I-Portal® - PAS (Portable Assessment System, NKI Pittsburgh) video-oculography (VOG) systems were utilized to objectively measure eye movements during oculomotor and vestibular function tests. Participants were classified as having vestibular dysfunction when ≥1 VOG tests

Table 1. Frequency of VOG abnormalities observed in LLA with vestibular dysfunction (n=27)

VOG Test	Abnormality	Peripheral	Central
	Criteria	(n=9)	(n=18)
vHIT L	VOR Gain < 0.8	4 (44%)	5 (28%)
vHIT R	VOR Gain < 0.8	7 (78%)	2 (11%)
MVT	Nystagmus	0 (0%)	0 (0%)
SN	PSPV > 3 °/sec	1 (11%)	5 (28%)
	Consistent $\geq 3$ beats	2 (22%)	13 (73%)
GEN	Consistent $\geq 3$ beats	6 (67%)	14 (78%)
SVV	Mean error ≥ 3°	3 (33%)	5 (28%)
Saccade - horizontal	Overshoot > 50%	0 (0%)	1 (6%)
	Undershoot > 50%	0 (0%)	3 (17%)
Saccade - vertical	Overshoot > 50%	0 (0%)	0 (0%)
	Undershoot > 50%	2 (22%)	5 (28%)
Smooth Pursuit - horiz .75 Hz	gain < 0.8	1 (11%)	3 (17%)
Smooth pursuit - vert .75 Hz	gain < 0.8	6 (67%)	8 (44%)
Saccade - horizontal Saccade - vertical Smooth Pursuit - horiz .75 Hz	Overshoot > 50% Undershoot > 50% Overshoot > 50% Undershoot > 50% gain < 0.8	0 (0%) 0 (0%) 0 (0%) 2 (22%) 1 (11%)	1 (6%) 3 (17%) 0 (0%) 5 (28%) 3 (17%)

had an abnormal result. Characterization of central lesions included observation of nystagmus that was non-fatiguing, purely vertical or direction changing.

#### **RESULTS**

Sixty adults aged  $48.8 \pm 13.9$  years with unilateral LLA (53% TTA, 47% TFA) were included. The majority of participants were community ambulators (MFCL K2 18.3%, K3 73.3%, K4 8.3%) with limb loss due to trauma. In this small cross-sectional study, the prevalence of vestibular dysfunction was found to be 45%. Two-thirds (n=18) of the LLA with vestibular dysfunction were subclassifed as having a central vestibular lesion, while one-third (n=9) were found to have peripheral lesions. The frequency of abnormal VOG testing results are described in Table 1.

#### **DISCUSSION AND CONCLUSION**

Vestibular rehabilitation therapy is effective for improving balance and mobility in individuals with vestibular dysfunction. In this small study of active community ambulators, we found high rates of central (30%) and peripheral (15%) vestibular dysfunction. Screening vestibular dysfunction in individual's with LLA could help inform healthcare providers when to refer to a vestibular specialist.

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# **ACKNOWLEDGEMENTS**

This work was funded by Department of Defense & Department of Veterans Affairs Joint Incentive Fund "Mobile Device Outcome-based Rehabilitation Program.



#### 2.2.7.f

# Incidence and Risk Factors for Reamputation after Dysvascular Amputation

Daniel Norvell<sup>1</sup>, Joseph Czerniecki<sup>2,3</sup>

<sup>1</sup>Spectrum Researach, Tacoma, USA. <sup>2</sup>CLiMB Research Center, Seattle, USA. <sup>3</sup>University of Washington, Seattle, USA

#### **BACKGROUND**

Failure of healing after amputation and need for reamputation has been associated with increased mortality, loss of function while healing, and poorer long-term mobility. Identifying patients at high risk of failure of healing may improve surgical decision-making. Prior studies of reamputation risk are limited in that they have not included transmetatarsal (TM) amputation in the same analysis cohort and have limited the analysis to 30-days post-amputation.

#### AIM

To identify the timing, incidence, and risk factors for ipsilateral reamputation in the first year after incident dysvascular amputation and to determine risk factors that are amputation level specific.

#### METHOD

Between 2004 and 2014, 7,158 subjects with incident unilateral TM, transtibial (TT), or transfemoral (TF) amputation secondary to diabetes and/or peripheral artery disease were identified in the VA Surgical Quality Improvement Program database. Reamputation was defined as the presence of any subsequent ipsilateral soft tissue or boney revision, or amputation to a higher level. Twenty-three potential pre-operative risk factors (and 9 potential interactions) were identified. A backward stepwise Cox regression using a cutoff of p<.05 was used to identify risk factors. Incidence rates were computed by taking the ratio of the number of events and total time at risk. The proportional hazards assumption was evaluated both quantitatively and qualitatively.

#### **RESULTS**

The mean time to reamputation was 60±70 (range, 2-365) days. The incidence rates were 65 (TM), 37 (TT), and 13 (TF) per 365 person-days at risk. From the final Cox model, TM patients who had diabetes without abnormal ankle brachial index (ABI) (HR,1.9; 95% CI: 1.4-2.5), diabetes with an abnormal ABI (HR,1.7; 95% CI: 1.8-3.2), and renal failure (HR,1.7; 95% CI: 1.3-2.1) were at greatest risk of reamputation. TT amputees who were smokers were also at an increased risk (HR,1.4; 95% CI: 1.2-1.6). Other risk factors associated with an increased risk of reamputation independent of amputation level included chronic obstructive pulmonary disease, elevated white blood cell counts, history of revascularization, and alcohol misuse.

### **DISCUSSION AND CONCLUSION**

To our knowledge this is the first study examining the risk of ipsilateral reamputation one year after incident amputation comparing all three major amputation levels. This research identified risk factors for reamputation at all levels and also amputation level subgroups at greater risk of reamputation. TM amputation should be considered with caution in patients with diabetes (with or without an abnormal ABI) and/or renal failure. At the TT level, caution should be exercised in those who smoke.



### 2.2.7.g

# Contralateral Amputation after Dysvascular Amputation: What are the Risks and what are the Risk Factors?

Joseph Czerniecki<sup>1,2</sup>, Daniel Norvell<sup>3</sup>
<sup>1</sup>CLiMB Research Center, Seattle, USA. <sup>2</sup>University of Washington, Seattle, USA. <sup>3</sup>Spectrum Research, Tacoma, USA

#### **BACKGROUND**

The preservation of function after dysvascular amputation is critically dependent on preserving the contralateral limb. This is important both for those who are ambulatory as well as those who are using the remaining limb for transfers. Prior published research has focused primarily on contralateral amputation after incident transfemoral (TF) or transtibial (TT) amputation and included an analysis of medical/surgical risk factors but did not include potentially important psychosocial risk factors.

#### AIM

To determine risk factors for contralateral amputation so that limb preservation health care practices can be focused on those at highest risk.

#### **METHOD**

Between 2004 and 2014, 7,161 subjects with incident unilateral transmetatarsal (TM), transtibial (TT), or transfemoral (TF) amputation secondary to diabetes and/or peripheral artery disease were identified in the VA Surgical Quality Improvement Program database. Procedure codes were used to identify subsequent amputation and natural language processing was used to establish laterality. Twenty-six potential pre-operative risk factors were considered based upon published literature and clinical experience. Backward stepwise logistic regression using a cutoff of p<.05 was used to identify significant risk factors.

#### **RESULTS**

The overall one-year risk of contralateral amputation was 7%. Risks were greatest in those who underwent an incident TF amputation (8.6%) followed by TT (6.4%) and TM amputation (5.7%), p<.0001. The amputation level on the contralateral limb was significantly correlated (p<.0001) to the incident amputation level (81% TF, 66% TT, 65% TM). In the multivariable model, the risk of contralateral amputation was greater in those who: 1) underwent an incident TF amputation compared to TM amputation (HR, 1.5; 95% CI: 1.1-1.9), 2) were Black (HR, 1.4; 95% CI: 1.2-1.72) or Hispanic (HR, 1.8; 95% CI: 1.4-2.5;), 3) had a lower BMI, 4) had diabetes and an abnormal ankle brachial index (ABI) (HR, 1.3; 95% CI: 1.1-1.6;). The strongest single risk factor for contralateral amputation was renal failure (HR, 2.0; 95% CI: 1.6-2.7; p<.001).

# **DISCUSSION AND CONCLUSION**

Risk factors that may cause patients to adequately follow protective health care recommendations for the remaining foot (mental health disorders, illicit drug use, alcohol misuse) were not associated with increased risk. Racial/ethnic factors did affect risk. Those with renal failure or with diabetes and an abnormal ABI are also greater risk. Amputation rehabilitation teams should pay particular attention to individuals with these risk factors to minimize the risk of contralateral amputation and further loss of function.



# Basic IC Psychosocial Issues / Quality of Life

### 2.2.8

# Peer Support for Amputees in the Hospital and in the Community

<u>Dieter Jűptner</u><sup>1</sup>, <u>Nils-Odd Tønnevold</u><sup>2</sup>, <u>Jean-Pascal Hons-Olivier</u><sup>3</sup>

Bundesverbands für Menschen mit Arm-oder Beinamputation (BMAM), Wedemark, Germany. Momentum, Oslo, Norway. Association de Défense et d'Etude des Personnes Amputées, Paris, France

#### **Abstract**

Peer support is a way of giving and receiving help based on the key principles of respect, shared responsibility and agreement on what is helpful. Peer support offers an empathetic understanding of another person's situation based on a mutual shared experience and can be seen in various settings manifest informally or formally in someone's life. In recent years there has been more research in this area and more organisations are offering peer support services.

This symposium will consider what peer support services are needed, available and effective and will have a particular focus on peer support for amputees. It will explore not only examples of peer hospital visiting, but also social forms of peer support.

A broad explanation of peer support is Social Support Theory. This theory explains the most important aspects of social relationships. Social support can be defined as the process of relationship interaction that improves coping, esteem, belonging and competence through exchanged physical and psychosocial resources (these can be perceived or actual). This definition focuses on the idea that the interaction within social support is vital as is the idea that social support is something that improves aspects of a person's life. Through this definition we can see how peer support can be included in social support. Social support has not only been shown to help with challenges and coping but also it has been shown to improve both health outcomes.

## Statement of the objective / learning objectives

Attendees will develop an improved understanding of peer support for amputees in its various forms. Best practice models of peer support from around the world will be shared during the symposium.



# **Symposium Other**

# 2.3.1

Assistive Technologies against Ageing Society - WHO Symposium

See 2.2.1 for the abstract.



# **Basic IC Orthotics: Lower Limb Orthopaedic**

#### 2.3.2

# Orthopedic Technology 4.0 - Digital Creation of 3D-Printed Orthoses For Immobilization, Storage or Correction

Tara Nicoll, Jannis Breuninger Mecuris GmbH, Munich, Germany

#### **Abstract**

Presenting an orthopedic technician's digital workshop as a web-based platform for automating the manufacturing process of a 3D printed immobilization, storage or correction orthosis. Based on the original manufacturing process, all steps are shown, from the scan to the finished end product. Further explained are the important tools in the digital environment, such as automatic posture correction. In addition, the pros and cons of the new manufacturing process and the final product (the 3D-printed orthosis) are shown from the orthopedic technician's perspective.

# Statement of the objective / learning objectives

Visitors gain insight into orthopedic technology 4.0 - the automation and digitization of an orthotic manufacturing process from the orthopedic technicians' and developers' perspectives.



# Free Paper Session Education

### 2.3.3.a

# The Challenges Faced by Students who are using Mobility Devices while Attaining Secondary School Education in Dodoma Municipality in Tanzania

<u>Hortensia Mranga</u>, Emmanuel Michael Kilimanjaro Christian Medical University College, Moshi, United Republic of Tanzania

#### **BACKGROUND**

Mobility aids like prostheses, orthoses, crutches, walking canes, walking frames and wheelchairs are among the common types of assistive devices used to improve personal mobility for people with disabilities (WHO, 2017). Disability as part of human condition almost everyone will temporarily or permanently be impaired at some point in life, those who survive to old age will experience difficulties in functioning. It is a leading cause of marginalization in education.

#### AIM

The study aimed at giving real situation facing students with physical disability attending secondary schools. It will help Government and Non-Government organizations towards the existing challenges facing physical disabled students.

#### **METHOD**

Quantitative, descriptive cross-sectional study was used. It was carried out in Dodoma Municipal, with 23 Secondary Schools involved.

Convenience sampling method was used. Sample size of 38 students with physical disability using mobility assistive devices within selected Secondary Schools was obtained. While the ones using mobility devices but not willing to participate, or those do not use mobility assistive devices were excluded.

The information collected analyzed using Software Package for Social Science (SPSS) version 20 and Microsoft Excel. Figures, tables and narrations were used to present the findings. The ethical clearance was obtained from Faculty of Rehabilitation Medicine Research Committee.

#### **RESULTS**

The study involved 38 participants of which 27 (71%) were males and 11 (29%) were females. The age ranges between 13 to 24 years. The mean age was 25 years. Their study classes were; 6 (15.8%) Form One, 7 (18.4%) Form Two, 14 (36.8%) Form Three, 1 (2.6%) Form Four, 8 (21.1%) Form Five and 2 (5.3%) Form Six.

The devices used were; 16 (42.1%) Prostheses, 4 (10.5%) Orthoses, 10 (26.3%) walking canes/clutches and 8 (21.1%) wheelchairs. Some participants mentioned that they are facing problems in using assistive devices for accessibility of leisure places, washrooms and classrooms. The devices were obtained either by donation which was 20/38 (52.63%), or bought which was 18/38 (47.37%).

The major barriers were failure to participate in sports and not able to access infrastructures. However, students were well handled by teachers.

# **DISCUSSION AND CONCLUSION**

The study showed that teachers had positive attitude towards inclusive education for the students with disability. Yet, the ability to move is an important prerequisite for the performance of their school activities. The students experienced limitation in mobility which hinders them from performing daily activities in schools, including denied rights of accessibility to infrastructures and freedom to health care services.

The challenges faced by disabled students must be addressed urgently.



#### 2.3.3.b

# An International Collaborative Journal Club for Prosthetics and Orthotics Students in Ghana and the United States

Cody Mcdonald<sup>1</sup>, Nana Agyei<sup>2</sup>, Ann Yamane<sup>1</sup>, Michael Murphy<sup>2</sup>, Karen Freisem<sup>1</sup>
<sup>1</sup>University of Washington, SEATTLE, USA. <sup>2</sup>Br. Tarcisius Prosthetics & Orthotics Training College, Nsawam, Ghana

#### **BACKGROUND**

Journal clubs are commonly used to teach allied health, such as prosthetics and orthotics, students to be critical consumers of the scientific literature.[1] Through discussion of peer-reviewed literature, prosthetics and orthotics students develop skills in communication, research appraisal, and current topics in the field. With improved video conferencing technology, virtual journal clubs can provide the additional learning opportunity for students to collaborate across cultural and national borders.[2]

The aim of this study was to explore the potential of intercultural virtual journal clubs for prosthetics and orthotics students in Seattle, WA and Nsawam, Ghana.

#### METHOD

We conducted a cross-sectional survey to evaluate the impact of a virtual journal club between two prosthetic and orthotic educational programs: the University of Washington (UW) Master of Prosthetics and Orthotics in Seattle, Washington, USA and Brother Tarcisius Prosthetics & Orthotics Training College (BTPOTC) in Nsawam, Ghana. Participants in the virtual journal club were assigned to small groups and attended three one-hour sessions conducted via Zoom software. A survey assessment of 10 questions with response options on a Likert-type scale (1-5, 1=strongly disagree, 3=neutral, 5=strongly agree) and 3 open-ended questions was administered. Descriptive statistics (e.g., median, interquartile range and frequency) were calculated.

#### **RESULTS**

Nineteen of the twenty-three prosthetics and orthotics students (11 UW, 8 BTPOTC) who participated in the virtual journal club (10 male, 9 female), returned the survey (83% response). Participants reported mixed perceptions of the virtual journal club experience with BTPOTC students satisfied (median:4, IQR:0.25) and UW students neutral (median:3, IQR:1.0). All BTPOTC students expressed desire to participate in future journal clubs, while three UW students declined future participation.

The most commonly reported benefits of the journal club included increased awareness of global prosthetic and orthotic education and clinical practice (median:4, IQR:0.5) and improved ability to communicate with peers (median:4, IQR:0.5). Areas for future improvement include improved internet connection and/or implementation of other technology (i.e., Google Docs, WhatsApp). Additionally, a number of students suggested discussion of case studies rather than journal articles for future meetings.

#### **DISCUSSION AND CONCLUSION**

Virtual journal clubs are a viable option to build intercultural understanding, promote student skill in communication, and expand professional networks. However, technology remains a challenge for virtual collaborative projects. Students, particularly those in Ghana, remain optimistic about international collaboration and support future opportunities to interact with prosthetist orthotist peers. Future efforts could include alternate technologies and explore the use of case studies rather than journal articles.

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#### 2.3.3.c

# Aiming for Impact: How Can Clinical Academic Roles Within Prosthetic Rehabilitation Help Maximise the Impact of Research?

Chantel Ostler<sup>1,2</sup>, Sisary Kheng<sup>3</sup>

Portsmouth Hospitals NHS Trust, Portsmouth, United Kingdom. <sup>2</sup>University of Southampton, Southampton, United Kingdom. <sup>3</sup>Exceed Worldwide, Phnom Penh, Cambodia

#### **BACKGROUND**

Clinical Academics are healthcare clinicians working with patients in hospitals, outpatient departments or community settings who are also research active. They often have joint posts with academic institutions and as they remain clinically active they are in an ideal positon to identify gaps in healthcare provision and research areas that really matters for patients, clinicians and healthcare providers.

There is a growing body of evidence showing that research active healthcare organisations provide better quality care and have improved patient outcomes. Clinical academics contribute to this impact by advancing the day to day issues they face in their clinical practice through research. Clinical academics can also help to build a culture of research within a department or organisation, promoting evidence based healthcare, attracting and retaining staff and championing the adoption of new and novel interventions.

#### AIM

This free paper aims to share the learning and impact from two case studies of clinical academic roles within prosthetic rehabilitation.

#### **METHOD**

The case studies describe the learning and impact from two clinical academics roles on different sides of the world but linked via an Engineering and Physical Sciences Research Council (EPSRC) Global Challenges research grant. One role is situated in the Uk National health service (NHS)/ University of Southampton and the second in the Exceed prosthetic centres in Cambodia.

#### **RESULTS**

Through these examples we consider the barriers and facilitators to developing and undertaking clinical academic roles within prosthetic rehabilitation including how these roles function and where they sit within the clinical academic career pathway, now and for the future. We also discuss how clinical academic roles are similar and differ in the two settings, what each can learn from the other and what is the real impact for the clinicians involved, the organisations they work within and crucially their patients.

## **DISCUSSION AND CONCLUSION**

These case studies demonstrate that clinical academic roles in both the UK and Cambodia can have a positive impact on building and leading a culture of evidence based practice within prosthetic rehabilitation. In the future these roles need further development and prioritisation by health care providers, academic institutions and funders to both increase clinically focused prosthetic research and to develop a research active, clinically relevant workforce for the future.

### **ACKNOWLEDGEMENTS**

Funders: EPSRC/NIHR (EP/R014213/1).



#### 2.3.3.d

# Scaffolding Communication Skills Across the Master of Clinical Prosthetics and Orthotics at La Trobe University, Australia

Renee Mackenzie

La Trobe University, Bundoora, Australia

#### **BACKGROUND**

Clinical communication skills are widely regarded as a core competency for both professionals and students training to work with clients who use prosthetic and orthotic devices.[1] However, some literature describing communication can be difficult to translate, due to the subjective nature of how we individually classify and enact 'good communication'. A constructive alignment review of prosthetics/orthotics curriculum regarding student/ client interaction showed a lack of description of the competency and limited student feedback until their final year.[2]

#### AIM

This project aimed to strategically scaffold core communication skills with greater clarity and student feedback across the across the entire educational program at La Trobe University, Australia.

#### METHOD

Three core frameworks of the scaffolding were established and defined (Table 1). Application of the core frameworks were applied to existing curriculum involving client interaction.

#### **RESULTS**

Foundation core skills, student self-reflection and feedback mechanisms were built into a new reflective pathway involving a client interview in second year. In third year, the application of core skills was contextualised to working with trans-tibial clients, with in-class time for debrief and feedback. In the final year, core skills are translated in the context of students' clinical placement. Reflective practice is integrated into in- class sessions that occur pre and post placement and feedback is formalised in the context of observed clinical assessments.

Core Frameworks	Application of Framework to Curriculum
IMPROVE CLARITY	<ul> <li>Identify current curriculum related to clinical communication.</li> <li>Review and edit language to improve the overall clarity concerning description of the competency and its application in the program. Where no description exists, new language will be crafted and imbedded in the relevant documents.</li> </ul>
INCREASE FEEDBACK MECHANISMS	<ul> <li>Ensure students receive feedback on the competency at strategic moments in the program where they will be working with clients. This may manifest in assessments but will also include the students' application of reflective practice to their clinical experiences.</li> </ul>
EMBED TRANSLATIONAL CORE SKILLS	<ul> <li>Integrate core communication skills early in the program and refine these at strategic stages contextualised to the clients they are working with in their education.</li> <li>Bring students' awareness to how core skills may translate in a variety of clinical contexts, with a view to equip them for further translation post graduation in their independent clinical practice.</li> <li>Link to assessment where relevant. Core skills include - Reflective practice, active listening, empathy, client interview techniques, non-verbal skills, assertiveness, referral, self-awareness and personality frameworks.</li> </ul>

#### **DISCUSSION AND CONCLUSION**

Student engagement in reflective activities and assessments have yielded insightful reflections as they speculate how personality traits may translate in clinical practice. A new communication scaffold was designed and integrated into the Master of Clinical Prosthetics and Orthotics at La Trobe University. The application of this model is hoped to better equip students with core skills relevant to future practice as a reflective and competent clinical communicator.

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#### 2.3.3.e

# **Building Graduate Identity through Portfolio Based Assessment**

Sarah Anderson, <u>Nathan Collins</u>, Anthony Francis La Trobe University, Melbourne, Australia

#### **BACKGROUND**

Since 2016, the department of Prosthetics and Orthotics at La Trobe University, Melbourne has utilised an online assessment workbook for Clinical Placement using PebblePad. PebblePad is a web-based program provided to all staff and students at La Trobe University to support the creation of personal learning space (PLS) and eportfolios.

#### AIM

To inform the Prosthetic and Orthotic Education community about Portfolio based assessment.

#### METHOD

PebblePad allows students to collect and create evidence of their clinical learning in the form of journals, blogs, reflections, web folios, photos, and assessor initiated workbooks. The workbooks are clearly structured to link to the Intended Learning Outcomes of the clinical placements subjects. The workbooks also align with the Australian Association of Prosthetics and Orthotics (AOPA) Graduate Entry Competency Standards,[1] thus complying with National Accreditation requirements. The workbooks are competency based, structured and assessor initiated.

#### **RESULTS**

The recent focus on tangible graduate outcomes has resulted in higher expectations of external stakeholders and an intensified global pursuit of the work-ready graduate, accelerated by recent softening in graduate labour markets and ongoing global economic stagnation.[2] The need for graduates to establish their own Graduate Identity, for positional advantages in highly competitive labour markets are well documented.[3]

To address the issue of Graduate Identity and to create students who can thrive in a rapidly changing world, an additional focus was incorporated. It was clearly understood that while structured, competency based workbooks were important, a focus on learners and learning was needed—especially learning through real world experience. This has resulted in us introducing a portfolio-based assessment that places the learner at the heart of his or her own learning.

### **DISCUSSION AND CONCLUSION**

Pebblepad has seen student create a reflective portfolio of work belonging to them. This can be used to demonstrate to prospective employers their strengths and challenges and what they as a learner have gained from their experiences on clinical placements.

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### 2.3.3.f

### **Cultural Competency Training to Ensure Graduates can Provide a Culturally Sensitive and Safe Clinical Service**

Michael Dillon, Sarah Anderson La Trobe University, Melbourne, Australia

#### **BACKGROUND**

La Trobe University requires all commencing students to complete an online program - Wominjeka La Trobe: Indigenous Cultural Literacy for Higher Education - which introduces Indigenous Australian history, culture and customs. The course emphasises the importance of a rich and relevant cultural heritage and makes the link to the broader graduate competency of cultural literacy. The course helps students critically reflect on their own attitudes, values and beliefs.

### AIM

To broaden the cultural literacy of graduates such that they can work with people from diverse cultures reflective of Australia's multicultural population.

### **METHOD**

The Cultural Competencies training program [1] is an online or blended training course developed by SBS in concert with Multicultural New South Wales, the Australian MultiCultural Foundation, and International Education Services. The course features multimedia learning modules that explore topics including: cross-cultural communication, addressing stereotypes, unconscious bias, diversity and the benefits of multiculturalism in the workplace. The course includes animations and films, quizzes, and people telling real stories, as well as an indepth cultural atlas [2] that provides country/cultural specific information such as expectations of modesty that extend the general principles taught in the training program.

### **RESULTS**

The course has been introduced as part of the usual pre-clinical placement workshops for final year prosthetic/orthotic students. Having completed the face-to-face introduction prior to placement, students complete the online training while on clinical placement through the university's Learning Management System. In this way, students are able to undertake this study and reflect on their experiences working with cultural and ethnically diverse groups typical of Australia's multicultural population at the time they are most engaging. Students participate in a second face-to-face workshop after clinical placement where they are able to reflect on and discuss their encounters and experiences while on placement; thus extending their learning experience.

### **DISCUSSION AND CONCLUSION**

Embedding the SBS Cultural Competencies training program has provided prosthetic/orthotic students with access to a high-quality curricula to develop the cultural competencies needed to work with a culturally diverse population typical of Australia's multicultural society, and thereby meet the requirements set forth by the Australian Orthotic Prosthetic Association's Entry-Level Compensarcy Standards.[3]

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### 2.3.3.g

## Prosthetics and Orthotics Students' Views Regarding Improving Clinical Education: A Qualitative Study

### Saeed Shahabi

Iran University of Medical Sciences, Tehran, Islamic Republic of Iran

#### **BACKGROUND**

Clinical education is an essential part of Prosthetics & Orthotics (P&O) education. During this period, students gradually acquire experience and prepare their minds to solve the patient's problem. The aim of this study was to explore Iranian P&O students' views and expectations regarding improving clinical education.

### AIM

The aim of this study was to explore Iranian P&O students' views and expectations regarding improving clinical education.

### **METHOD**

A qualitative content analysis method was used to obtain an understanding of prosthetics & orthotics students' views. Qualitative data were collected in Focus Group Discussion (FGD) sessions were held (8 group discussions with 26 participants) in a quiet and comfortable room at the student's clinical education environment. Sessions continued until data saturation.

### **RESULTS**

During the FGD sessions, notes and ideas were classified and assorted. The themes of the study are (1) implementation of the educational curriculum, (2) teaching and evaluation methods, (3) personal and professional characteristics, and (4) Relationships of the clinical learning environment.

### **DISCUSSION AND CONCLUSION**

The result of this study showed that prosthetics & orthotics educational planners must pay attention to some issues to improve the clinical education process such as: the proportion between the number of students and facilities of clinical education centers, provide appropriate educational services for the job market, compiled educational program, presence of faculty members in clinical education centers, and formulating a specific evaluation framework.

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### **ACKNOWLEDGEMENTS**

This article is based on a thesis written by the first author in partial fulfillment of the MSc Degree.



## Symposium Prosthetics: Lower Limb Transfemoral

### 2.3.4

### Scientific Explorations Regarding Osseointegration to Inform Clinical Practice and Support Consumer Decision Making

Sally Cavenett<sup>1,2,3</sup>, Laurent Frossard<sup>4,5,6,7</sup>, Mark Taylor<sup>8</sup>, Kerstin Hagberg<sup>9,10</sup>

Orthotics & Prosthetics Sth Australia, SA Health, Adelaide, Australia. <sup>2</sup>Flinders University SA, Adelaide, Australia. <sup>3</sup>ISPO Australia, Adelaide, Australia. <sup>4</sup>YourResearchProject, Brisbane, Australia. <sup>5</sup>Griffith University, Gold Coast, Australia. <sup>6</sup>Sunshine Coast University, Maroochydore, Australia. <sup>7</sup>Queensland University of Technology, Brisbane, Australia. <sup>8</sup>Medical Device Research Institute, Flinders University, Adelaide, Australia. <sup>9</sup>Sahlgrenska University Hospital, Gothenburg, Sweden. <sup>10</sup>Dept of Orthopaedics, Sahlgrenska Academy, Gothenburg University, Gothenburg, Sweden

### **Abstract**

As Osseointegration (OI) surgery for prosthetic limb attachment is becoming more commonplace globally, clinicians in rehabilitation and prosthetic care, and decision makers, need to be informed of the contributing factors for success, and understand adverse events that may arise. Consumer quality of life, and lived experience with traditional sockets and OI procedure need to be considered, coupled with scientific data of bone fragility and integrity and long term behaviour.

This symposium aims to inform the clinical audience of research conducted with OI and hip implant patients to improve the understanding of the evidence outside of the surgical arena. Relevant patient selection, understanding unique bone characteristics, awareness of surgical techniques and available funding pathways, can contribute to successful patient outcomes.

Presentation will be delivered by expert in clinical care providing long term knowledge after 28 years of experience with OI procedure following lower limb amputation. Scientific research presentation will share observations and evidence from studies reporting on OI global trends, program accessibility and data from funding providers. Biomedical research presentation will deliver learnings from research including bone fracture and assessment of performance of orthopaedic devices; and discuss how we can use computational modelling to simulate bone and implant compatibility to inform implant design and surgical decisions, and to assess the safety and efficacy of osseointegrated prosthetic devices.

Concept of comprehensive worldwide patient registries, and establishment of prosthetic and rehabilitation extended scope of practice education will be explored; enhancing the ISPO practitioner community through collaborative research, and best clinical care.

### Statement of the objective / learning objectives

Learning's include: Global osseointegration uptake; literature review; long-term patient experience in Sweden; learning's from fixation and bone adaptation in joint replacements; and computational modelling to inform safety and efficacy of osseointegrated prosthetic devices.



### **Free Paper Session**

### **Prosthetics: Lower Limb Ankle & Foot - General**

### 2.3.5.a

### Improving Decision Making for Prosthetic Fitting Using Advanced Technologies in a Bilateral Transtibial Amputee – Case Study

<u>Yael Dotan Marom</u>, Richard Levi, Yana Moisescu, Oren Barzel, Israel Dudkiewicz Sheba Medical Center, Ramat Gan, Israel

### **BACKGROUND**

Choosing the correct prosthetic foot type is a major decision for the rehabilitation team. The correct choice greatly enhances the amputees gait abilities and independence, however the rehab team should ensure that the amputee's mobility level is appropriate to the characteristics of the foot. In this case study we examined different prosthetic feet using advanced technologies thus gaining exact measurements and not relying on subjective decision making.

### AIM

The aim of the study was to choose the most appropriate prosthetic foot type based on data collected from gait analysis advanced technologies combined with functional tests.

### **METHOD**

Our subject is a young traumatic K3 bilateral transtibial amputee toward the end of the gait learning and prosthetic fitting stage. Two different prosthetic feet were fitted and aligned, and a week of adaptation and physical therapy. Each foot was evaluated using functional tests (TUG, 6 min walk), gait analysis (kinetics, kinematics, spatiotemporal measurements, pressure mapping and COP fluctuations) using the GRAIL (Motek), ZEBRIS and a video study. The feet evaluated were multiaxial type foot (Navigator, Endolite) and stored energy (STEN) (Variflex Ossur). Data was analyzed by physical therapy and gait analysis lab team reaching an evidence based decision.

### **RESULTS**

Walking with the Stored energy prosthesis showed the following results: 31% faster in the TUG and 200% further in the 6 min walk. Similar spatiotemporal parameters, however the step length was 15% longer and the cadence 12% lower. The Center Of Pressure movement along a single limb (single support line) was 40% longer (as demonstrated in figure 1). Average maximum pressure showed increased pressure in the push off phase. The video study showed a marked advantage in favor of the STEN.

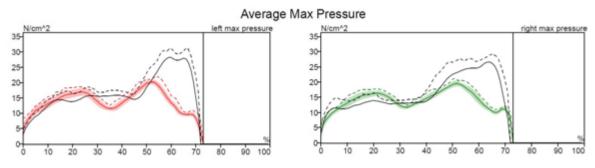


Figure 1. Maximal pressure graph from Zebris STEN: Grey, Multiaxial: Coloured

### **DISCUSSION AND CONCLUSION**

The results suggest a quicker and more efficient gait pattern in the functional test. Gait analysis demonstrated a more effective COP movement in single limb support phase allowing improved Cadence & Step length. Walking with STEN showed push off suggesting 3<sup>RD</sup> rocker . The above results demonstrate active tibial progression and full length toe lever. In our opinion, using scientific evidence from these technologies greatly enhanced decision making when choosing prosthetics.



### 2.3.5.b

### An Innovative Foot Module with Easily Accessible Frontal Plane Adaptation Enhances the Locomotion on Uneven Ground

Bjoern Altenburg, Michael Ernst, Malte Bellmann, Thomas Schmalz, Henrik Gerke Ottobock SE & Co. KGaA, Goettingen, Germany

### **BACKGROUND**

Uneven ground is a frequent challenge for amputees locomotion. An adaptation in sagittal plane or frontal plane or both is required. The lack of adaptability of prosthetic components requires compensational movement strategies by the user. For frontal plane adaptations the split toe feature adds some functionality. However, even with split toe the ROM is clearly limited and needs high force impact for minor adaptations. Now there is a novel foot module allowing for 10° inversion/eversion through a dedicated joint.

### AIM

This study investigates the hypothesis that a novel foot module with easily accessible frontal plane adaptation enhances the locomotion on uneven ground and makes a valuable contribution to up to date limited data available of amputees gait on cross-slopes.[1-5]

### **METHOD**

12 unilateral TT amputees participated in this study. Walking on level ground and cross slopes (5°, 10°) was measured, completed with 3 setups: everyday foot (individual ESR), the novel foot module, a reference ESR (Triton LP, Ottobock or Proflex LP, Össur). The accommodation time for each was minimum four weeks. For the measurements a gait analysis system (12 Vicon Bonita cameras, 2 Kistler force plates) was used. Next to the biomechanical measurements the participants walked an indoor course (gravel, obstacles, cross slopes, tight turns) and completed questionnaires with respect to socket comfort, safety and overall satisfaction during the indoor course and their >4 weeks daily use of the components.

### **RESULTS**

For the carbon structure of the novel foot module an early and nearly full adaptation to the cross slope at the beginning of mid stance was measured. The reference ESR feet showed significant (p<0,05) less adaptation with maxima at the end of terminal stance. The COP path of the novel foot clearly shows a more physiological pattern (referring to measurements of the sound side and control group) compared to the ESR feet. The measured external knee adduction moment (EAM) at the 10° valley condition was significantly reduced with the novel foot module. The questionnaires report significantly higher ratings for perceived safety and socket comfort using the novel foot module compared to the reference ESR foot used in the study. Eight out of twelve TT users preferred the novel foot module over the reference ESRs for their daily routine.

### **DISCUSSION AND CONCLUSION**

The results confirm benefits of the novel foot module when ambulating on cross slopes as one condition of uneven ground. Especially for TT amputees it's crucial to minimize recurring improper frontal knee loads on the affected side. Such component functionality contributes to minimize frontal knee loads. Due to the faster and more comprehensive adaptation to the cross slope condition, less compensation is required and users feel more safe and comfortable when ambulating on uneven ground using the novel foot module.

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### **ACKNOWLEDGEMENTS**

The foot module was developed from the Ottobock SE & Co. KGaA.



### 2.3.5.c

### **Design and Computer Simulation of Adjustable Prosthetic Foot**

<u>Carlos Galván-Duque</u><sup>1</sup>, Daniela Sánchez<sup>2</sup>, Isabel Bolivar<sup>1</sup>, Jorge Letechipia<sup>2</sup>

<sup>1</sup>Applied Research and Technology Institute, Universidad Iberoamericana, Mexico City, Mexico. <sup>2</sup>Department of Engineering Studies for Innovation, Universidad Iberoamericana, Mexico City, Mexico

### **BACKGROUND**

Near 90% of the amputees need lower limb prosthesis. Therefore, the prosthetic foot is one of the most important prosthetic components. It must fit in size and grade of mobility for each patient. Higher mobility feet are usually expensive, making difficult to obtain an appropriate prosthesis in size and mobility for the paediatric patients who grow in an accelerated ratio. An adjustable, dynamic response, prosthetic foot could offer a solution for this population.

### AIM

To design a prosthetic foot with dynamic response that can adjust its size, and test it in a computer simulation.

#### **METHOD**

A carbon fibre prosthetic foot was designed. It has a stainless steel mechanism which provides manual adjustment of 4 sizes. The mechanic properties of the carbon fibre arrangement were obtained as specified by the ASTM D3039 standard in a certified laboratory. The keel and the heel were tested following AOPA's Foot Project methodology<sup>1</sup> using a CAD model of the designed foot. APOA's Heel Test and Keel Test were simulated in a static structural model using ANSYS (PA, USA) and Finite Element Analysis was used to calculate deflection and security factor for each part of the prosthetic foot.

### **RESULTS**

The adjustable prosthetic foot (figure 1) has a height of 70 mm and an adjustment of 30 mm. This allows to adapt to 4 sizes. The change between sizes is continuous, therefore, it would be possible to achieve "half sizes".

The simulation of AOPA's Prosthetic Foot Project Heel Test and Keel Test, are shown in figure 2. Figures 2A and 2B present the maximum total deformation for heel (13.613 mm) and keel (34.151 mm) at 1230 N load. Figures 2C and 2D show the minimum security factor achieved for heel (1.478) and keel (1.30) for the same load.

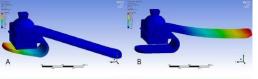
### **DISCUSSION AND CONCLUSION**

The adjustment mechanism allows to change the prosthetic foot in 4 sizes, it would permit to start, for example, with a 19cm initial size to a 22cm final size. The total displacement of the heel fulfils AOPA's criteria for dynamic response feet (13mm), while keel's displacement is higher (25mm required). Keel's energy return must be calculated to fully conclude if it complies with AOPA's dynamic requirements.[1] Safety factor is enough for both, heel and keel.

### REFERENCES

[1] AOPA's Prosthetic Foot Project, 2010.

Figure 1. Carbon fibre adjustable prosthetic foot.



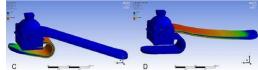


Figure 2. Finite Element Analysis results for AOPA's Heel and Keel tests. A. Total heel deflexion, B. Total keel deflexion, C. Heel safety factor, D. Keel safety factor.

### **ACKNOWLEDGEMENTS**

This project is funded by the Applied Research and Technology Institute (project F145006-SNI), and the Research Division at IBERO.



### 2.3.5.d

### A Model to Predict Roll-Over Shape Radii of Prosthetic Feet for Clinical Prescription

Steven Gard<sup>1,2</sup>, Sarah Chang<sup>3</sup>, Matthew Major<sup>1,2</sup>, Michael Cavanaugh<sup>1</sup>, Paul Hammond II<sup>2</sup>, Rebecca Stine<sup>2</sup>
<sup>1</sup>Northwestern University Prosthetics-Orthotics Center, Chicago, IL, USA. <sup>2</sup>Jesse Brown VAMC, Chicago, IL, USA. <sup>3</sup>Orthocare Innovations, Edmonds, WA, USA

### **BACKGROUND**

The mechanical properties of prosthetic ankle-foot devices affect the standing and walking abilities of lower-limb prosthesis users.[1-4] Ankle-foot roll-over shape (ROS) is the effective geometry of the ankle-foot rocker system created between heel contact and contralateral heel contact during stance phase of gait.[5] ROS characteristics can be modified by changing the mechanical properties of prosthetic ankle-foot devices.[4]

#### AIM

The purpose of this study was to validate a prediction model that estimates ROS radii from the effective ankle joint rotational stiffness for different combinations of prosthetic keels and articulated ankle joint dorsiflexion bumpers.

### **METHOD**

Mechanical properties of different combinations of 'Soft', 'Medium', and 'Hard' stiffness prosthetic keels and ankle dorsiflexion bumpers were determined for a Venture prosthetic foot (size 27 left) (College Park Industries, Warren, MI, USA).[6] These mechanical properties were input to a prediction model that estimated effective ROS radii for different keel-bumper combinations subjected to an effective applied mass of 80kg. The prediction model was validated through comparison of laboratory-measured ROS radii for different keel-bumper combinations of the prosthetic foot using a weighted, inverted pendulum-like apparatus. ROS radii were calculated from marker kinematic trajectories and center of pressure position.[5] Trends between the prediction model and laboratory measurement were compared.

#### **RESULTS**

The ROS radii increased proportionally with the stiffness of the different keel-bumper combinations. The ROS radii prediction model estimated the Venture Foot ROS radii to be in the range from 32.0-46.4 cm, with an average of 39.1 cm (Table 1). The ROS radius for an able-bodied adult during gait is approximately 36-40 cm. The validation experiment demonstrated similar trends for the ROS radii as determined from the prediction model.

		bumper			
	Ī	soft	med	hard	
	soft	32.0 [27.9]	37.3 [32.3]	39.3 [33.5]	
keel	med	34.1 [29.1]	40.3 [33.6]	42.7 [34.5]	
	hard	36.3 [31.0]	43.6 [34.1]	46.4 [35.4]	

Table 1: ROS radii (in cm) predicted by the model and from [laboratory measurement] for different combinations of foot keels and ankle dorsiflexion bumpers in a size 27 Venture foot.

### **DISCUSSION AND CONCLUSION**

This study used laboratory-measured ROS radii to validate a ROS prediction model and demonstrate the relationship between ROS radii and the stiffness of keel-bumper combinations. Given the stiffness values of prosthetic foot keel and bumper components, the validated ROS prediction model could be used by prosthetists in the clinic when prescribing a foot with interchangeable keels and ankle bumpers.

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### **ACKNOWLEDGEMENTS**

This study was supported by VA RR&D Service (grant no. RX002107) and NIDILRR (grant no. 90AR5031).



### 2.3.5.e

### Biomechanical Analysis of Stair Ascending Subjects with Chopart Amputation

Thomas Kaib<sup>1</sup>, Johanna Schäfer<sup>2</sup>, <u>Julia Block</u><sup>1</sup>, Daniel W.W. Heitzmann<sup>1</sup>, Merkur Alimusaj<sup>1</sup>, Sebastian I. Wolf<sup>1</sup> Heidelberg University Hospital, Dept. for Orthopaedics and Trauma Surgery, Heidelberg, Germany. <sup>2</sup>Koblenz University, RheinAhrCampus, Remagen, Germany

### **BACKGROUND**

Ascending stairs demands a higher range of motion (ROM) in all lower limb joints compared to gait on level ground, especially in the ankle joint.[1] Chopart amputees provided with clamshell devices rely on a fixed physiological ankle substituted by limited deformation of a carbon fiber foot plate with a reduced ROM compared to prosthetic feet in transtibial prosthesis. An increased compensatory effect, compared to typical transtibial amputees behaviors seen in the literature,[2] was expected.

### AIM

The aim of this study was to investigate stair ascent in subjects with chopart amputation who are provided with a clamshell device to identify the compensatory movements due to the lack of ankle motion compared to reference subjects.

### **METHOD**

Six subjects with unilateral chopart amputation (5 male, 1 female,  $55 \pm 10$ years,  $1.80 \pm 0.05$ m,  $94 \pm 17$ kg) and 17 unimpaired reference subjects (8 male, 9 female, age:  $28y \pm 6$ , size:  $1.76m \pm 0.07$ , weight: 71kg  $\pm 10$ ) performed a 3D motion analysis including plantar and socket pressure measurement while ascending stairs using a step-over-step strategy. Kinematics and kinetics of the lower limbs and trunk motion was analyzed, normal force and CoP excursion of the pressure sensors, as well as the sole angle were calculated. A Mann-Whitney-U-Test was performed between the three groups (involved, sound, references).

### **RESULTS**

The ankle ROM was increased in the sound side compared to the reference data whereas the prosthetic ROM was reduced. The foot positioning and initial contact on the involved side resulted in a forefoot contact comparable to an 'apparent equinus'.

During weight acceptance the involved side showed higher hip flexion, increased hip flexing moment, reduced knee flexing moment. The sound side showed higher knee flexing moments and ankle power absorption compared to reference.

Throughout forward continuance the trunk was tilted towards the involved side, accompanied with an increased knee and hip flexion compared to reference. Correspondingly external hip adduction moment and dorsal flexing moment on the involved side as well as knee extending moment on the sound side were lower compared to the reference.

### **DISCUSSION AND CONCLUSION**

Gait pattern of subjects after chopart amputation differ from reference in both limbs. Chopart amputees tend to use compensatory movements to countervail the missing ROM through the clamshell device. The principle patterns on the involved side were comparable to already known mechanisms found in earlier research concerning transtibial amputees [2, 3]. The main compensatory movements on the sound side however were in the ankle and knee joint deviating from subjects with more proximal amputations.

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### **ACKNOWLEDGEMENTS**

We would like to thank all participants for their attendance.



### 2.3.5.f

### Deformable Link Segment (DLS) Analysis of Deformation Power in Prosthetic Foot-Ankle Components

Stacey R. Zhao<sup>1,2</sup>, <u>J. Timothy Bryant</u><sup>1,2</sup>, Qingguo Li<sup>1</sup>

<sup>1</sup>Mechanical and Materials Engineering, Queen's University, Kingston, Canada. <sup>2</sup>Human Mobility Research Centre, Queen's University and Kingston Health Sciences Centre, Kingston, Canada

### **BACKGROUND**

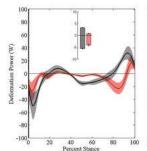
Modern foot components, designed to aid in forward propulsion, store and return energy during stance through the deformation of elastic components.[1] As such, biomechanical power analyses of these devices incorporate deformable regions.[2,3,4] However, current approaches may be restricted by imposing rigid body motion assumptions for the deforming region.[2] DLS analysis was recently reported, which overcomes previous limitations by solving segment angular velocity and deformation velocity simultaneously.

#### AIM

Estimates of stance phase prosthetic foot-ankle deformation power were compared in a cohort of active transtibial prosthesis users using three current methods from the literature and the DLS analysis.

### **METHOD**

Lower limb kinematics were recorded for three participants during level walking using optical motion tracking (Qualisys, Sweden). Ground reaction forces and centre of pressure trajectories were simultaneously recorded using embedded force plates (AMTI, USA). Unified Deformable (UD) segment, Distal Foot (DF), and Compliant Power (CP) power estimates were obtained using previously described procedures.[3,4,5] DLS deformation velocity was estimated using methods described by Zhao,[6] then its scalar product with the ground reaction force vector was used to compute deformation power. Individual subject results were



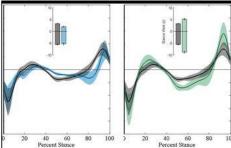


Figure 1. Stance phase deformation power for a typical subject: DF (red), CP (blue) and UD (green) estimates compared to DLS anlysis (grey). Inset bars represent stance work (integral of power with respect to time).

ensemble averaged across steps to provide mean profiles and 95% confidence intervals.

### **RESULTS**

DLS deformation power estimates were greater in magnitude than DF throughout stance (Figure 1a). Of note are the low estimates for DF power in mid-stance, which correspond to a near-zero angular velocity for the foot. DLS peak collision and push-off power were similar in magnitude to CP (Figure 1b). However, differences are apparent in the timing of transitions between positive and negative regions of power. DLS and UD power displayed similar timing in the transitions between power regions (Figure 1c). The UD model exhibited greater peak push-off power and stance work than DLS estimates; this corresponds to higher angular velocity estimates in the UD model.

### **DISCUSSION AND CONCLUSION**

Estimation of deformation power (the time rate of change of elastic potential energy) of a prosthetic foot-ankle device requires approximation of the deformation velocity. This in turn, requires estimation of segment angular velocity. Results indicated that deformation power values are highly sensitive to these kinematic estimates and further suggest that care should be taken in the interpretation of data obtained using different methods described in the literature.

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### 2.3.5.g

### Method for Predicting Midstance Deformation Characteristics of Prosthetic Foot Systems

Sydney Low<sup>1,2</sup>, Stacey Zhao<sup>1,2</sup>, Megan Hamilton<sup>1,2</sup>, Justin Saddlemyre<sup>1,2</sup>, Tim Bryant<sup>1,2</sup> Queen's University, Kingston, Canada. <sup>2</sup>Human Mobility Research Centre, Kingston, Canada

### **BACKGROUND**

Mechanical characterization of passive prosthetic feet is used to provide insight into the influence of different designs on amputee walking performance. Previous studies have investigated prosthetic foot properties throughout single-keel and double-keel loading, however there is a lack of characterization during the transitions between these contact phases.[1-4] The deformation properties during these transition periods are particularly relevant with respect to simulated plantarflexion for advancement into a stable foot-flat position, and dorsiflexion for progression out of midstance into push-off.[4-5]

### **AIM**

The objective is to develop a method that predicts vertical deformation characteristics of foot systems throughout stance, including single-keel and double-keel loading, and that demonstrates the ability to detect differences related to foot design during midstance loading.

### **METHOD**

Mechanical testing was performed on five passive prosthetic foot specimens using an MTS (Eden Prairie, MN) universal testing machine and a similar loading protocol as proposed by Zhao, et al.[4] To capture mechanical properties throughout stance, 17 critical points were extracted from the ISO reference force and shank angle waveforms (ISO22675). Specimens were cyclically loaded at each angular configuration, and one steady state cycle of force-displacement data was extracted. Based on the critical forces and shank angles, and corresponding loading regions, critical displacements were extracted from each curve. Double-keel loading was distinguished by comparing the force at which double-keel

contact was initiated, to stiffness transitions on the forcedeflection curves.

### **RESULTS**

The 17 extracted critical displacements were fit with a spline interpolant and plotted with respect to percent stance for each the five foot specimens to represent predicted foot deformation (Figure 1). A thicker line is used to display the region corresponding to the predicted duration of double-keel loading. The transitions into and out of double-keel contact for the SACH (pink), Niagara Foot (black), Celsus (green), TruStep (orange), and Velocity (blue) occurred at approximately 40-50%, 25-63%, 36-60%, 25-53%, and 25-63% of stance, respectively (Figure 1). More compliant rearfoot designs (Celsus and Velocity) with

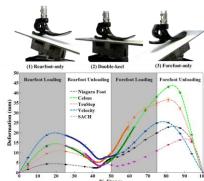


Figure 1. Predicted Deformation Characteristics

larger amounts of deflection were associated with earlier transitions into double-keel contact. Likewise, more compliant forefoot designs (TruStep) were associated with later transitions out of double-keel contact. Stiffer rearfoot and forefoot designs (Niagara Foot and SACH) were observed to exhibit the opposite effect.

### **DISCUSSION AND CONCLUSION**

A method was described to predict the continuous deformation characteristics of prosthetic foot systems throughout stance, with the ability to include both single-keel and double-keel loading phases. The method successfully detected expected differences related to foot design, specifically determining how the initiation and termination of double-keel contact related to keel stiffness.

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### **ACKNOWLEDGEMENTS**

College Park Industries®, Otto Bock®, DuPont™, and Niagara Prosthetics and Orthotics International Ltd. donated samples used in this study.



# Free Paper Session Orthotics: Upper Limb

### 2.3.6.a

### The Effect of Ulnar Deviation Orthosis in Patients with Zigzag Deformity due to Rheumatoid Hand

Aliyeh Daryabor<sup>1,2</sup>, Reza Yazdan Rmaji<sup>1</sup>

<sup>1</sup>Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences, Tehran, Islamic Republic of Iran. <sup>2</sup>Student Researcher in International University of Health and Welfare, Tehran, Islamic Republic of Iran

### **BACKGROUND**

Rheumatoid arthritis (RA) is known as a chronic and multisystem disease accompanied by synovial inflammation leading to deformities such as finger ulnar deviation, pain, as well as functional difficulties. Thus, a conservative treatment in this domain is comprised of orthoses, i.e. features added to the body that aim to correct deformity, reduce pain, and finally improve functionality.

### AIM

The purpose of this study was to evaluate the effect of ulnar deviation orthosis in patients with zigzag deformity due to rheumatoid arthritis.

### **METHOD**

This study was of quasi-experimental research type. In total, 12 patients with rheumatoid arthritis were measured two times: before the start of orthosis use and 4 weeks after use of it. The rate of pain, grip strength, and upper limb function were also measured employing a Visual Analog Scale (VSA), the Jamar Hydraulic Hand Dynamometer, and the Disability of the Arm, Shoulder, and Hand (DASH) Questionnaire; respectively.

### **RESULTS**

After 4 weeks of orthosis use (figure 1), it was found that the scores of pain (p=0.03), upper limb function (p=0.008), and grip strength (p=0.004) had improved significantly in the hands treated over time.



Figure 1: Hand-based ulnar deviation orthosis

### **DISCUSSION AND CONCLUSION**

The results of the present study showed that the use of an ulnar deviation orthosis by patients with zigzag deformity due to RA could reduce hand pain, improve grip strength, and promote the upper limb function. Because of the small sample size as well as lack of a control group in this study, further investigations were needed to support these findings.



### 2.3.6.b

### Biomedical Flexible Sensor Glove as a Monitoring and Diagnostic Tool

Shival Indermun, Taahirah Mangera University of Witwatersrand, Johannesburg, South Africa

### **BACKGROUND**

Hand therapy for patients suffering with hand impairments, caused by physical injury or neurological disorders is often inaccessible to patients that live far from local clinics. In South Africa, 35.2% [1] of the population are situated in rural settlements. Additionally, therapy can be a financial burden either in the cost of treatment, transportation or through repercussions of hindered employment due to the impairment. Therefore, it is imperative that there are accessible and low-cost means for hand impairment monitoring and diagnosis.

### AIM

To develop a low-cost flexible sensor glove that is capable of measuring the range of motion of the fingers for the application of rehabilitation in developing countries.

#### METHOD

Flexible sensors were attached to the PIP and MCP Joints of the fingers onto gloves. The sensors were tested at different bending radii and locations, which resulting in negligible variation. The gloves were validated through testing each joint at  $30^{\circ}$ ,  $45^{\circ}$  and  $60^{\circ}$  degrees. Fluctuations had a maximum variation of  $\pm 5^{\circ}$ . The glove measured the range of motion on 50 healthy subjects in performing daily activities that were derived from the ICF (International Classification of Functioning, Disability and Health) guide [2]. There were no criteria for subject participation apart the fit of the gloves. The procedure included: questionnaire, calibration, basic activities and an evaluation of the device from the participants.

### **RESULTS**

The flexible sensor gloves recorded the range of motion of both hands for each candidate. Each participant performed 20 activities that encompassed the ICF categories of self-care, mobility, communication and domestic. Figure 1 is an example of a candidate's maximum range of motion for 9 of the finger joints during the simulation of brushing teeth. Based on observation, the right hand had a greater functional range of motion during the activity which correlates to the candidate being a right-handed participate.

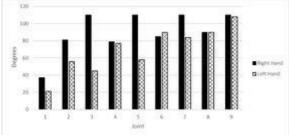


Figure 1. Max and Min ROM Brushing Teeth

### **DISCUSSION AND CONCLUSION**

The gloves proved capable of measuring the degrees of motion of the finger joints. Each glove required medical tape as an additional means of securing the sensors to cater for the narrowness of the candidate's fingers. The candidates felt that the glove had a minor resistance during some of the activities. The data collected provided a minimum range of motion of an individual's daily life routine and validated the gloves use as a finger motion measurement tool.

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### **ACKNOWLEDGEMENTS**

merSETA SA for contributing towards the funding of the research.



### 2.3.6.c

### A Passive Exoskeleton for Overhead Work: What are Biomechanical, Metabolic and Ergonomic Benefits for the User?

Thomas Schmalz
Ottobock SE & Co. KGaA, Goettingen, Germany

### **BACKGROUND**

Overhead work represents a risk factor for developing musculo-skeletal disorders of the shoulder joint.[1] Ergonomic devices (e.g. hand-guided manipulators) have been established for supporting different overhead work activities. However, clear disadvantages have been reported.[2] Therefore, newly developed passive exoskeletons might be beneficial alternatives due to their light weight, high flexibility and wearing comfort. Scientific investigations are essential to define the specific benefits of these new orthotic aids.

### AIM

The aim of the present study was to examine the functional effect of a passive exoskeleton during two different overhead work activities by means of metabolic, kinematic and electromyographic parameters.

### **METHOD**

The passive exoskeleton PAEXO (Ottobock, Germany) was tested under lab conditions by 12 healthy subjects  $(24 \pm 3y, 176 \pm 15 \text{cm}, 73 \pm 15 \text{kg})$  for two overhead activities for 5 minutes, respectively (session A): screw nuts (static condition – SC, fig. 1) and drilling (semi static condition - SSC) in randomized order (10min break). The tasks were also studied without the exoskeleton (session B, order of A and B randomized too). During exercises 3D upper extremity joint angles (VICON, GB and ALKASKA/Dynamicus, Germany), electromyographic parameters of shoulder, back and arm muscles (NORAXON TelemyoDTS, USA) and oxygen rate (CORTEX, Germany) were measured.

### **RESULTS**

With the exoskeleton the oxygen rate was significantly reduced by 10% (SC) and 11% (SSC). During the exercises, the shoulder joint anteversion angle was approximately the same between both conditions for SC (95°) and SSC (115°). With the exoskeleton, the shoulder abduction was increased (35 vs 29° (SC) and 40 vs 32° (SSC), p  $\leq$  0.01). The elbow joint was more flexed with the exoskeleton for SSC (73 vs 67°, p  $\leq$  0.01) and nearly the same for SC (61°). With the exoskeleton the



Fig. 1: Analysis of overhead work: exercise "screw nuts" without (left) and with exoskeleton (right)

mean rectified and RMS-smoothed EMG amplitude was significantly decreased for all muscles. The strongest reductions were identified for the deltoideus (55% SC, 44% SSC, p  $\leq$  0.01), trapezius (41% SC, 28% SSC, p  $\leq$  0.01) and biceps brachii muscles (60% SC, 48% SSC, p  $\leq$  0.01).

### **DISCUSSION AND CONCLUSION**

The differences in EMG activity in conjunction with the very little joint angle alterations indicate reduced shoulder joint loading when wearing the exoskeleton. These biomechanical results as well as the reduced metabolic effort are arguments that the general strain to the user and the risk of developing musculo-skeletal disorders may be reduced when the exoskeleton is used for overhead work activities on a regular basis.

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### 2.3.6.d

### A Newly Designed Shoulder Orthosis for Patients with Glenohumeral Subluxation: A Clinical Evaluation Study

Willemijn Verloop<sup>1</sup>, Claudia Haarman<sup>2</sup>, Reinout van Vliet<sup>1</sup>, John-John de Koning<sup>3</sup>, Hans Rietman<sup>1,2</sup>
<sup>1</sup>Roessingh, Centre for Rehabilitation, Enschede, Netherlands. <sup>2</sup>Department of Biomechanical Engineering, University of Twente, Enschede, Netherlands. <sup>3</sup>Roessingh Rehabilitation Technique, Enschede, Netherlands

### **BACKGROUND**

In the general population many patients are suffering from shoulder complaints (6.9-26%).[1] Glenohumeral subluxation is one of the causes. Providing an orthosis is one of the treatment options.[2] The clinical effect of shoulder orthoses is moderately investigated.[3] Roessingh Centre for Rehabilitation and Roessingh Rehabilitation Technique developed a new type of custom made shoulder orthosis, Roessingh Omo Support (ROS), to achieve approximation of the head of the humerus to the glenoid. Patients should experience high comfort and decrease in pain.

### AIM

This study aimed to assess the usability, clinical benefits and disadvantages of the ROS in patients with shoulder complaints due to glenohumeral subluxation.

### **METHOD**

It concerns a retrospective evaluation study. All patients over eighteen years with shoulder complaints due to shoulder subluxation who received the ROS in Roessingh Center for Rehabilitation between January 2016 - December 2018 were invited. Medical information about patient characteristics was collected from the medical files. Three questionnaires were sent to the patient: two copies of the 'Shoulder Rating Questionnaire' (SRQ, maximum of 100 points) [4] to evaluate before and during use and one self-developed orthosis usability questionnaire. Descriptive analyses of data were performed: mean with SD of the SRQ and satisfaction rating

were calculated. To detect a significant change in the SRQ, a paired

t-test was used.

### **RESULTS**

In total 55 orthoses were prescribed. 29 patients (35 orthoses) admitted the study. The mean age was 50.1 years. Neuralgic amyotrophy was the most common diagnosis (65.5%). The SRQ (before usage) had a mean of 34.9 (SD 12.6) points and the SRQ (during usage) 44.3 (SD 15.0) points. This difference was significant (9.4 points, SD 11.2, p In the orthosis usability questionnaire the most mentioned goals were less pain (71.4%) and arm support (55.2%). 46.4% of the patients reached their goal. The highest benefit was experienced during walking and standing-related activities. The most mentioned benefit was less pain (67.9%) and reported disadvantage was discomfort (57.1%). 69.0% of the patients is still using the orthosis. The mean satisfaction rating is 7.1 (SD 1.4, range 4-10).

### **DISCUSSION AND CONCLUSION**

To our knowledge, there are only few studies that investigate the clinical effect of shoulder orthoses.[2] This retrospective clinical evaluation study of the ROS in 29 patients with complaints from shoulder subluxation shows a significant improvement in functioning (SRQ), decrease of pain and a high rate of satisfaction although the

individual experiences of the patients are very variable. The design of the ROS will need some adjustments to improve comfort.

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## Symposium Orthotics

### 2.3.7

### **Orthotic Reporting Guide**

MS Wong<sup>1</sup>, Marco Cavallaro<sup>2</sup>, Arezoo Eshraghi<sup>3</sup>, Helena Burger<sup>4,5</sup>

<sup>1</sup>Department of Biomedical Engineering, The Hong Kong Polytechnic University, Hong Kong, China. <sup>2</sup>Institute of Materials and Manufacturing Design Department, Brunel University, London, United Kingdom. <sup>3</sup>Prosthetics Department, West Park Healthcare Centre, Toronto, Canada. <sup>4</sup>University Rehabilitation Institute, Ljubljana, Slovenia. <sup>5</sup>University of Ljubljana, Faculty of Medicine, Ljubljana, Slovenia

### **Abstract**

In published literature, there is a large diversity in description of the included subjects and orthoses used. For this reason, direct comparisons of the relevant results are difficult and meta-analyses are likely not possible. Moreover, the levels of existing evidence for most orthotic interventions or related studies are relatively low.

In order to improve the quality of proposal and manuscript preparations on orthotics related studies, ISPO Scientific Committee would like to develop an Orthotic Data Set – a set of minimal data that researchers should present in their proposals and manuscripts, and reviewers could appreciate and assess the researchers' quality of work in a more logical and systemic approach.

The Orthotic Data set is divided into three sections:

- 1) Overall description its contents are general information about participants, such as age, height, weight and other relevant demographic data.
- 2) Health condition and functioning in this part we focus on the data which are necessary to present about health condition and functioning of the included participants, separately for the users of upper limb orthoses, lower limb orthoses and spinal orthoses.
- 3) Description of orthosis characteristics this part describes the data about the orthoses used in the relevant study. Examples of upper limb orthoses, lower limb orthoses and spinal orthoses will be presented.

### Statement of the objective / learning objectives

To develop a common data set of orthotics related research for enhancement of study design, proposal writing and manuscript preparation



## Free Paper Session Paediatrics

### 2.3.8.a

### Changeable Hip Flexion-Abduction Brace after Gradual Reduction using Overhead Traction in DDH

Akihiro Suzuki<sup>1</sup>, Shinjiro Kato<sup>1</sup>, Yoshiki Matsumoto<sup>1</sup>, Tadashi Hattori<sup>2</sup>, Hiroshi Kaneko<sup>2</sup>
<sup>1</sup>Matsumoto P&O Co.,Ltd, Komaki, Japan. <sup>2</sup>Aichi Children's Health and Medical Center, Obu, Japan

### **BACKGROUND**

The treatment of DDH which has not been repaired by pelvic harness or overlooked at the beginning is diverse. For such patients, surgery is often done and there are also various reports on braces after non-invasive reduction. We will report this because we have good results using changeable hip flexion-abduction brace which can change 3 position (Lorenz-Range-Bachelor) after gradual reduction using overhead traction.

#### AIM

We examined 60 patients with DDH (63 hips) aged 6-31months between 2007 to 2015. All patients gradual reduction using overhead traction and the after using changeable hip flexion-abduction brace.

### **METHOD**

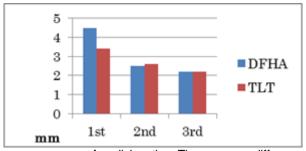
In our hospital, after 4 weeks of horizontal traction we will try to reduce with Over Head Traction for 2 weeks. After checking the reduction by arthroscopy, we cast 4 weeks Lorenz limb position .After that we change to the brace. The brace will change position to Lorentz,-Range- Bachelor every 4 weeks.

From 12 weeks onwards, we will increase the time to remove the brace every hour for 1 day and will be wearing only nighttime in one week. After that, it becomes completely absent after approximately 3 months.

### **RESULTS**

MRI for 63 hips immediately after reduction and 16 weeks after we measured the thickness of the inclusions and confirmed the reduction situation. MRIs under sedation at 1 week, 6 weeks, and 4-10 months\* after reduction. \*the 3rd MRI: ONLY WHEN non-concentric reduction was seen on the 2nd MRI.

- 1. Distance between the femoral head and acetabulum, DFHA (mm)
- 2. Thickness of the ligamentum teres, TLT (mm)



All cases were rescued and there were no cases of re-dislocation. There was no difference in reduction between before and after starting walking.

### **DISCUSSION AND CONCLUSION**

We are producing by changing the position of the fixed limb greatly every 4 weeks, it is possible to prevent the necrosis of the head from being possible because it can be applied for a long time without raising part of the head pressure. Moreover, due to the change of the limb position the joint contracture.

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### 2.3.8.b

### Effect of Ankle-Foot Orthoses on Muscle Activity in Children with Spastic Unilateral Cerebral Palsy During Gait

<u>Lærke Lindskov</u><sup>1</sup>, Ann-Britt Huse<sup>1,2</sup>, Marie Johansson<sup>2</sup>, Ståle Nygård<sup>3</sup>

Sophies Minde, Oslo, Norway. <sup>2</sup>Oslo University Hospital, Oslo, Norway. <sup>3</sup>Oslo Centre for Biostatistics and Epidemiology, Oslo, Norway

### **BACKGROUND**

Hinged ankle-foot orthoses are common prescriptions for children with unilateral cerebral palsy to improve gait function by correcting spastic equinus. Such orthotic management has been found effective in improving kinematic, kinetic and spatiotemporal gait parameters, yet little is known about the effect of orthotic function and orthotic design on muscle activity during walking.

### **AIM**

The aim of this study was to examine if muscle activity in shank muscles of children with spastic unilateral cerebral palsy changes when walking with two designs of hinged ankle-foot orthosis compared to barefoot.

### **METHOD**

This study was a prospective, repeated measures trial with intra-subject comparison between conditions. Electromyography of medial gastrocnemius and tibialis anterior was recorded from 15 children (mean: 8,5 years, range: 5,6 years–10,3 years) with spastic unilateral cerebral palsy during three-dimensional gait analysis. Orthotic interventions consisted of custom-made hinged ankle-foot orthoses with flat and contoured footplates. One-way ANOVA with repeated measures was applied to detect change in total muscle activity across the gait cycle quantified as the area under each ensemble averaged linear envelope. Relative difference in muscle activity profiles between conditions was assessed using bootstrapping from which mean curves were plotted with 95% confidence intervals.

### **RESULTS**

No significant difference was found in total muscle activity across the gait cycle for either medial gastrocnemius (p-value 0.365) or tibialis anterior (pvalue 0.124) between the three walking conditions. For the ankle-foot orthosis with flat footplate (AFO), a significant reduction in muscle activity was observed between 7-23% and 75-80% of the gait cycle for medial gastrocnemius and 10-28%, 47-52% and 70-89% for tibialis anterior (Figure 1). For the ankle-foot orthosis with contoured footplate (AFOc), a significant reduction in muscle activity was observed between 0-20% of the gait cycle for medial gastrocnemius and 7-27% and 68-85% for tibialis anterior.

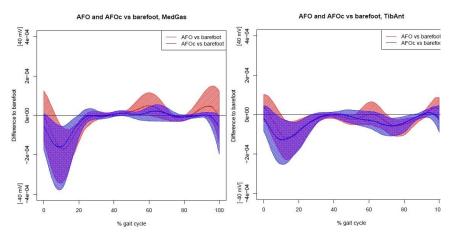


Figure 1. Difference plots with 95% confidence intervals for medial gastrocnemius(left) and tibialis anterior(right). The plots depict the difference from barefoot to orthotic conditions with AFO in red and AFOc in blue. Significant change is detected where outer plot limits clear the x-axis.

### **DISCUSSION AND CONCLUSION**

This study found that total muscle activity remained unchanged between the three gait conditions for both medial gastrocnemius and tibialis anterior. However, the profile of muscle activity when walking with ankle-foot orthoses differed from that of barefoot gait. Differences were most pronounced in early stance phase which may indicate an absence of spastic activation in medial gastrocnemius and the subsequent lack of co-activation in its antagonist, tibialis anterior, when walking with ankle-foot orthoses.

### **ACKNOWLEDGEMENTS**

This project received financial support from Sophies Minde Research and Development fund and NITO Ortopedi Veres fund.



### 2.3.8.c

### 3D Helmet therapy in Plagiocephaly - Factors Influencing Predictability of Reduction in Cranial Asymmetry

Ken Shaw<sup>1</sup>, Sarah Anderson<sup>2</sup>, Brianna King<sup>1</sup>
Orthokids, Melbourne, Australia. <sup>2</sup>La Trobe University, Melbourne, Australia

### **BACKGROUND**

Advocates for helmet therapy cite persistent deformation, concerns about cosmetic outcome and the potential social effects on the child.[1] Measurement of plagiocephaly is subjective, more recently objective measures such as Cranial-Vault-Asymmetry-Index (CVAI) has been used to quantify the degree of deformity.[2] With no cocensus as to level of improvement achievable, treatment it is left to the decision of the referring Doctor, Orthotist and parent. Recent studies suggest that beginning treatment early results in a higher degree of correction.[3]

#### AIM

The aim of this study was to determine what factors are likely to influence the success of helmet therapy in reducing CVAI score.

### **METHOD**

Infants were referred to an orthotic clinic for assessment and/or treatment of plagiocephaly. Infants were assessed and a 3-Dimensional scan (TechMed3D Bodyscan) was taken of the infants' head. CVAI score was determined by the Techmed3D MSoft software. If helmet therapy was prescribed, the head scan data was modified (Rodin 4D) by a qualified orthotist. Software engineers used this data to create a custom 3D printed helmet and custom bamboo foam liner. A fitting appointment occurred approximately 7 days later. Infants were reviewed approximately every 2-4 weeks with scans taken at each appointment. Treatment was ceased when CVAI measurements improved to within normal limits or parents chose to cease treatment.

### **RESULTS**

300 cases were included in the analysis of infants who had undergone helmet therapy for plagiocephaly. A linear regression was undertaken exploring the extent to which the change in the dependent variable, CVAI obtained through helmet therapy could be explained by each of the independent variables, age at treatment, severity of deformation, length of treatment, the presence of torticollis, positioning therapy.

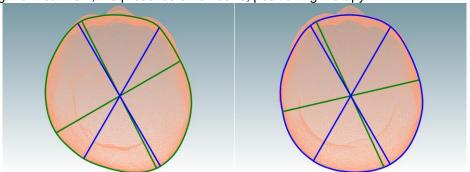


Figure 1. Initial scan and scan following four months treatment

### **DISCUSSION AND CONCLUSION**

Reported problems of compliance with helmets around skin irritation, discomfort and heat retention are all addressed by utilizing a 3D printed model with bamboo liner to achieve a close fit, reduction in weight, less skin irritation and heat retention. The results of the linear regression will be presented to explain how much variance in CVAI score can be explained by the influencing factors.

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### 2.3.8.d

### To Helmet or not to Helmet: A Longitudinal Study of the Asymmetric Head

Simon Lalor<sup>1</sup>, Matt Carlile<sup>1</sup>, Robert Reitmaier<sup>2</sup>

Orthotic and Prosthetic Department, The Royal Childrens Hospital, Melbourne, Australia. <sup>2</sup>The Creative Studio, The Royal Childrens Hospital, Melbourne, Australia

### **BACKGROUND**

Infant head size and rate of growth are commonly evaluated by tape measurement in routine check-ups, there are few evaluations of skull symmetry despite rates of skull asymmetries, including plagiocephaly, increasing in the past 30 years. Helmets are commonly used to treat moderate to severe plagiocephaly. However, there is conflicting evidence on short-term outcomes and limited evidence on long-term outcomes. There are currently no studies that document growth and level of deformity in plagiocephaly from 6-48 months of age.

### AIM

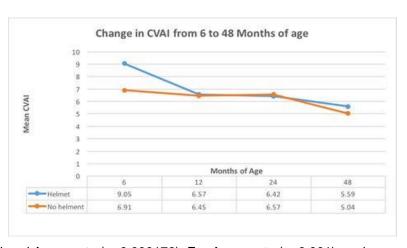
To evaluate skull growth and asymmetry from 6 to 48 months of age in (a) children with mild plagiocephaly treated with repositioning and physiotherapy and (b) in children with moderate to severe plagiocephaly treated with a helmet.

### **METHOD**

Children (n=91) with plagiocephaly who received 3D images of their head at the Royal Children's Hospital, Melbourne were included. Helmets were provided to infants who scored 3 in a single deformational change and/or a total score of ≥4, on the Modified Severity Scale for Assessment of Plagiocephaly (MSSAP).[1] The non-helmet group (classified mild) were provided with head re-positioning advice and physiotherapy. All participants had 3D images of their head at 6, 24 and 48 months of age with Cranial Vault Asymmetry Index (CVAI), MSSAP and maximum head circumference recorded. The helmet group had an image taken at the end of treatment and non-helmet group at 12 months old.

### **RESULTS**

CVAI improved in both groups from 6-48 months of age (Fig 1). The non-helmet group had no significant CVAI difference between 6-12 months (p=0.6306), 12-48 months (p=0.130663) and 6-48 months of age (p=0.050907). Wearing a helmet significantly improved CVAI from 6 months of age to finishing helmet therapy (p<0.001), but not from the finish of therapy to 48 months of age (p=0.084). Treatment effect was significantly greater (p=0.015) when wearing helmets between 6-9months compared with 10-12months of age. The helmet made significant changes in MSSAP



scores in Posterior Flattening (p<0.001), Forehead Asymmetry(p=0.000176), Ear Asymmetry(p<0.001), and Facial Asymmetry (p=0.003385) from age 6-48 months. A significant change in MSSAP scores for the no-helmet group existed from 6-48 months in Posterior Flattening (p=0.00248), but not in Forehead Asymmetry (p=0.222312), Ear Asymmetry (p=0.710117) or Facial Asymmetry (p=0.302363).

### **DISCUSSION AND CONCLUSION**

In all degrees of plagiocephaly, skull asymmetry improves from 6 to 48 months of age. Infants who present with asymmetric skulls (CVAI ≥3.5 MSSAP>3) at 6 months of age continue to exhibit asymmetry into middle childhood. Helmet therapy used in moderate and severe plagiocephaly reduces the severity of skull asymmetry in the domains of posterior flattening, forehead asymmetry, ear asymmetry and facial asymmetry. Helmet therapy is most effective when started at 6 months of age.

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### 2.3.8.e

### Orthotic Treatment for Knee Pathologies in Children with Congenital Insensitivity to Pain with Anhidrosis

Nobuhiko Haga<sup>1</sup>, Yusuke Shinoda<sup>1</sup>, Sayaka Fujiwara<sup>1</sup>, Hiroshi Mano<sup>1,2</sup>, Chika Nishizaka<sup>1</sup>
Department of Rehabilitation Medicine, The University of Tokyo, Tokyo, Japan. <sup>2</sup>Department of Rehabilitation Medicine, Shizuoka Children's Hospital, Shizuoka, Japan

### **BACKGROUND**

Congenital insensitivity to pain with anhidrosis (CIPA) is an autosomal recessive disorder manifesting in a generalized loss of pain and thermal sensation, a lack of sweating, and is associated with variable degrees of intellectual disability. In patients with CIPA, musculoskeletal complications are frequent including repeated fractures and joint dislocations, avascular bone necrosis, and Charcot arthropathy. Though complications in knee joints may lead to difficulty in ambulation, prevention and management are scarcely reported.

#### ΔIM

The aim of this study is to clarify the knee pathologies and the effect of orthotic treatments in patients with CIPA.

### **METHOD**

We retrospectively reviewed the medical records of 19 patients (ten males and nine females) who visited our department since 2006. The age at final visit ranged from four to 64 years (mean 20). The collected data included presence/absence of knee pathologies, treatment methods including application of orthoses and surgeries, and the effect of each treatment.

### **RESULTS**

Knee pathologies existed in ten joints in nine patients, excluding mild joint instability or genu varum. Two joints had already been destroyed at initial visit. One joint developed a severe Charcot joint without any treatment. Knee-ankle-foot orthosis was prescribed for five joints in four patients, but they all led to Charcot joints and three joints underwent surgery. Knee orthosis was prescribed for two joints and was effective in reducing joint effusion in both joints. The degree of joint effusion and presence/absence of bone necrosis did not relate to the effect of orthoses. In the patients in whom knee orthoses were effective in reducing joint effusion, the orthoses were applied in the very early stage and ambulation was properly restricted by using wheelchairs.

### **DISCUSSION AND CONCLUSION**

Knee pathologies were frequent in CIPA and led to severe joint destruction without proper treatments. Orthotic treatments were tried in many patients, but the effects of orthoses were varied and many joints developed Charcot joints. Though earlier application of orthoses and restriction of ambulation may lead to preferable prognosis, accumulation of data from more patients is necessary to prove this.

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### **ACKNOWLEDGEMENTS**

This study was supported by the Health and Labor Sciences Research Grants for Research on Intractable Diseases, MHLW of Japan.



### 2.3.8.f

### Advancement of 3D Digitized Scanning in Outcome Evaluation of Positional Cranial Deformation after Cranial Remoulding Therapy in Singapore and HK

<u>Helen Lee</u>, Susanna Koh, Heidi Mak Orthopaedia Pte Ltd, Singapore

### **BACKGROUND**

Positional cranial deformation (PCD) denotes flattening of the skull due to prolonged pressure to one side of skull in infants. The prevalence and awareness of PCD increased after "Back to sleep" campaign in 1992 launched by American Acedemy of Paediatrics (AAP). Cranial remoulding therapy (CRT) has been documented in 1970s by using manual anthropometric measurement as diagnostic tool and outcome evaluation. With the advancement of technology in digitized scanning, it optimized the accuracy of small arthropometric change.

### AIM

The aim is to investigate the robustness of digitized scanning on outcome evaluation of CRT in terms of 2-dimensional cranial ratio (CR), cranial vault asymmetry index (CVAI), cranial vault asymmetry (CVA) and 3-dimensional anterior and posterior volumetric data.

### **METHOD**

A retrospective study of infants with PCD were evaluated from two CRT centers in Singapore and Hong Kong from 2017-2019. All infants were evaluated under standard protocol with digitized method of anthropometric measurement, including head circumference (HC), head width (HW) and head length (HL) for CR, head diagonals for CVAI and CVA, and volumes of anterior and posterior quadrants of head. Demographics, treatment duration, compliance, change of severity score, anthropometric parameters, 2-dimensional and 3- dimensional data, were evaluated. Statistical student t-test was used in data analysis.

### **RESULTS**

A total of 252 infants (male 63.6%, female 36.4%) with mean age 5.3+-31.1months were recruited at the beginning of treatment. Mean treatment duration was 117.5 +-39.7 days with mean compliance 20.5 hours daily. Distribution of plagiocephaly, brachycephaly and mixed were 63.6%, 9.1% and 27.3% respectively, in which 60% were right plagiocephaly. Significantly differences were found in cranial ratios (digitized p=0.002), CVAI (digitized p=0.000) and CVA (digitized p=0.000) after CRT. Level of severity was improved by 33.3% with respect to baseline digitized measurement. Changes in overall symmetry ratio (p=0.000) in terms of volume changes in anterior (p=0.001) and posterior (p=0.001) quadrants showed significantly differences after CRT.

### **DISCUSSION AND CONCLUSION**

Technological advancement in 3-dimentional digitized scanning sufficiently visualized the change of symmetry in skull shape after CRT and greatly facilitated the accuracy in outcome evaluation.

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### 2.3.8.g

### Orthosis and Assistive Device Intervention for Fukuyama Congenital Muscular Dystrophy

Futoshi Wada, Michiru Adachi

Department of Rehabilitation Medicine, Tokyo Women's Medical University, Tokyo, Japan

### **BACKGROUND**

Fukuyama congenital muscular dystrophy (FCMD) is a genetic disease affecting the muscles, brain, and eyes.[1] From the infantile period, patients exhibit muscle weakness with hypotonia (floppy infant), joint contractures, and delayed motor and intellectual development. Early orthosis or assistive device intervention is needed to promote the child's development. However, adequate application of these interventions is not clearly understood since FCMD is a rare genetic disorder across the world except Japan.

#### ΔIM

This preliminary study aimed to elucidate the relationships between the mobility performance of the FCMD patients and the prescribed orthosis and assistive devices.

#### METHOD

We conducted a retrospective study using the medical records of patients who were prescribed an orthosis, seating device, or wheelchair over a four-year period (2013–2017). Data regarding the age, gender, genetic form of the disease, medical complications, mobility performance, and orthosis or assistive device intervention were collected for each participant. Mobility performance was assessed according to the following 4 levels: inability to sit, sitting, moving while sitting, and walking. The relationships between mobility performance and the prescribed device were

evaluated.

Table 1 Patient's demographic data and orthotic or assistive device prescription

### **RESULTS**

Sixteen patients (six females, ten males) were recruited. The female and male patients were aged 1–20 years and 4–17 years, respectively.

Case	Gender	Age	Mobility performance	Medical complication	Wheelchair	Seating device	Orthosis	
					wneelchair	seaung device	HKFO	AFO
- 1	M	17	inability to sit	Gastrostomy	Powered	Seating device	etrone)	Plastic AFO
2	F	15	inability to sit		Attendant			
3	M	10	inability to sit	Gastrostomy				Plastic AFO
4	F	7	inability to sit	Scoliosis, Hip dislocation	Attendant Powered	Seating device	HKFO	Plastic AFO (joint)
5	M	7	inability to sit	Respirator Dependence	Attendant, Stretcher type			
6	F	4	inability to sit			Seating device		
7	M	4	inability to sit		Control of the Control	Seating device	HKFO	0.00000
8	M	7	Sitting		Self, Lightweight	CHANGE CONTRACTOR CONT	HKFO	AFO
9	F	4	Sitting			Seating device	HKFO	
10	M	4	Sitting			Seating device	HKFO	Plastic AFO
-11	F	1	Sitting		and the same of th	Seating device		Plastic AFO
12	F	20	Moving while sitting	Varus equinus (severe)	Powered			Plastic AFO
13	M	8	Moving while sitting	Varus equinus (severe)	AL NOVEMBER DE LA CONTRACTION		HKFO	AFO
14	M	5	Moving while sitting		Self, Lightweight	Seating device	HKFO	
15	M	10	Walking		Self, Lightweight			Plastic AFO (joint)
16	M	7	Walking			Seating device		AFO

The results of

mobility performance showed that 43% were unable to sit, 25% could sit, 18% could move while sitting and 13% could walk. Almost 50% of the patients were prescribed a wheelchair; 56%, seating device; 43%, hip-knee-ankle orthosis (HKAFO); and 63%, ankle foot orthosis (AFO). The selection of the wheelchair was based on the patient's mobility level. In case of manual wheelchairs, a lightweight model was especially selected. Seating device and AFO were generally prescribed, regardless of the patient's mobility level, while HKAFO was mainly prescribed for the patents who were able to sit.

### **DISCUSSION AND CONCLUSION**

Patients with FCMD showed more severe motor disability than those with Duchenne muscular dystrophy because of early-onset muscle weakness and multiple contractures.[2] This severe motor disability may require orthotic interventions. Our findings show that the patients' mobility performance affects the prescription of wheelchair and HKAFO use. AFO is widely used to avoid the contracture of the ankle joints, which can improve balance while sitting in the wheelchair. This study has some limitations, namely, selection bias and a small sample size.

### **REFERENCES**

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## Advanced IC Outcome Measurements

### 2.4.1

### Mobile Technologies, Evidenced-based Healthcare and Your Clinical Practice: Demonstrating the Value of Prosthetic Care

Robert Gailey<sup>1</sup>, Ignacio Gaunaurd<sup>1,2</sup>
<sup>1</sup>University of Miami Miller School of Medicine, Coral Gables, USA. <sup>2</sup>Miami Veterans Affairs Medical Center, Miami, USA

### **Abstract**

Today hospitals, clinics, and universities use mobile technologies with almost every facet of healthcare including scheduling, diagnostics, and patient follow-up. The prosthetic and orthotic (P&O) professions have embraced mobile technologies with the use of microprocessor prosthetics, electronic medical record and other applications. An evidence-based O&P practice that captures the right patient data, outcome measures and other selected metrics will be able to use this information to enhance patient care, demonstrate the value of their interventions and perform analytics on clinical operations. The combination of mobile technologies with an evidence-based O&P practice is a necessity to keep pace with other healthcare practices today. The ability to share objective data with patients, referral sources, allied health professionals and payers is critical to every clinical practice and the profession of O&P. This presentation will discuss the integration of a variety of mobile technologies with evidence-based clinical practice models including: 1) patient care, 2) outcome measures, 3) clinical communications, 4) prosthetic prescription, 5) gait assessment, 6) exercise prescription, 7) performance feedback, 8) documentation and 9) clinical research. The focus will be on clinical strategies that will enable O&P professionals to demonstrate to patients, allied health providers and paying agents the functional and economic value of their interventions without reducing the time dedicated to direct patient care. The presenters for this session have employed mobile technology for over a decade in the administration of outcome measures, movement assessment, exercise prescription, clinical feedback, and home health care.

### Statement of the objective / learning objectives

At the conclusion of this presentation participants will be able to identify mobile technologies and selected outcome measures that will: 1) be beneficial to their clinical practice, 2) demonstrate the value of prosthetic rehabilitation interventions.



## Free Paper Session Orthotics: Lower Limb Orthopaedic - AFO

### 2.4.2.a

Weight-bearing X-ray and CT Scan Validation of Deformity Realignment, before and after utilizing Triplanar Management Techniques in Lower Limb Orthotics

### Marmaduke Loke

Dynamic Bracing Solutions, Inc., Carlsbad, California, USA

### **BACKGROUND**

X-ray validation of orthotic alignment control is standard practice in scoliosis and fracture treatment because alignment management is central to treatment outcomes. The quality of alignment management is widely variable in the common practice of orthotics for the treatment of other conditions that involve serious malalignment and its negative sequelae. When treatment outcomes in these cases also depend on alignment, x-ray validation should be part of standard practice as well.

### AIM

This study will illustrate the wide variation in quality that passes as acceptable in common practice with weight bearing lower limb orthoses and how x-ray controls may help.

### **METHOD**

In this study, two cases are presented with serious anatomic mal-alignment caused by disease. Patients began the study with standard, conventional treatments in place. The treatments had passed muster in orthopedic and orthotic clinics specializing in such conditions. No objective, measurable method was used to validate the efficacy of orthotic treatment. DBS bracing was fitted using the tri-planar management strategies introduced by Jean-Paul Nielson and advanced through the DBS systems and methods. X-ray validation was employed to verify optimum achievement of the needed alignment in three dimensions. Visualizations and measurements derived from the resulting images are evaluated for their usefulness in insuring efficacy of treatment.

### **RESULTS**

The X-rays clearly show that orthotic alignment control may vary widely within what is accepted in common practice without objective, measurable validation. In addition to the tibio-calcaneal angulation in the frontal plane, the view of the conventional brace at left shows transverse plane rotation, asymmetrical joint space compression, deviation of forefoot structures from alignment with appropriate weight transmission pathways, and deformation of the device under load. The DBS device shown at right reverses those characteristics. The risk of progressive deformity, arthrosis, joint pain, and instability, the magnitude of ambulatory range, and the quality of gait may be predicted by the elements illustrated by the x-rays.

### **DISCUSSION AND CONCLUSION**

Though x-rays have limits, insuring that alignment controls with orthotic treatment, appears well worth the effort and exposure. The current practice of using imaging to insure efficacious scoliosis and fracture treatment has an established history of success. Using images to control the quality of alignment treatment will have significant impact on reducing pathology.

Weight-bearing CT Scans are becoming more popular and offer three dimensional views to document orthotic value and alignment of the joint surfaces.



### 2.4.2.b

### Efficacy of Ankle Supports on Dynamic Postural Control in Patients with Chronic Ankle Instability

Aliyeh Daryabor<sup>1,2</sup>, Samira hassanpour<sup>3</sup>, Aliashraf Jamshidi<sup>4</sup>, Mehdi Rezaei<sup>5</sup>

Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Science, Tehran, Islamic Republic of Iran. <sup>2</sup>Student Researcher in International University of Health and Welfare, Tokyo, Japan. <sup>3</sup>Iran University of Medical Sciences, Department of Orthotics and Prosthetics, Tehran, Islamic Republic of Iran. <sup>4</sup>Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Department of Physiotherapy, Tehran, Islamic Republic of Iran. <sup>5</sup>Shahid Beheshti University of Medical Sciences, School of Rehabilitation, Tehran, Islamic Republic of Iran

### **BACKGROUND**

The chronic ankle instability (CAI) that results from a lateral ankle sprain causes balance deficits during quiet standing. Dynamic postural control in patients with CAI can be improved using soft and semi-rigid braces.

#### AIM

This study was aimed at investigating the effects of soft and semi-rigid ankle supports on dynamic postural stability in subjects with CAI.

### **METHOD**

Fifteen subjects with unilateral CAI as the CAI group and fifteen healthy control subjects as the control group were recruited for participation in the study. Stability indexes (SIs), including overall SI, anteroposterior SI, and mediolateral SI were determined using the Biodex Balance System (BBS), and lower extremity reach was ascertained using the Star Excursion Balance Test (SEBT). These indicators were measured under three conditions: without orthosis, with soft orthosis, and with semi-rigid orthosis.

### **RESULTS**

Significant differences in overall SI were found between the affected and healthy feet of the CAI group (p=0.009) and between the affected feet of the CAI group and the healthy feet of the control group (p=0.031). The SEBT revealed significant differences between the injured and uninjured sides of the CAI group in the anterior, anterior-medial, and anterior-lateral directions. With the use of soft ankle supports, no significant difference were found between the affected and unaffected limbs of the CAI group in the overall and mediolateral SIs of BBS test and the anterior-medial (p=0.057) and anterior-lateral (p=0.07) directions of SEBT.

### **DISCUSSION AND CONCLUSION**

The affected feet of the CAI group exhibited less ability to maintain dynamic and functional balance in comparison with the healthy feet of the CAI and control groups. This discrepancy may be due to joint proprioceptive deficits. The soft supports improved the balance and function of the CAI patients probably through the stimulation of skin receptors. Moreover, the semi-rigid support has less effect on improving balance likely because of movement restrictions to the ankle.



### 2.4.2.c

### **Analysis of Loads on PAFO During Gait**

Ichiro Kitayama<sup>1</sup>, Daisuke Morioka<sup>2</sup>, Miyuki Kawamura<sup>1</sup>
<sup>1</sup>Kindai Univercity, Kinokawa city, Japan. <sup>2</sup>Takushoku University, Hchioji city, Japan

### **BACKGROUND**

The mechanical stress in PAFOs with an orthotic ankle joint, the movements of PAFOs during gait, and new PAFO shapes have been investigated in many studies. However, the mechanical loads on plastic ankle foot orthoses (PAFOs) during gait have rarely been measured directly.

#### $\Delta IM$

We developed a system to measure the mechanical loads on a PAFO using 6-axis force-and-torque sensors attached to the PAFO. Then, the characteristics of the data were analyzed.

#### METHOD

To measure loads on the posterior region of the upper part and upper belts, the PAFO was divided into upper and lower parts at the level where there was no load from the body. These two parts were then reconnected solely with 6-axis force-and-torque sensors. The resulting system roughly maintained the original shape and enabled the measurement of loads on the PAFO. PAFOs were individually prepared for 9 patients with hemiplegia and 6 healthy individuals, to which 6-axis force-and-torque sensors and goniometers were attached for simultaneous measurement of loads on the PAFO and its deformation during gait.

### **RESULTS**

Analysis of the loads (data shown as the mean +-standard deviation) in the anterior-posterior direction (Fz) revealed an anterior-posterior load of 0.48 +-0.28 N/kg in the healthy individuals, and 0.68 +-0.46 N/kg in the patients with hemiplegia in early stance phase; while the posterior-anterior load was 1.1 +-0.26 N/kg in the healthy individuals, and 0.84 +-0.42 N/kg in the patients with hemiplegia in late stance phase. The differences between the healthy individuals and patients with hemiplegia were statistically significant (p < 0.05). Loads in the vertical directions (Fx) and lateral directions (Fy) were smaller than those in the anterior-posterior direction.

### **DISCUSSION AND CONCLUSION**

The significantly larger Fz values in the patients compared with the healthy individuals in early stance phase suggests that the PAFO may function as if it were a walking stick attached to the body. Changes in Fz over time were similar to changes in ankle angle over time. Changes in Fz over time were similar to changes in ankle angle over time. This suggests the possibility that deformation can predict the loads without the use of load sensors.

### **ACKNOWLEDGEMENTS**

This work was partially supported by a JSPS Grant-in-Aid for Science Research (C) (No. 16K01579).



### 2.4.2.d

### Patellar Tendon Weight-Bearing AFO in a Complicated Female Case with Comminuted Fracture Tibia as a Result of Conflict in Gaza

Mazen Hamam, <u>Heba Bashir</u> Artificial Limb and Polio Center, Gaza, Palestine

### **BACKGROUND**

A 44 years-old obese female was injured as a result of shelling in 2014, had comminuted fracture tibia distal third, refused amputation, multiple surgeries were done with Tibial Fibularization the last, has been in wheelchair for 4-years, presented with 8cm shortening, deformed leg, partial loss of calf-muscle, ankle arthrodesis in 40° planter-flexion, fluctuated leg circumference and poor general endurance. The prescription was to offload her weight from the affected area.

#### AIM

Protect the affected area by fitting her with offloading device as well as to restore walking in order to improve her quality of life.

### **METHOD**

Patellar tendon weight bearing Ankle Foot Orthosis (AFO) was done by using polypropylene for posterior shell, thermolyne for anterior shell, covered by leather, lacer to allow for easily adjustment to accommodate her fluctuating circumference. It is to make suspension in such a way to allow self-aligning within the frame of the orthosis. 8 cm compensation was added by using pedilen Rigid foam and a rocker shoes was also provided to

allow easily roll over. She was also referred for Gaittraining by physiotherapy team.

### **RESULTS**

She was fitted with the device with proper alignment between leg and foot. Comfortability as well as off-loading were achieved. She managed to confidently stand and restore her ambulation which she lost since the last 4 years. She is able now to walk independently with much better general endurance obtained. Happily to mention that her quality of life is improved.

### **DISCUSSION AND CONCLUSION**

Despite the complicated presentation of the mentioned case which wasn't the best surgical solution to maintain the complicated leg, however patients preferences is the limiting factor for such decisions and we should respect and be flexible with the complicated context in the Gaza strip. Follow-up of such complicated case should be continuous to better tackle any changes.

Each patient is unique with his/her presentation, and we should adapt ourselves accordingly.

### REFERENCES

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### **ACKNOWLEDGEMENTS**

Saeda El Barawi, Physiotherapist Field Officer, International Committee of the Red Cross.





### 2.4.2.e

### Rollover Characteristics of Functional AFO Measured on the Controlled Various Stance Phase Motion and Load Pattern Reproducible System

Shoji Morimoto<sup>1</sup>, Haruyuki Yoshida<sup>1</sup>, Saki Mizuse<sup>1</sup>, Hiroki Tomiyama<sup>2</sup>, Yasunori Hashimoto<sup>2</sup>

Osaka Electro-Communication University, Neyagawa, Osaka, Japan. <sup>2</sup>Hashimoto Artificial Limb Manufacture Co., Ltd., Okayama, Japan

### **BACKGROUND**

Rollover characteristics of ankle-foot orthosis for hemiplegic patient are important and useful to evaluate the function of orthosis fitted to each patient.

### AIM

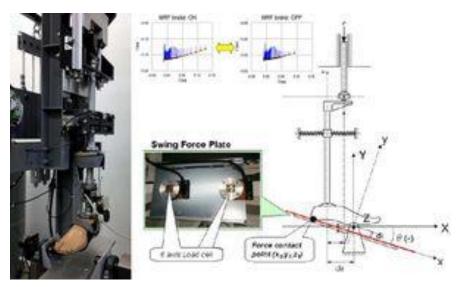
We have been developing the method to evaluate the MRF (Magneto-Rheological Fluid) brake installed ankle-foot orthosis on the modified testing machine based on the ISO22675.

### **METHOD**

The AFO is attached on the modified shank unit which emulates the hemiplegic ankle-foot function, and compressive force is applied and foot plate is inclined to emulate the motion from heel-contact to toe-off. From the measured field data of many hemiplegic patients by using the portable data acquisition system in which limb load sensors, inclination angle sensors and data recording device are installed, compressive force on the AFO and swing angle range of the foot plate were decided. 6 axis load cells are installed in the swing foot plate, and load line on which force and moment vectors are parallel is calculated from the output of these load cells.

### **RESULTS**

By adding the force vector and moment vector on the locus of the load line, "rollover characteristics" is derived. These characteristics are sensible to the angle range of the swing foot plate, compressive force of the testing machine, and brake moment of the AFO. The testing machine emulates the characteristics of each hemiplegic patient, and MRF brake installed AFO emulates the amplitude and duration time of the brake moment. Observing the pattern of these rollover characteristics, the best braking pattern can be estimated. By changing the angle range of the swing foot plate, the gait of slope up or down is settled, and wide range of gait pattern can be simulated.



### **DISCUSSION AND CONCLUSION**

These trials lead to construct the data bank to get the best adjustment of the high functional AFO, before applying to each hemiplegic patient. This approach leads to decrease the duration for the initial adjusting, by applying this knowledge data base. Furthermore, after the initial setting work, periodical adjustment work shall be applied according to the patient gait experience, and in this case, the knowledge data bank may be useful.



## 2.4.2.f Pre- and Post-Training Effects of a Dynamic Orthosis on Pain and Function

Andrea J. Ikeda<sup>1,2</sup>, John R. Fergason<sup>1</sup>

\*\*Center for the Intrepid, Brooke Army Medical Center, Fort Sam Houston, USA. <sup>2</sup>Extremity Trauma and Amputation Center of Excellence, Fort Sam Houston, USA

### **BACKGROUND**

Individuals with severe pain and/or loss of function of the foot or ankle may benefit from use of a dynamic orthosis such as the Intrepid Dynamic Exoskeletal Orthosis (IDEO), which has led to improved outcomes across a wide variety of injuries when paired with a training program.[1,2] However, little is known about the isolated effects of IDEO use prior to training. Additionally, longitudinal reports of pain and functional outcomes with and without such a device do not exist.

### AIM

The aim of this prospective study was to quantify changes in pain and function with and without a dynamic orthosis upon initial receipt of the device and after device-specific rehabilitation.

### **METHOD**

Individuals age 18–55 who were prescribed an IDEO for pain or loss of function were recruited and consented. Participants were assessed during 2 Sessions: upon device delivery (S1) and after approximately 4-6 weeks of IDEO-specific rehabilitation (S2). Resting, walking, and running pain were assessed on a 0–10 numerical rating scale. Participants completed the 10 Meter Walk Test (10MWT), 4 Square Step Test (4SST), Pro-Agility (P-A), and Lower Extremity Functional Scale (LEFS). Parametric and non-parametric tests were used to determine significant differences between conditions (with vs. without device) and Sessions (S1 vs. S2) with a significance level of p<0.05.

### **RESULTS**

Thirty-seven individuals (age 36±8 years,height 178±11 cm, mass 95.1±15.4 kg) completed S1; 36 individuals completed S2 after 5.3±2.3 weeks (Figure 1). All individuals participated in device-specific training and wore their devices 9.2±4.5 hours per day between S1 and S2.

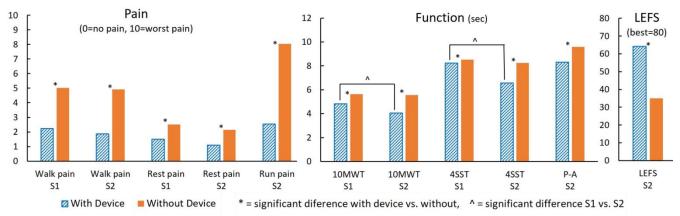


Figure 1. Outcomes for pain and function at S1 and S2. Run pain, P-A, and LEFS were not assessed at S1.

### **DISCUSSION AND CONCLUSION**

S1 results represent the isolated effects of device use without any training. S2 results indicate that use of the device during training and extended wear time did not have a detrimental effect on participants' pain or function without the device. Study limitations include a relatively short follow-up time for S2 testing. In conclusion, dynamic orthoses such as the IDEO may benefit individuals by immediately reducing pain and improving function, and device-specific training may further enhance their functional abilities.

### REFERENCES

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### **ACKNOWLEDGEMENTS**

The views expressed are those of the authors and do not reflect official policy of the DoD, or U.S. Government.



### 2.4.2.g

### The Evidence for using Orthotics and/or Exercises in the Management of Posterior Tibialis Tendon Dysfunction

<u>Jessica Makwana</u><sup>1,2</sup>, Tim Pigott<sup>2</sup>

<sup>1</sup>Opcare, London, United Kingdom. <sup>2</sup>Salford University, Manchester, United Kingdom.

#### **BACKGROUND**

Posterior tibial tendon dysfunction (PTTD) can cause an array of problems ranging from minimal to unbearable pain. PTTD initially presents with a flattened medial longitudinal arch and correctable hindfoot valgus which later progresses to fixed valgus and osteoarthritic changes in the ankle. Commonly orthotic insoles are used to reduce the stress on the tibialis posterior tendon and a gradual and progressive load management program is utilised to strengthen the tibialis posterior (TP).

### AIM

To ascertain if evidence supports the use of any specific exercises and/or orthoses for the management and treatment of PTTD.

### **METHOD**

Five medical databases were searched with specific keywords relating to both orthotics and/or exercise rehabilitation.

### **RESULTS**

Taping and bracing was shown to help manage initial PTTD symptoms. Insoles were commonly used throughout disease progression. Superior pain relief occurred when using custom-made insoles alongside a progressive eccentric TP exercise program. Double legged heel raises were most commonly prescribed to specifically strengthen the TP; these were further progressed by gastro-soleus and TP concentric contractions. Closed chain foot adduction exercises created the greatest TP selective signal intensity. TP muscle activity was nearly two times higher when performing the exercises with orthoses as compared to barefoot. After treatment, the concentric and eccentric muscle strengths of the affected side significantly increased to be equivocal to baseline strengths of the unaffected side. Two studies supplemented the TP exercise programme with proximal muscle strengthening. One study interestingly further looked into weening off the orthotics once the symptoms had reduced.

### **DISCUSSION AND CONCLUSION**

Overall, an average increase in TP strength and pain reduction was evident after implementing an exercise program with and without the use of orthotics. Further high quality evidence is required as a number of methodological weaknesses were present; one includes some exercises being scientifically optimised for muscle endurance as opposed to the study's objective of muscle strength. It was difficult to draw firm conclusions as a wide variety of exercises with differing repetitions, sets and progressions were utilized.

### **REFERENCES**

[1] Ross et al, BMJ Open Sport & Exercise Medicine, 2018; 4(1), 1-11.



# Symposium Developing Countries

### 2.4.3

### Learnings from the AT2030 Programme for Service Delivery in LMICs

<u>Catherine Holloway</u><sup>1</sup>, <u>Chapal Khasnabis</u><sup>2</sup>, <u>Bishnu Dhungana</u><sup>3</sup>

Global Disability Innovation Hub, London, United Kingdom. World Health Organization, Geneva, Switzerland. Asian Institute of Technology, Khlong Luang, Thailand

### **Abstract**

The current model of AT delivery in LMICs relies heavily on the charity sector. How can this be evolved to enable a more sustainable ecosystem? This is the primary question being explored in this symposium.

This symposium will be opened by a challenge, laid down by Chapal Khasnabis of the GATE Programme at WHO – what should the AT2030 Programme look to achieve to ensure sustainable service delivery of assistive technology (AT) for all citizens in lower and middle-income countries (LMICs).

Catherine Holloway, Research & Evidence Director of the AT2030 programme will respond to this challenge and share the initial learnings from the AT2030 programme and how these are feeding into the new vision of the ATscale Global Partnership on AT. AT2030 has the ambition to provide Low cost, mass market, life-changing AT for all. It is a £10 investment by the UK Department for International Development. AT2030 will help to lay the foundations for global AT access through finding evidence of what works; testing the user-centred design of technology; trailing new service delivery innovation, and opening market access in priority LMICs.

Finally, these will be critiqued by Bishnu Dhungana, who is both an expert in the field of AT and a user of the service herself.

### Statement of the objective / learning objectives

This symposium will focus on AT service delivery learnt lessons in LMICs from the AT2030 programme.



## Free Paper Session Prosthetics: Lower Limb Transtibial - Feet

### 2.4.4.a

### Literature Review on the Evidence for Advanced Ankle-Foot Mechanisms

Andreas Kannenberg
Otto Bock Healthcare LP, Austin, USA

### **BACKGROUND**

Unlike microprocessor (MP) controlled knees and in spite of an impressive number of publications, advanced non-microprocessor (non-MP) and microprocessor controlled (MP) ankle-foot mechanisms are considered "investigational" by many health care payers. Therefore, a review of the literature on the benefits of these advanced ankle-foot technologies was performed..

### **AIM**

The aim of this work was to analyze and summarize the published evidence on benefits of non-microprocessor controlled (non-MP) as well as passive and powered microprocessor controlled (MP) ankle-foot mechanisms.

### **METHOD**

The Medline and EMBASE databases were searched for publications using search terms related to feet with non-MP hydraulic ankles/dorsiflexion feature, or passive or powered MP controlled feet. Methodological quality was rated using the criteria of a Cochrane review of prosthetic foot research.[1]

### **RESULTS**

The literature search yielded 39 publications with acceptable methodological quality. Compared to ESAR feet, non-MP ankles demonstrated a significantly increased toe clearance and self-selected walking speed in the gait lab as well as reduced socket-residual limb interface pressures. A passive MP controlled foot demonstrated significantly improved toe clearance in the gait lab. Studies on slope ambulation found improvements but also deteriorations in biomechanical parameters. One study with a MP controlled foot with instant terrain adaption found standing on slopes to be more physiologic. One study also demonstrated significantly reduced socket-residual limb interface stress. For a powered MP controlled ankle-foot component, evidence was conflicting regarding the ability to increase self-selected walking speed and energy expenditure during level walking and slope ambulation. A powered ankle may reduce sound knee loading at higher walking speeds.

### **DISCUSSION AND CONCLUSION**

The most relevant finding was that non-MP and passive MP controlled ankles may increase toe clearance and reduce the risk of tripping. Improved ankle motion may result in reduced braking forces, increased self-selected walking speed, and reduced interface pressures between the residual limb and the socket on varying terrains. Powered feet may enable high-functioning individuals to further increase their self-selected walking speed, even up to the level of able-bodied subjects.

### **REFERENCES**

[1] Hofstad et al, Cochrane Database of Systematic Reviews 2004, (1):CD003978.



### 2.4.4.b

### The Effect of Blade Alignment on Prosthetic Stiffness and Gait Pattern while Running with Simulated Running-Specific Prosthesis

Han Houdijk<sup>1,2</sup>, Ashley Groothuis<sup>1</sup>

Vrije Universiteit Amsterdam, Amsterdam, Netherlands. <sup>2</sup>Heliomare Rehabilitation, Wijk aan Zee, Netherlands

### **BACKGROUND**

Running Specific Prostheses (RSP) are designed to replicate the spring-like behavior of the human leg.[1] The key property that determines running performance is the stiffness of the leg. Hence, it is very important to understand the stiffness properties of the RSP. It has been shown previously that RSP stiffness is not a fixed property, but depends on the angle of loading of the blade when tested in a test bench.[2] Consequently, alignment of the blade might affect its stiffness during running.

### AIM

The aim of this study was to investigate the effects of different angles of alignment of the RSP blade relative to the socket on the RSP stiffness, and how this translates into gait changes during running

### **METHOD**

Ten able-bodied athletes performed eight running trials on a treadmill at a fixed speed using running-specific dummy prostheses. During these trials, the alignment of the blade relative to the socket was set in four different angles (0°, 5°, 10° and 15°) during two different step frequency conditions (free and imposed). RSP stiffness( $K_{RSP}$ ), total leg stiffness ( $K_{tot}$ ), residual leg stiffness( $K_{res}$ ), stride time, ground contact time, flight time, angle of attack, knee joint stiffness ( $K_{knee}$ ) and knee angle at initial contact were compared as a function of alignment.

### **RESULTS**

In both step frequency conditions RSP stiffness decreased linearly by as much as 19% when the angle of alignment increased. In contrast, total leg stiffness remained constant or even slightly increased. This was caused by an increase in residual leg stiffness, which was realized by an increased knee extension at initial contact. Table 1 shows the effect of angle of alignment on the primary and secondary outcomes.

Table 1: The effect of angle of alignment on the primary and secondary outcomes.

	K <sub>RSP</sub>	K <sub>tot</sub>	K <sub>res</sub>	Angle of attack	Step frequency	Contact time	K <sub>knee</sub>	Knee angle at initial contact
Free	1	=	1	J	<b>+</b>	=	=	<b>↓</b>
Fixed	<b>1</b>	1	1	1	=	=	=	1

↓ sign, Decrease, ↑ sign increase, = no significant difference

### **DISCUSSION AND CONCLUSION**

Alignment of the blade relative to the socket has a substantial effect on RSP stiffness. Able-bodied runners are able to compensate for the decrease in RSP stiffness and run with similar or even higher total leg stiffness by increasing knee angle at initial contact. Whether such compensation can be used by amputee runners remains to be investigated.[3] Nevertheless, it can be concluded that alignment of the blade is an important factor to take into account when optimizing the RSP.

### **REFERENCES**

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[3] Oudenhoven et al. J Biomech 2016.



### 2.4.4.c

### Prosthetic Foot Selection for Surfing Based on Subjective Assessment and using Video Analysis: A Case Report

Akito Tamura, Teruki Shibata, Eiji Tazawa Tazawa Mfg. Co., Tokyo, Japan

### **BACKGROUND**

We have been providing the prosthesis for a surfer, who lost his leg in an industrial accident, and he is determined to get back up on a surf board. For surfing, unlike track and field athletes, analysis by using 3D motion analysis etc., there is no established method to evaluate the function of prosthetics that leads to the best performances of amputee surfing.

#### AIM

This presentation is based on analyzing the video of the surfer's performance and with subjective feedback from him. In this study, evaluation is only with prosthetic feet, not including socket, liner and suspension.

#### **METHOD**

Male, age 43, a right transtibial amputee (short stump). He is an experienced surfer and stands with a regular stance (left foot forward on the board). He is now ranked No.1 transtibial amputee surfer by international surfing association. Prosthetic feet were selected based on subjective assessment of the patient and video analysis during surfing. Approximate knee flexion angle and posture were compared. Dorsi-flexion angle was unable to be measured because foot part was invisible during surfing. However, ankle angulation is the most important and influences performance when riding a surfboard. The goal was to obtain the same function and feedback during surfing as before he was amputated.

### **RESULTS**

We used 3 different activity levels of feet; Vari-FlexXC (OSSUR); ordinary carbon fiber foot with high energy return, Durawalk(Willowwood); multi-axial and low activity, and Challenger Foot (Ottobock); designed for multi-sports. Ordinary carbon fiber foot was difficult with retaining balance and allowed less flexion angle of knee and high posture was observed. Balance and posture were much improved with Durawalk, but the complaints were that it is difficult to react to the wave and generate speed on prosthesis side. We also observed that he shifted the weight to the sound side and used flexion and extension of the knee to maneuver the board. Retaining maximum speed is very important to outperform in riding and he used knee motions on prosthetic side more with Challenger foot.



Figure 1. Analyzing the video of surfer's performance

### **DISCUSSION AND CONCLUSION**

Selection of prosthetic foot for surfing depends on the ability and style of the surfers. It is difficult to measure the kinematic data during surfing, so we had to rely on his comments. But, video analysis is helpful to understand his feedback. A low activity multi-axial foot is recommended for initial phase to learn balance on the board. But for higher performance, a foot with high energy return and wide range of motion are needed.

### **REFERENCES**

[1] Lundgren L, JASC 2013.



### 2.4.4.d

### The Biomechanical Effects of Prosthetic Ankle-Foot Types for Trans-tibial Amputees Standing on Slopes

Piotr Laszczak, Michael McGrath, <u>Saeed Zahedi</u>, David Moser Chas. A. Blatchford and Sons Ltd, Basingstoke, United Kingdom

### **BACKGROUND**

Lower limb amputees have a high incidence of osteoarthritis (particularly in the sound limb) [1] and back pain,[2] which are believed to be caused by kinetic asymmetries. A lack of prosthetic adaptation to different terrains requires kinematic compensations, which may influence these asymmetries. Previous work has reported the influence of prosthetic technology on the biomechanics of trans-femoral amputees when standing on slopes.[3] This study brings new insight by investigating a similar problem in trans-tibial amputees.

#### AIM

To investigate the influence of prosthetic ankle-foot technology on the biomechanics of trans-tibial amputees when standing on a slope.

### **METHOD**

A cohort of K3 trans-tibial amputees (n=6, including one bilateral) volunteered for this study. Participants stood facing down a 5° slope. Motion capture markers and two adjacent force plates were used to examine kinematic compensations and the prosthetic/sound limb load distribution as outcome measures. The participants were tested with three prosthetic conditions in a randomised order:

- An energy storing and return foot (FIX Esprit, Blatchford)
- A microprocessor-controlled hydraulic ankle with standing mode switched off (HYD Elan, Blatchford)
- A microprocessor-controlled hydraulic ankle with standing mode switched on (MPF Elan, Blatchford)

Each patient had experience with all prosthetic conditions and was allowed acclimatisation time between testing sessions.

### **RESULTS**

For the unilateral amputees, the distribution of ground reaction force (GRF) between sound and prosthetic limbs was not significantly affected by prosthetic foot type. However, kinematic compensations, particularly at the residual knee, led to external flexion knee moments for the FIX condition, but external extension moments for the HYD and MPF conditions. Using Winter's support moment [4] as a metric, the MPF reduced the loading on the joints of the sound limb by approximately 60% compared to FIX, and by approximately 40% compared to HYD.

In the case of the bilateral amputee, only the MPF condition permitted extended knees (due to ground compliance and standing support resistance), leading to an approximate 57% reduction in support moment, compared to the FIX condition. Meanwhile the HYD condition required the largest knee flexion compensation, resting on the dorsiflexion stops.

### **DISCUSSION AND CONCLUSION**

A previous related study [3] found that the ground compliance of hydraulic ankles led to more even weight distribution and improved balance for trans-femoral amputees. For trans-tibial amputees, this study shows that while GRF distribution is not significantly influenced by prosthetic ankle-foot type, the loading on the joints is, due to kinematic compensations. MPFs with standing support resistance demonstrated the best performance.

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### 2.4.4.e

### The use of a Prototype Powered Ankle Prosthesis Improves Clinical Outcomes of Walking on Level and Inclined Surfaces

Polly McGuigan<sup>1,2</sup>, Elena Seminati<sup>1,2</sup>, Tian Tu<sup>3</sup>, Pejman Iravani<sup>3</sup>, Jawaad Bhatti<sup>4</sup>, Mike McGrath<sup>4</sup>, Saeed Zahedi<sup>4</sup>, David Moser<sup>4</sup>

<sup>1</sup>Department for Health University of Bath, Bath, United Kingdom. <sup>2</sup>CAMERA centre, University of Bath, Bath, United Kingdom. <sup>3</sup>Department of Mechanical Engineering, University of Bath, Bath, United Kingdom. <sup>4</sup>Chas. A. Blatchford and Sons Ltd, Basingstoke, United Kingdom

### **BACKGROUND**

It has been suggested that external energy input is required for a prosthesis to fully replicate the natural behaviour of the ankle joint.[1] Studies of powered ankle prostheses have often focused on improvements in metabolic cost [2,3] or sound side loading.[4] This investigation used a development device [5] created using additive manufacture techniques and performed a full biomechanical analysis, with a focus on identifying clinical patient benefits.

#### AIM

Investigate the clinical benefits of a powered prosthetic ankle joint.

### **METHOD**

A single trans-tibial participant completed the gait analysis (M, 54 years old, 61kg, 1.68m). Ethical approval was granted by the University of Bath Research Ethics Approval Committee for Health. Kinematic data were captured using a 16-camera motion capture system (Qualysis, Gothenburg, Sweden) and kinetic data with two force platforms (Kistler, Winterhur, Switzerland). The participant completed 6 level walking trials with the device in powered and unpowered conditions at self-selected (SS), slow (SL)

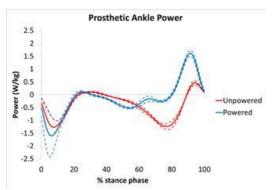


Figure 1. Prosthetic 'ankle' power for level walking.

and fast (FA) walking speeds and inclined and declined walking on a 5° slope at SS speed. An 8 segment model was constructed in Visual 3D (C motion, MD, USA) and used to determine clinically relevant outcome measures.

### **RESULTS**

In the powered condition (PC), the prosthetic 'ankle' plantarflexed in late stance phase, before returning to a dorsiflexed position for swing phase. The ankle moment transitioned from dorsiflexion to plantarflexion earlier in the gait cycle in the PC, contributing to a greater prosthetic 'support' moment. On level ground peak ankle power in late stance was increased by 250% (Figure 1). There was an increase in the propulsive impulse of the ground reaction force of the prosthetic limb and a reduction in the weight acceptance peak of the sound limb in the PC. Sagittal and frontal plane moment was reduced by 56% on the sound knee and less power was generated from the sound knee and hip joints. Prosthetic toe clearance was increased for the PC (7% on level and 13% on incline).

### **DISCUSSION AND CONCLUSION**

This analysis helps to explain the cause-effect relationships between prosthetic technology and patient benefits. In addition to the primary aim of the prosthesis of providing power, there are some tangible clinical benefits. Reduction in reliance on the sound limb has been suggested to decrease the likelihood of degenerative joint conditions.[4] Crucially, the increased toe clearance during swing has been linked to reducing the likelihood of falling,[6] which is an immediate medical concern with large health-economic implications.

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This work was supported financially by Innovate UK.

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### 2.4.4.f

## Design and Testing of Passive Prosthetic Feet Optimized using the Lower Leg Trajectory Error Metric

<u>Victor Prost</u><sup>1</sup>, W. Brett Johnson<sup>1</sup>, Jenny A. Kent<sup>2</sup>, Matthew J. Major<sup>2</sup>, Amos G. Winter<sup>1</sup> MIT, Cambridge, USA. <sup>2</sup>Northwestern University, Chicago, USA

### **BACKGROUND**

We are creating low-cost prostheses that provide a more cosmetic gait for transtibial amputees in developing countries, expanding their capabilities and mitigating social stigmas associated with disability.[1] The prostheses are designed using the Lower Limb Trajectory Error (LLTE), which is an optimization metric that describes how well the design of a prosthesis enables a target motion, such as able-bodied gait.[2] This work builds upon our previous earlier work [3] and expands it to include the entire stance phase.

### AIM

The aim of this work is to design a single part, compliant, passive prosthetic foot optimized over a full step using the LLTE metric to replicate a reference walking pattern.

### **METHOD**

Adding target knee torques measured from able-body people as an additional input to our models allowed us to expand the calculation of the LLTE throughout the entire stance. Given a person's, physical characteristics we used a genetic algorithm combined with a finite element model to optimize the shape and stiffness of the foot according to this extended LLTE. The optimized feet were manufactured and tested with a universal material testing system to verify that their action under able-bodied loading would allow close to able-bodied kinematics. In addition, qualitative testing with transtibial amputees were conducted in India. Subjects' feedback was

collected after multiple sessions of level ground walking

trials.

### **RESULTS**

The optimized prosthetic foot features a single part, compliant structure with an extended heel keel. This new foot can be manufactured for under \$10. experimental testing showed that the measured vertical deflection differed from the vertical deflection predicted by FEA by less than 2 mm (Fig. 1.a,b), indicating that the foot performed as designed. The foot sustained hours of testing with transtibial amputees (Fig. 1.c) and presented no mechanical issues. Users walked faster, liked the increased energy storage and return (ESR) of 88% and preferred the reduced weight of this foot (0.36kg) compared to their prescribed Jaipur Foot (68% ESR, 0.98kg).

## **DISCUSSION AND CONCLUSION**

The optimized feet behaved as expected and matched our LLTE-based predictions. Using our framework, a prosthetic foot tailored to a person's weight and size was optimized and manufactured for under \$10, and enable

A. 700
600
500
E. 400
90
100
0 5 10 15 20 25 30
Displacement, [min]

Figure 1: (a) Instron-measured and FEA calculated vertical displacements under loads applied at a horizontal distance of 13 cm from the ankle (b) Photograph of the experimental setup (e) Indian amputee walking on level ground with the foot prototype.

them to exhibit walking motion similar to able-bodied gait. We are currently conducting another 2 month long field trial in India, as well as quantitative motion analyses to validate their performance with prosthesis users. The results of which, will be included in our presentation.

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### **ACKNOWLEDGEMENTS**

We would like to acknowledge Dr. Pooja at Bhagwan Mahaveer Viklang Sahayata Samiti and the DoD ORP funding program.



## 2.4.4.g

## Does Spring Stiffness Affect Symmetry in a Change of Direction Movement in Unilateral Transtibial Amputees when Wearing Running Specific Prostheses

Laura Ritchie<sup>1</sup>, Siobhán Strike<sup>2</sup>

Chas A Blatchford and Sons Ltd, Basingstoke, United Kingdom. <sup>2</sup>University of Roehampton, London, United Kingdom

### **BACKGROUND**

It is well established that amputees show asymmetry in walking, running and jumping.[1] Clinically, asymmetry is avoided to minimize overloading of either leg. It has been reported that a change in foot spring stiffness has a significant effect on symmetry with respect to peak ground reaction force (GRF) during a forward-bound movement;[2] however there is no reported evidence of a change in spring stiffness affecting the symmetry during a change of direction movement (CoDm).

### AIM

The aims of this research are (i) establish how asymmetrical amputees are while performing a CoDm, when wearing a running specific prosthesis (RSP) and (ii) determine if spring stiffness altered the results with respect to asymmetry.

### **METHOD**

Ten unilateral male trans-tibial amputees participated. Data was captured using 12 Vicon cameras and 2 Kistler force plates (FP), sampling at 120Hz and 960Hz respectively (filtered 4<sup>th</sup> order Butterworth filter, cut-off frequency 6Hz and 300Hz resp). Data was collected over two sessions - prescribed stiffness followed by increased stiffness. Participants jumped forward onto a FP, landing on the intact leg, then immediately side-jumped to land on the prosthetic leg on the adjacent target. The movement was repeated with the prosthetic leg leading. Ten good trials were collected with five analysed. Asymmetry index was calculated [(I-P)/0.5(I+P)] x100% for prosthetic v intact for both stiffnesses and paired T-tests run.

### **RESULTS**

There were no significant differences during the loading phase of the movement, when looking at vertical, braking and medio-lateral GRFs and three dimensional loading rates. Although there was some variation in the direction of asymmetry in all tested variables, most amputees displayed the same direction of asymmetry.

### **DISCUSSION AND CONCLUSION**

It was expected that amputees would not be able to achieve the same spring deflection under the same force in the stiffer condition, therefore it was hypothesised that increased spring stiffness would result in a significant change in asymmetry. This was not the case for any of the kinetic variables, therefore amputees may have accommodated with changes in the trunk and pelvis. This compensation could also explain the difference in direction of asymmetry between the two stiffness conditions.

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## Free Paper Session

## Prosthetics: Lower Limb Transfemoral – Rehab & Sport

### 2.4.5.a

## A Survey on Prosthesis Usage and Walking Ability in Community-Dwelling Individuals with Above-Knee Amputation

Yusuke Tezuka<sup>1,2</sup>, Mitsunori Toda<sup>1</sup>, Takaaki Chin<sup>1</sup>, Yasushi Miura<sup>2</sup>

Hyogo Rehabilitation Center, Kobe, Japan. <sup>2</sup>Kobe University Graduate School of Health Sciences, Kobe, Japan

### **BACKGROUND**

The number of patients with above-knee amputation (AKA) is still slightly increased associated with increased lower limb amputation (LLA), however the proportion of AKA among LLA is decreasing. The rate of successful prosthetic rehabilitation for people with AKA is extremely poor. To comprehend prosthesis usage and walking ability in community-dwelling amputees could facilitate appropriate prescription of prosthesis and rehabilitation. However, few studies have focused on people with AKA.

### AIM

To investigate prosthesis usage and walking ability in community-dwelling people with AKA by questionnaire.

### **METHOD**

Questionnaires were sent by post to 95 above-knee amputees (transpelvic amputation, hip disarticulation, and transfemoral amputation) who underwent prosthetic rehabilitation in our facility in the past 15 years. The primary outcome measure included frequency of prosthetic use, current use of the prosthesis indoors and outdoors, factors of reducing the prosthetic use indoors, the Locomotor Capabilities Index-5 (LCI-5), and the self-rating modification of the Frenchay Activities Index (FAI). Fisher's exact test and Mann-Whitney U test were used as statistical analysis. Statistical significance was set at p<0.05.

### **RESULTS**

Sixty-five people with AKA (68.4%) responded to the questionnaire, and 93.8% of them reported continued use of their prosthesis. The respondents used their prosthesis for 6.3±1.2 days per week and 8.7±4.7 hours per day, and the LCI-5 score was 44.8±12.9. All of the prosthetic users used their prosthesis for locomotion outdoors, while 52.5% used for indoors. As for the domestic housework, people with AKA not using the prosthesis indoors were found to have significantly lower FAI score than those using (6 versus 12, p<0.01). With regard to factors of reducing the prosthetic use indoors, non-users reported greater difficulties in donning and doffing their prosthesis (p<0.05).

## **DISCUSSION AND CONCLUSION**

The outcome of this study compared favorably with those reported in previous studies which included 59.8 to 84.2% of people with transtibial amputation. These results suggest that community-dwelling people with AKA could maintain their walking ability with prosthesis for a long period. However, there is a possibility that prosthetic non-users might be included in the non-respondents to the questionnaires. Therefore, careful long-period follow up is desired for people with AKA.



## 2.4.5.b

## Effects of Bicycle Geometry on Kinematics and Residual Muscle Potential during Pedaling with a Transfemoral Prosthesis: A Computer Simulation Study

<u>Yusuke Okita</u>, Takashi Nakamura National Rehabilitation Center for Persons with Disabilities, Tokorozawa, Japan

### **BACKGROUND**

Cycling or pedaling has possible benefits for individuals with transfemoral amputation, including increased exercise participation and aerobic conditioning. However, baseline biomechanical information that clinicians can use to set individualized bicycle configurations is scarce. Experiments manipulating the bicycle geometry could yield meaningful results; however, the number of conditions feasible to test during an experimental session is limited. Therefore, computer simulation can be used to test multiple conditions.

### AIM

This study evaluated the effects of seat height, seat-tube angle, and crank length on hip and knee kinematics and on residual limb muscle potential during pedaling with a transfemoral prosthesis.

### **METHOD**

In total, 30 models and their corresponding kinematics during one pedaling cycle (0°–360°) were generated from a baseline unilateral cycling model by varying the seat height, seat-tube angle, or crank length using OpenSim and MATLAB softwares. Induced acceleration analysis was performed to compute the residual limb muscle potential for crank rotation in each model. The effects of each variable on the magnitudes and timings of peak flexion or extension angles, hip and knee range of motion, and muscle potential in forward crank rotation during the downstroke phase were evaluated.

### **RESULTS**

The minimum hip angle was achieved 2.3° earlier with a 1% leg length increase using a higher versus lower seat. With a constant range of motion, a greater seat-tube angle delayed peak flexion and extension for the hip and knee joints and produced smaller hip flexion angles throughout the pedaling cycle. Extending the crank length by 5 mm increased the hip and knee range of motion by 1.5° and 2.5°, respectively. A higher seat induced a smaller muscle potential in forward crank rotation at the end of the downstroke phase, and a greater seat-tube angle increased the peak potential of the hip extensors. In contrast, the crank length had little effect on muscle potential compared with that on the other two variables.

### **DISCUSSION AND CONCLUSION**

The seat height during pedaling affected the hip and knee range of motion and residual hip muscle potential, especially at the end of the downstroke phase. The seat-tube angle manipulated hip kinematics without changing the joint range of motion, which was related to the pelvic tilt. The crank-arm length is distinct from other variables because it changed the range of motion without significantly affecting the muscle potential for pedaling.

### **ACKNOWLEDGEMENTS**

This study was supported by JSPS KAKENHI Grant Number JP18K17744.



### 2.4.5.c

## Prosthetic Rehabilitation Following Multiple Limb Loss: Basics to Bionics a Case Study

### Sioned Steventon

Queen Mary's Hospital, Roehampton, London, United Kingdom

### **BACKGROUND**

Multiple limb amputations are relatively rare. The Douglas Bader Centre at Queen Mary's Hospital, Roehampton, has seen an increasing number of this patient group engage in inpatient rehabilitation over the past ten years. Bilateral lower limb amputations are commonly due to diabetes and peripheral vascular disease however multiple limb amputations can be caused by a number of additional factors, including trauma and purpura fulimans.

### AIM

The aim of this paper is to record the multiple limb amputees who have undergone rehabilitation at Roehampton over the past fourteen years, focussing on a quadrilateral patient progressing from primary amputee through to microprocessor knee provision.

### **METHOD**

A substantial database has been collated at Roehampton from 2005 to present, detailing each patient who has attended for both inpatient and outpatient rehabilitation at Queen Mary's Hospital. This database was searched for multiple limb amputees. One of these patients was chosen for the case study. Video footage and outcome measures will be presented.

### **RESULTS**

From 2005 to present twenty-six primary multiple limb amputees were rehabilitated. The average length of rehabilitation was 85 days. 17 remain active, 3 inactive, 3 deceased and 3 have moved centre. Age range was 17-73 years, with a mean age of 49 years. The causes of amputations were 12% trauma, 4% diabetes mellitus and 85% infections, with 86% of these infections being septicaemia.

The case study comprises of a 46-year-old male who became a quadrilateral amputee due to pneumococcal sepsis. He has progressed from short rocker pylons, to SAKL and feet, to free knee walking and now uses microprocessor knees (MPK's). Six-month and one-year outcome measures identified a decline in *timed up & go* due to the sit to stand being complex with free knees, but an increase in distance for *6-minute walk test. PEQ* scores have also improved.

## **DISCUSSION AND CONCLUSION**

The rehabilitation process at Roehampton relies upon our past experiences managing this complex patient group. It is clear from our experience that patient specific goals are fundamental for each individual. This case study indicates that MPK provision will enhance quality of life for future multiple limb patients.

## **ACKNOWLEDGEMENTS**

Thank you to the patient, the multidisciplinary team at Queen Mary's Hospital, Roehampton and to opcare for their continued support.



### 2.4.5.d

## Results of Using the NAL-Knee Knee Joint on a Trans-femoral Prosthesis for Post-amputation Using from the Beginning of Training

Makoto Ninomiya<sup>1,2</sup>, Takashi Hasegawa<sup>3,4</sup>

<sup>1</sup>Nagasaki Kanae Co., Ltd, Nagasaki, Japan. <sup>2</sup>CPO, Nagasaki, Japan. <sup>3</sup>Wajinkai Hospital, Nagasaki, Japan. <sup>4</sup>CPT, Nagasaki, Japan

### **BACKGROUND**

The NAL-Knee, which we have developed, is a knee joint which provides flexure lock in response to toe loading, and yielding in response to heel loading. When lifted, the knee moves freely without resistance, allowing the user to walk and run with variable speed. This is not electronic control, so no batteries etc. are required.

#### ΔIM

To investigate whether new amputees, using this NAL-Knee in a highly-functional prosthesis from the beginning, could use it well from an early stage for tasks such as walking on stairs and slopes.

### METHOD

A male right trans-femoral amputee aged 23, who had lost a leg in a road accident and had a 17cm stump length, used a MAS socket with silicon pin-type liner, and a NAL-Knee knee joint. This NAL-Knee had the center of the bouncer link at the bottom specially brought somewhat further forward, to facilitate yielding under heel load. That means that knee buckling happens less easily. The subject used this prosthesis for gait training for three months before being discharged. During this training period, we measured the circumference of the stump end, and the walking speed over 10m. We also investigated how well the subject was able to descend stairs.

### **RESULTS**

We assembled a prosthesis using NAL-Knee from the stage of provisional matching with the first check socket. We checked socket fit and alignment, and thoroughly explained the functions of the NAL-Knee to the subject. Then with a crutch on one side he was able to walk without buckling, and bending the knee in the swing phase. His walking speed also rose after about 1 month, and he was able to walk without a crutch. He gradually gained the ability to use yielding to descend stairs. One month after the initial provisional fitting, the silicon size had dropped by two steps, from 45cm to 40cm, and we re-made the check socket. We tried other knee joints at the finishing stage, but the subject chose to use NAL-Knee when complete the training prosthesis.

## **DISCUSSION AND CONCLUSION**

Inexperienced lower-limb prosthesis users typically use safety knees such as load brake knees, or link knees with high stance phase stability. But in this case we used the NAL-Knee, which uses the amputee's voluntary control to maintain stability. As a result, the subject gained functions such as descending stairs with reciprocal gait at an early stage, and was able to raise his activity level such as walking at variable speeds.

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## 2.4.5.e

## How Zeneba, a Malian Double Amputee, Recovers her Autonomy Through the ICRC Multidisciplinary Approach

<u>Timothée Pakouyowou Mendemwelabou</u> ICRC, Bamako, Mali

### **BACKGROUND**

The ICRC through its physical rehabilitation program assists victims of conflicts as well as vulnerable people in countries affected by war. Zeneba was born with agenesis of the right leg and at age 11 she was amputated (trans-tibial) on the left side, following a gunshot wound. Zeneba came to the Bamako National Rehabilitation Centre with the objective of being able to walk and performing her daily activities including attending school.

#### AIM

The purpose here is to present how the ICRC's multidisciplinary approach has allowed to overcome, professionally speaking the challenges of the Zeneba's case allowing her to here perform daily activities.

### **METHOD**

Through a multidisciplinary approach involving several professionals along with Zeneba's inputs, to provide a comprehensive solution to ensure the optimal mobility solution taken into consideration Zeneba's environment (hot and dusty), to promote Zeneba's autonomy, well - being and social integration.

During the treatment Zeneba got access to:

- Psychosocial counseling;
- Surgical services: amputation on the right agenesis side to facilitate provision of prostheses
- Physical Therapy services: muscles strengthening, stump modeling, cognitive massage, gait training;
- Prosthetic services: provision of two prostheses manufactured using polypropylene technology developed by the ICRC. SACH feet and a single-axis knee joint were used.

## **RESULTS**

At the end of treatment process, Zeneba shows a great acceptance of her prostheses and was able to walk with an unlocked knee with the help of elbow crutches. She got used to the prostheses and achieved autonomy in walking.

To achieve this result, she started gait training with the prosthetic knee locked and as she gains confidence the prosthetic knee was progressively unlocked. Through the gait training, the adduction gait was solved by widening the base of support allowing her to feel safe. This was achieved by medial translation and adduction of the socket. Zeneba was also walking with hyperlordosis; which is common for double amputees. This was solved by working on the posture and a slight bending of the socket.



Figure 1. Zenaba's legs before and after procedure.

## **DISCUSSION AND CONCLUSION**

The ICRC's multidisciplinary approach has enabled Zenaba to regain mobility and perform her daily activities including attending school. Providing only prosthetic services will not have shown the same results; it is the involvement on the entire team and the involvement of Zeneba that allow her to be active in her community.



## 2.4.5.f

## **Ground Reaction Forces during Running in Unilateral Transfemoral Amputees**

Hiroyuki Sakata<sup>1,2</sup>, Satoru Hashizume<sup>2</sup>, Hiroshi Takemura<sup>1</sup>, Hiroaki Hobara<sup>2</sup>
<sup>1</sup>Tokyo University of Science, Chiba, Japan. <sup>2</sup>National Institute of AIST, Tokyo, Japan

### **BACKGROUND**

Analysis of ground reaction forces (GRFs) is a classical and basic approach to evaluate human locomotion.[1,2] Although the magnitudes of the GRFs are speed dependent [2], the available data for unilateral transfemoral amputees only focuses on maximal sprinting speed [3] or vertical component of GRF.[4] Therefore, the effect of running speed on each component of GRF should be examined in unilateral transfemoral amputees wearing running-specific prosthesis (RSP).

### AIM

To investigate GRF profiles for unilateral transfemoral amputees at various speeds.

### **METHOD**

Eleven unilateral transfemoral amputees wearing their own RSP ran on an instrumented treadmill at incremental speeds of 30%, 40%, 50%, 60%, and 70% of their maximum speed. The maximum speed was determined by dividing the race distance (100-m) by personal best time (17.64  $\pm$  2.55 s). GRF data were collected by two force plates at 1000 Hz. The GRF data were filtered by Butterworth filter with a cut-off frequency of 25 Hz [5]. The instants of touch-down and toe-off were detected using a threshold of 40 N for the vertical component of GRF [6]. Two-way repeated-measures ANOVA followed by Bonferroni multiple comparison was performed to compare peak GRFs between the limbs.

### **RESULTS**

Figure 1 shows mean GRF profiles of the affected and unaffected limbs across 5 speeds. Significant interactions between speed and limb were observed on peak vertical, anterior, and posterior GRFs, but not on peak medial and lateral GRFs. Peak vertical, anterior, and posterior GRFs of the affected limb were significantly smaller than the unaffected limb at 40%, 50%, 60%, and 70% speed (p < 0.05). However, there was no significant difference in peak medial and lateral GRFs between the limbs except for peak lateral GRF at 50% speed (Figure 1).

### **DISCUSSION AND CONCLUSION**

Peak vertical and anteroposterior GRFs increased with speed; however, unaffected limb increased more than affected limb. Similar trends were demonstrated in transtibial amputees [1]. Peak media GRF slightly increased with speed as well as non-amputees [2]. However, our findings that both limbs mainly generated medial GRF disagree with non-amputees [2] and transtibial amputees [1]. These results suggest that mediolateral GRFs is not the same among amputation levels. Our data will provide a useful reference for prostheses design and prosthetics education.

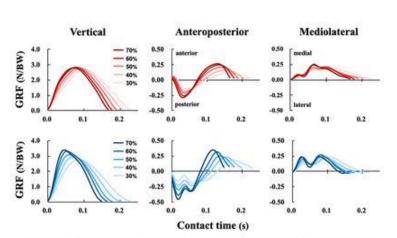


Figure 1. Mean ground reaction force (GRF) profiles of the affected (red) and unaffected (blue) limbs across 5 running speeds (N=11).

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# Symposium Orthotics: Spinal

### 2.4.6

## Application of 3D Assessment and Orthotic Design for the Patients with Adolescent Idiopathic Scoliosis

M. S. Wong<sup>1</sup>, Babak Hassan Beygi<sup>1</sup>, Yangmin Lin<sup>1</sup>, Chen He<sup>2</sup>

The Hong Kong Polytechnic University, Hong Kong, Hong Kong. The University of Shanghai for Science and Technology, Shanghai, China

### **Abstract**

Scoliosis is a 3-dimensional (3-D) spinal deformity with lateral curvature of the spine and vertebral rotation. Most cases are with unknown cause and found in adolescence, therefore, it is termed as adolescent idiopathic scoliosis (AIS). For severe cases, surgeries will be considered but for moderate AIS, the conventional treatment method is to apply rigid spinal orthoses to patients during their puberty to mechanically support the spine and prevent further deterioration. The outcome of orthotic treatment for AIS is generally considered being associated with the orthosis design and patient's compliance. Although scoliosis is a 3-D spinal deformity, there is lack of non-invasive, inexpensive and accurate assessment method to allow clinicians to reveal the change of deformity during the processes of orthotic design and patient fitting. Moreover, the current orthotic methods and techniques are lack of enough scientific evidence although there are some studies demonstrated the spinal orthosis being effective. In this symposium, the speakers will share with delegates their research studies, clinical experiences and scientific evidences to better understand the science behind the phenomenon that orthoses appear effective and go further for evidence-based practice. Moreover, application of the state-of-art ultrasound technique to the assessment of spinal deformity and flexibility, as well as in the design and fitting of spinal orthosis will be discussed and the relevant clinical results will be reported.

## Statement of the objective / learning objectives

The advanced technology of 3D assessment and design of spinal orthosis will be introduced. Some clinical findings will be discussed in the symposium.



# Advanced IC Rehabilitation Medicine & Surgery

### 2.4.7

## The Single stage Osseointegration Rehabilitation Program: Reducing Rehab From 18 Months to 2 Months with Improved Outcomes

Munjed Al Muderis<sup>1,2,3</sup>, William Lu<sup>1,2,3</sup>
<sup>1</sup>Osseointegration Group of Australia, Sydney, Australia. <sup>2</sup>Macquarie University, Sydney, Australia. <sup>3</sup>The University of Sydney, Sydney, Australia

### **Abstract**

Osseointegration is a new method for rehabilitating persons suffering from limb loss and overcomes many socket-related problems by directly attaching a prosthetic implant to the skeletal residuum. To date, the vast majority of osseointegration procedures worldwide have been performed in two stages, requiring up to 18 months for the entire rehabilitation process. This instructional course will provide a detailed overview on the key aspects of a new accelerated rehabilitation protocol we have adopted in our clinics, which dramatically reduces the time of rehabilitation to as little as 4-6 weeks. This was made possible via an improved implant design as well as new surgical techniques. The course will also report on the safety and efficacy outcomes of this single-stage osseointegration procedure performed in our centers.

A retrospective analysis on patients who experienced socket-related problems or difficulties in using socket prostheses and underwent osseointegrated reconstruction. Functional and quality of life outcome measures were analyzed preoperatively and postoperatively with minimum follow-up time of 2 years. Significant improvements for several outcome measures were detected, similar to the results obtained using the two-stage procedure.

Interestingly, the occurrence of adverse events including the infection rate, refashion rate and revision rate were also significantly lower compared to the two-stage procedures. These preliminary results suggest that the new single-stage osseointegration approach can be considered safe and effective treatment for amputees experiencing socket-related discomfort. This protocol has the potential to shorten the rehabilitation time to 4-6 weeks which dramatically reduces the time of recovery.

## Statement of the objective / learning objectives

Upon completion of this course, attendees will develop a good understanding on the surgical technique and rehabilitation program applied to enable a safe and effective single-staged osseointegrated reconstruction.



# Free Paper Session Paediatrics

### 2.4.8.a

## 3D-Printed Pediatric Prosthesis Validation Testing

<u>Benjamin Gröschel</u>, Bryce Schmidt Mecuris GmbH, Munich, Germany

### **BACKGROUND**

Pediatric patients with transtibial amputations require medical equipment that must be able to accomodate the physical changes that occur during childhood and adolescence. By transferring digital data from anatomical pediatric characteristics, individualized prosthesis are built using 3D-printing (selective laser sintering) that match the growth pattern of the child at any given time. This technique allows for countless design possibilities, all of which must be verified and validated.

#### AIM

The aim is to prove the mechanical durability of 3D-printed pediatric foot prosthetics according to ISO 10328:2016 and to simulate critical parametric designs with FEA to anticipate design weaknesses.

### **METHOD**

**Pediatric Prosthetic Foot Design:** Laser sintered body made from PA12 ("Nylon", EOS PA2200), glass fiber element for high energy return, SACH adaptor, two damper elements. Prosthesis length and width is 18 cm and 6 cm, respectively.

**Physical Testing:** DIN EN ISO 10328:2016 cyclic test at an adopted load level for approximately 40kg dynamic load 739,9N at 0,76 Hz with one million cycles. Ultimate strength load level P3 (60 kg) on heel and toe 3.220 N (Upper Limit). Six tests conducted total.

**Simulation:** Finite Element Analysis (FEA) using ANSYS, ISO10328:2016 loading conditions, approximate linear material behavior.

### **RESULTS**

Simulation: The individualized foot design is based on a parametric model which offer a considerable amount of design combinations. Since testing all design combinations is not feasible, the ISO 10328 test bench was replicated in an FE simulation model. By simulating multiple parameter combinations of the prosthetic design, the worst-case model was predicted and manufactured for physical testing.

Physical Testing: In a cyclic test, 2 prostheses were tested at an adopted loading level (cyclic test force: 739,9N at 0.76Hz) and showed no visible or internal damages after one million cycles. On the same prosthesis, a static proof test was conducted on the forefront and heel at an adopted loading level ( $F_{max} = 1.225N$ , 162.2N/s loading rate, 33s holding time) and showed no visible or internal damages.

## **DISCUSSION AND CONCLUSION**

The study shows that the pediatric prosthesis passed all defined mechanical tests, however, it is still unknown how the foot is loaded in real life. Children can be unpredictable during ambulation, thus, a patient based testing approach is recommended to be used in combination with virtual parametric design combinations for predicting pediatric prosthesis efficiency and patient acceptance.

Further research to be conducted and presented at ISPO conference:

- Gait lab studies of pediatric transtibial amputees
- Validated simulation for pediatric material failure



### 2.4.8.b

## Physical Performance of Children with Longitudinal Fibular Deficiency (Fibular Hemimelia)

<u>Eleanor Morris</u><sup>1</sup>, Louise Tofts<sup>1</sup>, Margaret Patterson<sup>2</sup>, Oliver Birke<sup>1</sup>, Roger Adams<sup>3</sup>, Adrienne Epps<sup>2,1</sup>, Kathrine Knox<sup>1</sup>, Verity Pacey<sup>3</sup>

<sup>1</sup>The Children's Hospital at Westmead, Sydney, Australia. <sup>2</sup>Sydney Children's Hospital, Sydney, Australia. <sup>3</sup>Macquarie University, Sydney, Australia

### **BACKGROUND**

Longitudinal Fibular Deficiency (LFD) is the most common congenital long bone deficiency. Whilst the varying spectrum of anatomical pathology of LFD is well-established, the impact of this pathology on physical performance is much less clear.

#### AIM

The primary aim of this study was to objectively assess the physical performance of children and adolescents with LFD and compare their performance to that of unaffected peers.

### **METHOD**

Children with LFD aged 3- 18 years performed five objective measures of physical performance: lower limb muscle strength dynamometry, 6-minute walk test, timed up and down stairs test, star-excursion balance test, and standing long jump. Performance differences between children with LFD and their unaffected age-matched peers were examined with independent groups t-tests. Age group comparison was analysed with ANOVA, and ANcOVA used to examine age-adjusted subgroup variation within the cohort of children with LFD.

### **RESULTS**

Thirty-nine children with LFD (46% male, mean age 9 years) and 284 unaffected peers participated. With the exception of jump performance (p-value 0.27), children with LFD performed worse on all measures of physical performance, including lower limb strength (mean of 2.2 standard deviations below norms, all p<0.01), and other functional measures. There was a significant difference in the linear trend component of the slope of the rise on all strength measures and walking performance, indicating the difference in strength and walking performance between children with and without LFD was smallest in children of a young age and largest in the oldest children (all p<0.015).

Subgroup analysis demonstrated that children who had undergone lengthening surgery had reduced walking performance compared to children with LFD who had not undergone lengthening surgery (mean difference 83 metres, p < 0.01).

## **DISCUSSION AND CONCLUSION**

Children with LFD are significantly weaker in both affected and non-affected lower limbs than their healthy peers, and this difference is greater in older children.

Whilst acknowledging the cross-sectional nature of these findings, this reveals a likely picture of children with LFD falling further behind their unaffected peers as they enter adulthood and is consistent with recent findings of a young adult population with congenital limb deficiencies.3

## **REFERENCES**

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### **ACKNOWLEDGEMENTS**

Professor David Little, Dr Michael Bellemore and Dr Paul Gibbons for additional advice and assistance in recruitment.



### 2.4.8.c

## Running-Based Anaerobic Performance of Dutch Children using Lower Limb Prostheses

Anka Michielsen, Olaf Verschuren, Iris van Wijk

Center of Excellence for Rehabilitation Medicine, Brain Center Rudolf Magnus, University Medical Center Utrecht, Utrecht University and De Hoogstraat Rehabilitation, Utrecht, Netherlands

### **BACKGROUND**

In the Netherlands about 500-600 children (< 18 years) use a lower limb prosthesis. To be able to participate in active play and sports, children need to alternate between high and low intensity movements which requires an optimal anaerobic performance. An important determinant of anaerobic performance is the ability to produce repeated sprint efforts [1]. No data is available on the anaerobic performance of children using lower limb prostheses and to what extend they can compete with their peers.

### AIM

To describe anaerobic performance of Dutch children using lower limb prostheses in comparison with typically developing children and to explore the differences in anaerobic performance between the various degrees of limb loss.

### **METHOD**

Anaerobic performance is assessed with the Muscle Power Sprint Test (MPST) in children and adolescents using a lower limb prosthesis, aged 6-18 years. The MPST is a running-based anaerobic test which requires the child to undertake six 15-m sprints at maximum pace with 10-seconds recovery between each sprint. Speed, acceleration, peak power and mean power of the lower extremities can be calculated. For the MPST normative values have been established for typically developing children of 6-18 years of age. The MPST is a valid and reliable test for measuring anaerobic performance and can be used as an evaluation tool in children and adolescents [2].

### **RESULTS**

Results of 52 children (age range 6-18 years; 34 boys 18 girls) with various degrees of limb loss depending on different kind of prostheses indicate that running-based anaerobic performance of Dutch children and adolescents differs from healthy peers. Most children (76%) perform on or below the 3<sup>rd</sup> percentile range of healthy peers. Six children (N= 24) with unilateral Below-knee prosthesis, one child (N= 6) with unilateral Above-Knee prosthesis, one child (N= 5) with rotationplasty, one child (N= 6) with extension prosthesis and two children (N= 8) with a unilateral sports prosthesis (blade) ran within the regular anaerobic performance of typically developing children.

## **DISCUSSION AND CONCLUSION**

Children and adolescents using lower limb prostheses perform less than their healthy peers on the running based anaerobic performance test (MPST). Their running performance seems limited by the prosthesis they depend on, although some children's anaerobic performance is comparable to their peers.

### **REFERENCES**

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[2] Verschuren O, Pediatr Phys Ther 2013.



### 2.4.8.d

## Fracture Prevention in Osteogenesis Imperfecta - Do Protective Bracing of the Lower Limbs have Additional Effect?

Shirley Meyer, Emanuel Kornitzer, Coos Weber, <u>Sharon Eylon</u>
Alyn Rehabilitation Hospital for Children & Adolescents, Jerusalem, Israel

### **BACKGROUND**

Osteogenesis Imperfecta (OI) is a genetic disease of collagen structural abnormality. Several types exist with different severities, all causing pathological fractures. Treatment of fractures may be surgical or conservative. Preventive treatment with Bisphosphonates changes bone metabolism and strengthens the bones, helping to prevent fractures. This treatment modality is common practice, although there are adverse effects. Bracing treatment using an HKAFO with anterior shells also prevents fractures and deformities, and enables ambulation, but has very little reports in the literature.

#### AIM

The aim of this work was to retrospectively assess the additive effect of bracing to fracture prevention in patients with OI.

### **METHOD**

A retrospective study was conducted, of all patients with the diagnosis of OI treated in our hospital since 1991 till 2017. Data was collected from files, including demographics, clinical data on treatment with HKAFO bracing and with Bisphosphonates, data on fractures and modalities of fracture treatment.

### **RESULTS**

129 patients were located, but only 78 had sufficient data and were included in the study. Primary treatment modalities included IV Bisphosphonates and bracing with HKAFO & anterior shells. All patients reported having numerous fractures along the years, most were casted. 43 patients reported having surgical procedures (number ranged 1-6 per patient) - 43 surgeries were elective, 34 acute fracture fixation, 4 spine fusion and 6 others. Bisphosphonates treatment was followed with reduction of fracture events, as was the use of HKAFO bracing, but the biggest reduction was seen with combined treatment of Bisphosphonates & HKAFO. Of the fracture events reported, 43 patients specified the fracture occurred while not using the HKAFO even though having them available. Data was not found to be related to OI types.

## **DISCUSSION AND CONCLUSION**

We believe that bracing of OI patients with HKAFO & anterior shells has an additive effect to Bisphosphonate treatment in fracture prevention.



### 2.4.8.e

## Estimated Prevalence of Congenital Upper Limb Deficiency in Japan: a Cross-Sectional Nationwide Survey on its Epidemiology

<u>Sayaka Fujiwara</u><sup>1</sup>, Hiroshi Mano<sup>1,2</sup>, Kazuyuki Takamura<sup>3</sup>, Hiroshi Kitoh<sup>4</sup>, Shinichiro Takayama<sup>5</sup>, Tsutomu Ogata<sup>6</sup>, Nobuhiko Haga<sup>1</sup>

<sup>1</sup>University of Tokyo Hospital, Tokyo, Japan. <sup>2</sup>Shizuoka Children's Hospital, Shizuoka, Japan. <sup>3</sup>Fukuoka Children's Hospital, Fukuoka, Japan. <sup>4</sup>Nagoya University Hospital, Nagoya, Japan. <sup>5</sup>National Center for Child Health and Development, Tokyo, Japan. <sup>6</sup>Hamamatsu University School of Medicine, Hamamatsu, Japan

### **BACKGROUND**

Congenital upper limb deficiency (CULD) is a rare disease which impairs both function and appearance of the limbs. Treatment approaches vary according to the type of deficiency. There are no epidemiological studies of CULD in Japan. To provide better evidence-based medical care, it is necessary to establish the concept of CULD, its estimated number of patients and its classification and grades of severity through detailed cataloging of CULD occurrences in the country.

#### ΔIM

The purpose of this study is to investigate the current epidemiological status of CULD in Japan.

### **METHOD**

From the data of the preceding nationwide epidemiological survey in Japan,[1] we extracted a total of 442 patients with CULD. In this study, we defined CULD as partial or total absence of the limbs, in proximity to the proximal interphalangeal joint of the fingers or interphalangeal joint of the thumb. By analyzing this data, we estimated the prevalence and revealed the basic patient features of CULD.

### **RESULTS**

The estimated prevalence of CULD in Japan was 3.39 per 10,000 live births. CULD accounts for approximately 69.7% of estimated total congenital limb deficiency. The breakdown of affected limbs was upper-right 49.3%, upper-left 50.7%. For upper limbs deficiencies, transverse deficiency was the most prevalent 45.5%, followed by longitudinal deficiency 31.2%, central deficiency 17.0%, other finger column deficiency 5.2%, and finally intercalary deficiency 1.1%. Distal deficiency comprised a large proportion of transverse deficiencies, with proximal deficiency occurring less frequently. The coexisting disorders with relatively high prevalence were cardiac anomaly, renal and urinary tract anomalies, cleft-lip/palate, and developmental disorders.

## **DISCUSSION AND CONCLUSION**

We revealed the estimated prevalence and clinical features of CULD in Japan. Our results will contribute to establishing the disease concept and treatment strategies of CULD in Japan.

## **REFERENCES**

[1] Mano H, BMC Musculoskelet Disord 2018.

### **ACKNOWLEDGEMENTS**

This work was supported by grant number H26-Nanchitou-Ippan-089 and H27-Nanchitou-Ippan-036, and by JSPS KAKENHI Grant Number 18K17890.



### 2.4.8.f

### Parent's Role in Decision and Treatment of Children with Limb Malformation

Lis Sjöberg<sup>1</sup>, <u>Liselotte Hermansson</u><sup>2,3,1</sup>, Helen Lindner<sup>1</sup>, Carin Fredriksson<sup>1</sup>

School of Health Sciences, Örebro University, Örebro, Sweden. <sup>2</sup>University Health Care Research Center, Faculty of Medicine and Health, Örebro University, Örebro, Sweden. <sup>3</sup>Dept of Prosthetics and Orthotics, Faculty of Medicine and Health, Örebro University, Örebro, Sweden

### **BACKGROUND**

Parents of children with limb malformation are facing many decisions related to their child during the child's first years, e.g. when, or if to start treatment, and to choose from different interventions. Usually the interventions concern surgical and/or prosthetic treatment options. A family-centred approach indicates the importance of providers to understand family belief systems with respect to the involvement of family members and is, thus, important to implement in childcare.

#### AIM

The aim of this study was to describe parent's experiences of their role in decision-making and treatment for children with limb malformation.

### **METHOD**

A descriptive, qualitative design was used. Semi-structured interviews were conducted with 17 parents of children with upper and/or lower limb reduction deficiency, including mothers (n=12) and fathers. Mean age of their child was 5.9 years. Data was analysed using qualitative content analysis with inductive approach.

### **RESULTS**

The results show that parental role in making decisions included awareness of being a decision-maker in this context and experiences of having a role to make the best decisions for another person's future as self-evident but maybe not wanted. The parental roles in the treatment processes included: i) being a collaborator within the family and between health care providers and family; ii) being a constant supporter for challenges in everyday life; and, iii) handling a variety of needs based on psychosocial issues.

### **DISCUSSION AND CONCLUSION**

Parents of children with limb deficiency experience an important but challenging role. We conclude that the results contribute to new knowledge and understanding of parents' as decision makers and may improve family centred health service and enhance the care for children with limb malformation.

### **ACKNOWLEDGEMENTS**

The research was funded in part by Norrbacka Eugenia-foundation, Region Örebro County, and Faculty of Medicine and Health, Örebro University, Sweden.



## 2.4.8.g

## Translation and Cross-cultural Validation of Children's Hand-use Experience Questionnaire (CHEQ) 2.0: Arabic Language Version

Ahmed Amer<sup>1</sup>, Mahmoud Alomari<sup>2</sup>, <u>Liselotte Hermansson</u><sup>3,1</sup>, Ann-Christin Eliasson<sup>4</sup>, Gustav Jarl<sup>1,3</sup>
<sup>1</sup>University Health Care Research Center, Faculty of Medicine and Health, Örebro University, Örebro, Sweden. <sup>2</sup>Division of Physical Education, Dept of Educational Sciences, Qatar University, Doha, Qatar. <sup>3</sup>Dept of Prosthetics and Orthotics, Faculty of Medicine and Health, Örebro University, Örebro, Sweden. <sup>4</sup>Neuropediatric Research Unit, Karolinska Institutet, Stockholm, Sweden

### **BACKGROUND**

Children with physical disability such as unilateral hand dysfunction need assessment-based rehabilitation interventions to increase their participation and independence in performing daily life activities. The Arabic speaking countries represent more than 400 million people and a substantial part of children with disability live in these countries. However, most instruments are developed in the western world and there is a shortage of culturally adapted instruments to be used in the Arabic speaking countries.

#### AIM

This study aimed to perform a translation and cross-cultural validation of the Arabic language version of Children's Hand-use Experience Questionnaire (CHEQ) 2.0.

### **METHOD**

This was a cross-cultural validity study, carried out based on principles of good practice in accordance with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines for translation and cultural adaption. Data collection was conducted in Jordan. The translation and cross-cultural validation process was performed in four phases: 1) forward translation and reconciliation with feedback from parents and typically developing children (n=14); 2) backward translation and review by two groups; 3) cognitive debriefing with parents and/or their children with unilateral hand dysfunction (n=17); and, 4) review and proofreading to produce the target version of CHEQ 2.0 in Arabic.

## **RESULTS**

A forward translation was performed. In the subsequent interviews, the children and their parents reported that all items were understandable. Backward translation revealed that the wording had changed for 5 items, which could affect the meaning. This step produced suggestions for a revised Arabic CHEQ 2.0.

The cognitive debriefing demonstrated that 28 of the 30 items (i.e. 93%) were culturally relevant. The comprehension rates of the items varied between 87 and 100% (average 95%) for the parents and children with hand dysfunction. The response option "Get help - how does it work if you try for yourself?" was unclear for 80% of participants. Sixty and 29% of children reported using knife and fork was not clear in two items respectively.

### **DISCUSSION AND CONCLUSION**

After the suggested changes are made, the Arabic version of CHEQ 2.0 will be considered cross-culturally valid to use in Arabic speaking countries. This study was the first step in a validation process for the Arabic version of CHEQ 2.0. Psychometric analyses of the Arabic version of CHEQ 2.0 in different patient groups are recommended in future studies.

## **REFERENCES**

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### **ACKNOWLEDGEMENTS**

Professor Alomari acknowledges the grant number MA 84/2017.



## Monday, 7 October

## **Keynote Lecture 3.0**

## **Complex Entanglements: People and Assistive Technologies**

Deirdre Desmond<sup>1</sup>
<sup>1</sup>Maynooth University, Maynooth, Ireland.

### **Abstract**

Complex interactions across multiple system levels – user, prosthesis, services, environment, community – influence the experiences of becoming and being a prosthesis user and shape a person's sense of self and identity. Technological advances in prosthetics and assistive technologies broadly, bring new possibilities, expectations, opportunities and challenges and inspire fundamental questions about personhood and embodiment. These potentials are situated within the wider landscape of growing hyper-connectivity between people, Things and intelligent systems that will in the future manage many aspects of our lives. Yet advances in technological capabilities continue to outpace our understanding of the personal and social significance of such developments and the ethical, legal, and policy frameworks to govern their deployment.

This presentation will consider issues posed by the growing complexity of interactions between humans and machines and reflect on experiences of human/technology integration and the complexity of these entanglements in the field of prosthetics.



# Symposium Orthotics: Lower Limb Neurological

### 3.1.1

## ANKLE-FOOT ORTHOSES: Considerations and Perspectives on the DESIGN and TIMING of PROVISION

Johan Rietman<sup>1,2</sup>, <u>Corien Nikamp</u><sup>1,2</sup>, <u>Juha Hijmans</u><sup>3</sup>, <u>Han Houdijk</u><sup>4</sup>
<sup>1</sup>Roessingh Research and Development, Enschede, Netherlands. <sup>2</sup>University of Twente, Enschede, Netherlands. <sup>3</sup>University Medical Center Groningen, Department of Rehabilitation Medicine, Groningen, Netherlands. <sup>4</sup>Vrije Universiteit Amsterdam, department of Human Movement Sciences, Amsterdam, Netherlands

### **Abstract**

Ankle-foot orthoses (AFOs) are frequently used to improve walking in a variety of diseases. The effect of such interventions relies on adequate prescription. This symposium provides insights from recent studies focusing on both optimizing timing of prescription and optimizing biomechanical properties of the AFO.

A recent study on the timing of AFO-provision after stroke showed that early AFO-provision results in functional improvements over time. These improvements were achieved without changes in affected limb kinematics or muscle-activity. This suggests that compensation mechanisms are important and highlights the importance of the unaffected leg in rehabilitation therapy. To improve the affected leg function, new AFO-designs should be considered.

Conventional AFOs also have disadvantages. For example, often too stiff AFOs are prescribed. These AFOs are less comfortable and restrict ankle movement, also in patients who potentially have some residual muscle strength. By restricting ankle plantarflexion movement, also ankle power is reduced. AFO-preference from literature, patient-perspectives on AFO-designs and the design of a new AFO taking both patient-perspective and biomechanics into account are presented in this symposium.

With respect to AFO-use, much attention has been paid to optimizing range of motion and stiffness around the ankle. From a biomechanical perspective however, the properties of the AFO footplate are just as important, as the leverage of the foot determines the loading of the ankle joint. In the final contribution of the symposium, the biomechanical effects of AFO footplate stiffness on ankle motion and foot and ankle power during the stance phase of gait will be demonstrated.

## Statement of the objective / learning objectives

The effect of timing of AFO-provision after stroke on gait kinematics and EMG. Patient-perspectives and biomechanical aspects of AFO design . Importance of AFO footplate stiffness on foot and ankle power during gait .



# Free Paper Session Prosthetics: Lower Limb Transfemoral - Knee

### 3.1.2.a

## Health-Economic Effects of Falls in elderly Transfemoral Amputees: Influence of the Microprocessor Controlled Knee C-Leg in Vascular and Non-vascular Etiology

Andreas Hahn<sup>1</sup>, Alexander Kuhlmann<sup>2</sup>, Susanne Seidinger<sup>1</sup>
Otto Bock Healthcare Products GmbH, Vienna, Austria. <sup>2</sup>Center for Health Economic Research Hanover (CHERH), Leibniz Universität Hannover, Hannover, Germany

### **BACKGROUND**

Falls as well as fear of falling severely impact the life of transfemoral amputees. The number of falls varies significantly between different prosthetic device types. The microprocessor-controlled knee joint (MPK) C-Leg has been reported to significant reduce fall frequency and related consequences.[1,2] Falls for subjects with vascular etiology are reported to lead more often to severe injuries.[3] Analysis of health economic effects has been provided by RAND for the USA.[4]

#### AIM

The aim of this study is to further detail health economic analysis of falls in transfemoral amputees and the influence of the use of the C-Leg exo-prosthetic knee joint on its cost-effectiveness in Germany.

### **METHOD**

Cost-effectiveness was performed for transfemoral amputees of vascular and non-vascular etiologies. Input parameters were derived from published literature and national cost data. A Markov modeling approach took into account the effects of prosthesis type on the risk of falling and fall-related medical events. Cost-effectiveness was performed for transfemoral amputees of vascular and non-vascular etiologies. Costs and QALYs were discounted by 3% according to the recommendations of the Institute for Quality and Efficiency in Health Care (IQWiG). The cycle length of the model was one year. The time horizon of the cost-effectiveness analysis was ten years.

### **RESULTS**

The model estimated that the C-Leg reduced the rate of fall-related hospitalizations by 75% to ca. 60 per 1,000 person years (PY) in both etiologies. C-Leg was predicted to prevent approx. 30 fall related death per 1,000 PY. In the base case, the incremental cost effectiveness ratio (ICER) was 12,712 Euro per quality adjusted life years gained (QALY) for non-vascular amputees and 12,798 Euro per QALY gained for vascular amputees. Results of the PSA revealed considerable uncertainty but ICER estimates remained acceptable with a high probability.

### **DISCUSSION AND CONCLUSION**

Results of the study indicate that the C-Leg provides substantial additional benefits and is cost-effective compared to NMPKs. The economic benefits of C-Leg in elderly patients with and without vascular disease are similar to or even greater than those earlier. Remarkable is the similarity of the ICER for both etiologies despite a significantly higher mortality for subjects suffering vascular disease.

### **REFERENCES**

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### **ACKNOWLEDGEMENTS**

The preparation of the manuscript was funded by Otto Bock Healthcare Products, the manufacturer of C-Leg.



### 3.1.2.b

## Comparative Analysis of Subjective and Objective Outcome Measures on Mechanical and Micro-Processor Controlled Knees

Katy McIntosh<sup>1</sup>, Katharine Atkin<sup>2</sup>
<sup>1</sup>Opcare, Bristol, United Kingdom. <sup>2</sup>NHS, Bristol, United Kingdom

### **BACKGROUND**

In 2016 NHS England introduced a Microprocessor-Knee (MPK) Policy [1] to allow the prescription of these under specific criteria. Current studies on MPK's are generally either supplier led, look at just one product or compare 'body function' as opposed to more functional outcomes.[2] Few recent studies look at links between previous and new prescription or different MPK's. Information of this nature is essential for continual funding of these knees and is imperative for future prescription choices to be evidence-based.

### AIM

To compare outcome measures on previous mechanical knee and new MPK prescriptions, assessing any links between them to facilitate prescription choices for optimal patient outcomes.

### **METHOD**

Outcome measures were completed on 36 transfemoral prosthetic users at the Bristol Centre for Enablement, England, on their established mechanical knee prescription. The cohort were selected using NHS directed inclusion/exclusion criteria<sup>1</sup> following clinical assessment. An average 30-day trial was then completed on one of four different MPK's and measures repeated. The resultant data was analysed in full prior to being separated into subgroups to assess significant links (p≤0.05) between previous and new prescriptions. Average changes were calculated to identify links and statistically significant changes for each measure as well as each prescription. Subjective feedback and falls data was gathered to support findings.

### **RESULTS**

All results except the PCI gave a t-statistic >2, suggestive of a significant coefficient. This shows that the change of prescription from mechanical to MPK in this group is likely to result in positive outcomes regardless of previous or new prescription with >95% confidence. Greatest average differences were seen in subgroups where individuals moved from non-hydraulic stance units to an MPK. Largest average change was observed in RNLI (p=0.005) and ABC (p=0.004) overall. Specific MPK's demonstrated greater overall change in some measures than others. Subjective feedback supported positive findings in the majority of cases.

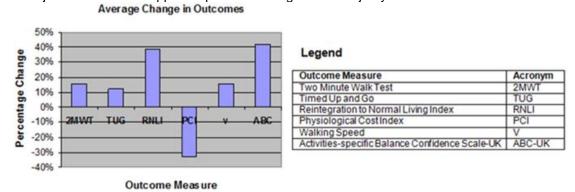


Figure 1: Average improvement in outcome between previous prescription and MPK

## **DISCUSSION AND CONCLUSION**

Results confirm that MPK's in general improve clinical and functional outcomes over a range of measures - irrespective of previous prescription and subsequent intervention. Greater improvements occurred in subgroups where the knee used previously differed most in functionality (e.g. geometric-stability). Average change in outcomes also varied between the MPK's. This supports evidence-based prescription criteria. Not all parameters gave positive average outcomes (PCI) and recommendations would include a 12-month follow-up of this following acclimatisation.

## **REFERENCES**

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### 3.1.2.c

## The Influence of Microprocessor Knee Use on Self-Reported Trips and Falls

Alison Stenson<sup>1</sup>, Jane McLean<sup>2</sup>, Ramesh Munjal<sup>2</sup>, Michael McGrath<sup>1</sup>, Beata Rek<sup>1</sup>, Saeed Zahedi<sup>1</sup>, David Moser<sup>1</sup>
Blatchford, Basingstoke, United Kingdom. <sup>2</sup>Sheffield Teaching Hospitals, Sheffield, United Kingdom

### **BACKGROUND**

Trans-femoral amputees, have a high rate of falling, with 64% reporting at least one fall per year.[1] Studies have suggested that microprocessor knees (MPKs) are effective at significantly reducing the number of falls [2] and, consequently, they are considered cost effective.[3] The latest generation of MPKs have enhanced standing support and stumble recovery features to further mitigate the risk of falls. Since December 2016, MPKs have been funded by NHS England.[4]

#### ΔIM

To investigate whether MPK use has a significant effect on the number of self-reported trips and/or falls of an NHS England population.

### **METHOD**

A custom questionnaire gathered patient demographic and trips and falls history over the previous four weeks. Only data from above knee amputees were used. Those respondents that used an MPK (Orion3, Blatchford) completed the questionnaire at the end of their mandatory four week trial, in accordance with the NHS England MPK commissioning policy.[4]

Multiple regression analyses were performed, taking number of trips and number of falls as dependent variables and patient demographics and MPK use as factors.

Finally, the cohort was reduced to only those that reported tripping. Another regression, with number of falls as the dependent variable, was performed on this reduced cohort.

### **RESULTS**

For the first regression, there were 150 usable datasets, of which 29 were MPK users. Contributing factors that significantly increased the likelihood of tripping were having a comorbidity affecting balance (p=0.0018) and using one walking stick (p=0.0058). MPK use did not significantly affect the number of self-reported trips.

For the second regression, there were 151 usable datasets, including 29 MPK users. Those who used MPKs were shown to be significantly less likely to falls (p=0.0334). Additionally, those who tripped 1-5 times (p=0.001) or more than five times (p=0.0001) in the previous four weeks were significantly more likely to fall.

For the final regression, there were 97 usable datasets, including 16 MPK users. The only factor that was shown to be statistically significantly protective against falls was MPK use (p=0.0051).

### **DISCUSSION AND CONCLUSION**

This study confirms the assertions of previous research that MPKs are protective against falls and provides justification for the NHS England MPK commissioning policy.[4] An interesting observation is that while this MPK did not reduce the number of trips, it did reduce the number of falls for those that did trip. This could be attributed to the device's stumble recovery mode working effectively.

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### 3.1.2.d

## Classifying Amputees who will Benefit from a Microprocessor-Controlled Knee

<u>Kenton Kaufman</u>, Kathie Bernhardt, Kevin Symms Mayo Clinic, Rochester, MN, USA

### **BACKGROUND**

The benefits of a microprocessor-controlled knee (MPK) have been demonstrated for Medicare Functional Classification Level (MFCL) K2 and K3 transfemoral amputees (TFA).[1-3] However, there is a need to accurately define which amputees will benefit.

#### ΔIM

The aim of this study was to predict which amputees would benefit from a MPK.

### **METHOD**

Study Design: Each subject was tested using their NMPK and retested with a randomly assigned MPK from one of four manufacturers.

Subjects: 50 unilateral TFA over age 55 who were MFCL K2 were studied. Subjects were excluded if they had neuromuscular problems, partial amputation of the contralateral limb, were on dialysis, had poor prosthetic socket fit, or had residual limb breakdown.

Outcome measures: Subject's characteristics were assessed using the Prosthesis Evaluation Questionnaire and the Patient Assessment Validation Evaluation Test. Falls were assessed using the PEQ addendum. The MPK was deemed effective if falls were reduced.

Data Analysis: Discriminant analysis was used to differentiate who benefit from a MPK.

### **RESULTS**

Eight selection criteria were identified (Figure 1). The selection models differed in their sensitivity (ability to predict which subjects will benefit from a MPK) and specificity (ability to predict which subjects won't benefit from a MPK, e.g. should remain on a NMPK). Gait speed and the ambulation sub-scale of the PEQ were the most sensitive measures. The PAVET had the highest specificity.

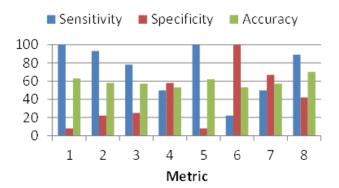


Figure 1. Sensitivity and specificity for various metrics: 1=Gait speed, 2=PEQ, 3=Utility sub-scale of PEQ, 4=Appearance sub-scale of PEQ, 5=Ambulation sub-scale of PEQ, 6=PAVET, 7=Limb strength score of PAVET, 8=carry items & car ingress/egress.

### **DISCUSSION AND CONCLUSION**

There are known limitations to the Medicare Functional Classification Level (K-Level) system for patient classification. K-Level assignment relies heavily on subjective information and the varied experience and personal opinions of care providers. Additionally, content validity of the K-Level system was not established from research evidence.[4] The proposed metrics are an initial attempt to develop an objective classification method to identify patients who will benefit from a MPK.

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### **ACKNOWLEDGEMENTS**

Funding provided by the American Orthotic and Prosthetic Association. Support also provided by Hanger Clinic.



### 3.1.2.e

## An Open Source Robotic Leg Prosthesis: Design and Locomotion

Alejandro F. Azocar<sup>1</sup>, Luke M. Mooney<sup>2</sup>, Jean-François Duval<sup>2</sup>, Ann M. Simon<sup>3,4</sup>, <u>Levi J. Hargrove</u><sup>3,4</sup>, Elliott J. Rouse<sup>1</sup>

<sup>1</sup>University of Michigan, Ann Arbor, MI, USA. <sup>2</sup>Dephy, Inc., Maynard, MA, USA. <sup>3</sup>Shirley Ryan AbilityLab, Chicago, IL, USA. <sup>4</sup>Northwestern University, Evanston, IL, USA

### **BACKGROUND**

Passive prosthetic legs limit the well-being of millions of amputees, leading them to walk slower, use more energy, fall more often, and develop bone/back problems.[1-4] Robotic prostheses have the potential to address these issues but have yet to make significant clinical impacts, partly because controls research and clinical testing are typically performed independently. Additionally, researchers invest considerable time/resources developing hardware before performing research; even after research is complete, comparison of results is hindered by different mechatronic designs.

### AIM

To facilitate the study and fair comparison of control approaches, and lower the barrier to entry to robotic prostheses, we created the Open Source Leg (OSL): a robotic knee-ankle prosthesis for biomechanics and controls research.

### **METHOD**

To ensure that the OSL is accessible by researchers from diverse Backgrounds, we designed it to be simple,

portable, scalable, customizable, and economical (Fig. 1). The OSL uses high-torque motors, resulting in low-cost, simple transmission elements. An open-source motor controller reduces the computational burden from researchers, enabling them to focus on higher-level clinical goals. The OSL includes several sensors; provides simple position, current/torque, and impedance controllers; and automatically implements various communication protocols for easy integration with other sensors and control systems.





Figure 1. (Left) Rendering of the OSL. (Right) Patient walking up a ramp using the OSL.

Finally, the knee joint can be equipped with a series-elastic actuator, allowing for multiple levels of stiffness.

## **RESULTS**

We intended to provide the highest performance prosthesis while facilitating ease-of-use and reducing mass/cost. The OSL (4 kg) is 20% lighter than similar prostheses, has a 120°/30° range of motion at the knee/ankle, and has onboard batteries that last for about 3 hours (8,750 strides) of continuous use. The OSL produces approximately 120 Nm of peak torque and has a position bandwidth of up to 5 times higher than the biological knee/ankle joints.[2] In our initial clinical testing, 3 individuals with transfemoral amputations successfully ambulated through a circuit that included walking, ramp ascent/descent, and stair ascent/descent (Fig. 1). Across most ambulation modes, joint angle and torque trajectories followed similar timing and amplitude patterns to able-bodied data.

## **DISCUSSION AND CONCLUSION**

This abstract provides an overview of the design of an open-source robotic knee-ankle prosthesis and discusses 3 subjects with transfemoral amputations successfully ambulating with the leg on level ground, ramps, and stairs. The OSL provides a common hardware platform, lowers the barrier to entry for prosthesis research, and enables research beyond the lab: in more realistic environments such as the community and home.

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### **ACKNOWLEDGEMENTS**

This work was supported by the National Science Foundation (NSF) and the MSL Renewed Hope Foundation.



### 3.1.2.f

## Can Microprocessor-Controlled Prosthetic Knees Reduce Attentional Demand during Singleand Dual-task Walking?

Saffran Möller<sup>1</sup>, Nerrolyn Ramstrand<sup>1</sup>, Kerstin Hagberg<sup>2</sup>, David Rusaw<sup>1</sup>
<sup>1</sup>School of Health and Welfare, Jönköping University, Jönköping, Sweden. <sup>2</sup>Advanced Reconstruction of Extremities, Sahlgrenska University Hospital, 3 Department of Orthopaedics, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Sahlgrenska University Hospital, Göteborg, Sweden

### **BACKGROUND**

Walking with a lower-limb prosthesis while performing a secondary task (dual-tasking) has been suggested to increase demand on attentional resources, negatively affecting balance and gait performance.[1, 2] Brain imaging research has suggested that microprocessor-controlled prosthetic knees (MPKs) reduce attentional demands during single-task walking.[3] To date the effects of MPK on brain activity during dual-task walking has not been investigated.

### AIM

To evaluate effects of single- and dual-task walking on cortical brain activity in individuals using a non-MPK or MPK and controls and compare differences between the 3 groups.

### **METHOD**

A cross-sectional study was performed involving twenty-nine individuals with a transfemoral amputation or knee disarticulation who were provided with either a non-MPK or an MPK, and 16 controls. Functional near-infrared spectroscopy was used to evaluate cortical brain activity (oxygenated haemoglobin (oxyHb) concentration level changes) while participants walked on a stable level surface and simultanously performed 2 dual-task activities; 1) walking while sorting through keys; and, 2) walking in sequence around randomly number cones. Temporospatial variables was recorded for each activity.

### **RESULTS**

Increased brain activity (oxyHb concentration level changes) were observed when a secondary task was added in the MPK-group (p=.000) and in the control group (p=.007). No significant differences were observed between single- and dual-task walking in the non-MPK group (p>.05). Significantly increased brain activity (oxyHb concentrations level changes) was observed during single-task walking in the non-MPK group when compared to the MPK-group and controls. Significantly different results in temporospatial parameters were also observed.

## **DISCUSSION AND CONCLUSION**

Results suggest that dual-task walking increases cognitive demand in individuals fitted with MPKs and controls. The lack of difference with the non-MPK group may suggests that their maximum capacity was already reached during single-task walking.

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## **ACKNOWLEDGEMENTS**

Thanks to Jette Schack, Evin Güler, Vera Kooiman, Lamija Pasalic, Promobilia Foundation, ALF/LUA Research Grants, Össur and Team Olmed.



### 3.1.2.g

## Development of Transfemoral Prosthetic Knee with a Passive Mechanism for Ascending and Descending Stairs

<u>Takahisa Yamamoto</u><sup>1</sup>, Koh Inoue<sup>1</sup>, Shin'ichi Tachiwana<sup>1</sup>, Takahiro Wada<sup>2</sup> Kagawa University, Takamatsu, Japan. <sup>2</sup>Ritsumeikan University, Kusatsu, Japan

### **BACKGROUND**

Ascending stairs is demanding for transfemoral amputees. We have developed a passive mechanism for transfemoral prosthetic knees that realized stair ascents in the step-over-step manner in previous studies. However, the passive mechanism was specific for stair ascending, and a mechanism for stair descending, which functions to yield the prosthetic knee, was not embedded.

#### AIM

Develop a transfemoral prosthetic knee joint for stair ascent and descent with a passive mechanism.

### **METHOD**

In our previous studies, we developed a passive mechanism for transfemoral prosthetic knees by applying a four-link mechanism that realized stair ascending and level walking. In the present study, to add a stair descent function to the previously developed mechanism, we proposed an additional rotary joint that was controlled with a rotary damper for the existing mechanism. Then, an evaluation experiment was conducted with the prototype of the proposed knee and a simulated thigh socket. The motion of stair ascent and descent, and level walking was recorded with a motion capture system and force plates. Inverse dynamics was used to analyze the motion data.

### **RESULTS**

Stair descending, stair ascending, and level walking were tested in the evaluation experiment and accomplished with the proposed prosthetic knee. These motion tasks were performed without manipulation of the proposed knee by the users; therefore, the functions of the proposed knee were automatically changed with human motion. The patterns of the knee joint angle and moment were similar between the prosthetic users and ablebodied subjects. However, the amount of mechanical work done by the prosthetic knee joint was nearly half (-30 J) at the stance phase of stair descent compared to the knee joint of the able-bodied subjects (-65 J).

### **DISCUSSION AND CONCLUSION**

The shortage of mechanical work for the prosthetic knee joint was probably due to the capacity of the damper embedded in the proposed knee. A stronger damping may reduce the difference between the prosthesis users and able-bodied subjects. In conclusion, we proposed a passive mechanism for fransfemoral prosthetic knee joint that allowed users to ascend and descend stairs, and walk on the ground.



## Symposium Education

## 3.1.3

## Importance of Government and Non Governmental Collaboration for Developing Higher Educational Competences in Junior Prosthetic Orthotic Professionals in Developing Countries

Stephney Weerasinghe<sup>1,2</sup>, Khin Thantzin<sup>3</sup>, May Zun Phoo Aung<sup>4,3</sup>, Uthpala Mihiran<sup>4</sup>

Mandalay Orthopaedic Hospital PO center, Mandalay, Myanmar. Myanmar School of Prosthetics and Orthotics, University of Medical Technology, Yangon, Myanmar. Myanmar School Of Prosthetics and Orthotics, University of Medical Technology, Yangon, Myanmar. Mandalay Orthopaedic Hospital Prosthetic Orthotic center, Mandalay, Myanmar

### **Abstract**

Myanmar is a developing country and started the formal PO education in category 2 in 2015. Later with the implementation of ISPO standards the Prosthetic and Orthotic education and service provision has broadened. In 2017 Myanmar gained international recognition in ISPO world congress by presenting the developments in Prosthetics and Orthotics.

This symposium is mainly presented by a local and international team of Junior Prosthetists and Orthotists who are currently working and studying in Myanmar and trying to gain qualifications in Category 1 from Mahidol University, Bangkok and Masters from University of Strathclyde, Glasgow, UK.

At present Myanmar has several PO clinics and these started through the collaboration between government and non governmental organizations. Today they provide services mainly for the patients in need.

Through this symposium our main attempt is to share the positive impact of having these clinics in serving as invaluable resources to provide clinical experiences to gain competences in pursuing higher PO qualifications even with not so advanced technical resources.

Nevertheless there are challenges yet we hope this symposium will be a platform in finding some practical solutions through discussion with the teachers, clinicians, educators who have overcome similar situations successfully.

Finally I thank sincerely the ISPO committee for creating equal opportunities for everyone. And should say Myanmar does not get opportunities like this often. Therefore if the respected ISPO congress committee opens an opportunity for our symposium it will be a tremendous achievement in our PO career and an honor for Myanmar.

## Statement of the objective / learning objectives

Importance of collaboration between government and non governmental organizations in implementing PO clinical set ups and it's impact in building competencies for obtaining higher educational qualifications after category 2 qualification



# Advanced IC Prosthetics: Lower Limb Transtibial

### 3.1.4

## State-of-the-art Technologies for Residuum Volume and Shape Monitoring: Innovative Solutions and Challenges

<u>Elena Seminati</u><sup>1</sup>, <u>Alex Dickinson</u><sup>2</sup>, <u>James Bilzon</u><sup>1</sup>, <u>Martin Twiste</u><sup>3</sup>

<sup>1</sup>University of Bath, Bath, United Kingdom. <sup>2</sup>University of Southampton, Southampton, United Kingdom. <sup>3</sup>University of Salford, Manchester, United Kingdom

### **Abstract**

Objective assessment methods to monitor residuum volume and shape changes following lower limb amputation are required to inform treatment decisions with regard to timing and design of prosthetic sockets.

Due to the importance of these characteristics for the success of prosthetic limb fitting, improvements in measurement validity and reliability has received considerable attention. Many techniques have been described, with varying success, particularly reflecting the development of digital technology over time.

Portable 3D non-contact scanning methods have been vastly improved over the years. Some more recent ones have shown good accuracy and reliability, with reliability coefficients for volume measurements <5%. However, accurate measurement of residuum volume and shape remains challenging, due to patient and measurement related factors (e.g. movements, post doffing volume changes, distortion of limb shape, system accuracy and resolution, costs and environmental conditions).

This symposium will give an overview of what techniques have been used to measure residuum volume and shape and critically appraise the evidence as to how effectively they measure these attributes in lower limb amputees. The state-of-the-art methods in the field of residuum monitoring will be presented, highlighting advantages/disadvantages based on experimental data from laboratory (i.e. residuum models) and clinical (i.e. patient residuum) trials. A multidisciplinary team comprising two engineers, one prosthetist and a physiologist will present some of the new features for residuum monitoring (e.g. portability, improved accuracy/resolution, colour/texture information and costs), with the possibility to do some practical tests on the day (see figure below) and identify common scanning artefacts/errors.



## Statement of the objective / learning objectives

Attendees will learn about the different features of the state-of-the-art technologies for residuum monitoring. The symposium will help prosthetist/healthcare professionals choose the right tool for the right patient and the relevant clinical/research purpose.



# Free Paper Session Prosthetics: Upper Limb - Evaluation

### 3.1.5.a

## **Externally Powered Prosthetic Wrist Flexion Device**

<u>Jeff Christenson</u>, Gregory Jacobs, Edwin Iversen, Scott Hosie Motion Control, SLC, USA

### **BACKGROUND**

Externally powered prosthetic wrist rotators have been used by individuals with upper limb loss for over 20 years.[1, 2] The recent availability of an externally powered prosthetic wrist flexion device raises two questions: 1) what are the functional benefits for individuals with upper-limb deficiencies of an externally powered wrist flexion device, and 2) are there advantages to externally powered wrist flexion over externally powered wrist rotation?

### AIM

It is the aim of this paper to help physicians and prosthetists to determine when an externally powered wrist flexion device might benefit their patients' with upper-limb deficiencies.

### **METHOD**

There were three steps in the evaluation of the powered wrist flexion device. These steps were: 1) development of a functional design, 2) kinematic analysis comparing powered flexion versus powered rotation, and 3) obtaining of user feedback from individuals using powered flexion prostheses. To design the powered flexion wrist, prosthesis users, industry experts, and the literature were queried and reviewed. Design trade-offs leading to the powered wrist flexion device will be presented. A kinematic analysis comparing the work space of the powered rotation and powered flexion will be presented and discussed. The results from questionnaires of individuals using the flexion devices will also be presented and discussed.

### **RESULTS**

A powered flexion device was developed and is now commercially available. Design target failures and successes will be discussed. The kinematic analysis was performed for four systems: one with no wrist, one with powered flexion, one with powered rotation and one with both powered wrists. The analysis showed that wrist function benefits terminal device prepositioning. It also showed that the advantages of powered flexion verses powered rotation are task and work space dependent. Systems with both wrists have the greatest work space functionality. The user surveys indicated overall user satisfaction with the device. As with the kinematic analysis, user surveys also indicate that benefits of each powered wrist are highly dependent on the task being performed and the task work space.

### **DISCUSSION AND CONCLUSION**

The design of the powered flexion unit seems to be acceptable to improve user functionality. The kinematic analysis and the results from user questionnaires clearly show that there are potentially significant functional benefits for individuals with upper-limb loss to use a powered flexion device, but its usefulness is dependent on the tasks the individual desires to perform. When forced to choose just one wrist, clinicians should help patients understand the functional trade-offs of each system.

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### **ACKNOWLEDGEMENTS**

This work was financed by the Fillauer Corporation and United States Congressionally Directed Medical Research Program (CDMRP).



## 3.1.5.b

## Differences in Multigrip Myoelectric Hands For Facilitating Activities of Daily Living

Andreas Kannenberg<sup>1</sup>, Russell Lundstrom<sup>1</sup>, Arri Morris<sup>1</sup>, Shawn Swanson-Johnson<sup>2</sup>, Karl Hibler<sup>3</sup>
<sup>1</sup>Otto Bock Healthcare LP, Austin, USA. <sup>2</sup>SSJ Rehab Services, PLLC, Houston, USA. <sup>3</sup>retired statistician, Bradenton, USA

### **BACKGROUND**

Most transradial amputees are fitted with a prosthetic hand but it actively for only 50% of activities of daily living (ADLs).[1,2] A study with the multigrip Michelangelo hand reported that many ADLs were perceived to be easier to perform than with a conventional hand.[3] Other multigrip hands offer more grip types, but it is unknown whether this might make ADLs even easier to perform.

### AIM

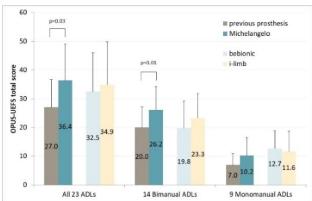
The aim of this study was to investigate whether other multigrip myoelectric hands with even more grip functions might further reduce the difficulty of performing ADLs.

### **METHOD**

Subjects wearing bebionic and i-limb hands were assessed with the same hybrid questionnaire as used in the Michelangelo study: a combination of the Orthotics and Prosthetics User Survey Upper Extremity Functional Status (OPUS-UEFS), and the Prosthetic Upper Extremity Functional Index (PUFI). The modified OPUS-UEFS rates how easily ADLs could be performed with the prosthetic hand, and the PUFI records how each ADL was performed and how useful the prosthesis was. Demographic information on all subjects were also collected. These results were then compared to data previously collected from 16 users of both the Michelangelo and conventional myoelectric Hands.

### **RESULTS**

Data were available from 36 unilateral subjects with transradial amputations, 10 each wearing a bebionic or i-limb, respectively, and 16 subjects who used a Michelangelo and conventional hand, respectively. Means for ease scores across 23 ADLs are shown in Figure 1. There were no statistical differences between the 3 multigrip hands. The mean numbers of ADLs by usefulness and method of use rating were also similar. In Table 1, green cells indicate ADLs rated as easier or more useful vs. conventional myoelectric hands, red indicating less.



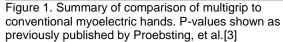




Table 1. Differences in the mean scores for multigrip compared to conventional hands. Blanks = no real difference.

### **DISCUSSION AND CONCLUSION**

Multigrip myoelectric hands may reduce the difficulty for performing ADLs vs. conventional hands. For some activities, there was a clear advantage for some hands over others (Table 1). More grip patterns (bebionic/i-limb) did not result in ADLs being rated as easier vs. a hand with fewer grip patterns (Michelangelo). This study highlights the need for more sophisticated control (e.g. pattern recognition) for a hand with greater number of grips to facilitate intuitive access to grip types.

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### 3.1.5.c

## Mechanical Testing of a Partial Prosthetic Finger for Strength, Reliability, and Fatigue

Jacob Segil<sup>1</sup>, Stephen Huddle<sup>2</sup>, <u>Levin Sliker</u><sup>3</sup>, Richard Weir<sup>2</sup>
<sup>1</sup>University of Colorado at Boulder, Boulder, USA. <sup>2</sup>University of Colorado, Denver | Anschutz Medical Campus, USA. <sup>3</sup>Point Designs LLC, Louisville, USA

### **BACKGROUND**

There are approximately 500,000 people living with partial hand amputation in the USA.[1, 2] Loss of both the index and middle fingers results in 40% impairment of the hand.[3] While the number of individuals with partial hand amputation is 10 times more than all other upper limb amputation categories combined, the state of available technology for this under-served patient population is relatively poor.[4]

#### AIM

There is a need for an anatomically appropriate, scalable, single-hand operable, and durable prosthetic partial finger. Can the Point Partial prosthetic finger withstand the loads, torques, and cycles of sustained use by a partial hand amputee?

### **METHOD**

A battery of mechanical tests will be conducted to determine the mechanical properties of a ratcheting partial prosthetic finger design. The size and weight of the device will be measured compared 50% percentile male anthropomorphic measurements to

	Mass	Length	Knuckle Radius	Unloaded Durability	Dynamic Strength (10,000 cycles @ 1Hz)			Static Strength (Load to failure)		
	≤28 g	40 – 60 mm	10 – 14 mm	250,000 cycles	Distal 66 N	Proximal 98 N	Lateral 98 N	Distally ≥66 N	Proximally ≥98 N	Lateral ≥98 N
Completion Status	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Testing Result	25.1 g	52 mm	11.5 mm	294,477 completed	10,000 cycles at 222N	10,000 cycles at 222N	10,000 cycles at 98N	≥660 N	≥200 N	≥200 N
Meets Specification	✓	✓	✓	<b>√</b> +	<b>√</b> ++	√+	✓	<b>√</b> +++	<b>√</b> +	√+
Exceeds Specification by				1.2x	3x	2x	1x	<u>10x</u>	2x	2x

Table 1. Engineering specifications and results for partial prosthetic finger.

ensure proper sizing. The unloaded durability of the device will be tested in a custom cycle machine which will flex and extend the digit over 250,000 cycles (approximately 3 years of use). The dynamic strength and static strength tests will measure the robustness of the device to fatigue loads and high static loads respectively using an Instron material testing machine.

## **RESULTS**

The engineering specifications and mechanical testing results for a partial prosthetic finger design are provided in Table 1. The size and weight specifications were all met by the design. The unloaded durability was completed to 294,477 cycles of flexion/extension of the partial finger prosthesis and exceeded the specification by 1.2 times. The dynamic strength specification was met or exceeded when the load was applied at the distal, proximal, and lateral positions of the finger. Finally, the static strength specification was exceeded when the load was applied at all positions of the finger. In fact, the 660N (150lbs) was applied to the distal fingertip without causing failure.

### **DISCUSSION AND CONCLUSION**

The mechanical testing of a partial prosthetic finger indicate that the mechanical design can withstand the loads, torques, and cycles of everyday use. The design enables single-handed operation and can be scaled to the required size. Further work is required to measure and evaluate the clinical outcomes when using this prosthetic finger design.

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### **ACKNOWLEDGEMENTS**

Work supported by the NIH 1 R41 HD096942-01 and the Rocky Mountain Regional VA Medical Center.



### 3.1.5.d

## Visuomotor Behaviour of Prosthesis Users During Functional Tasks

<u>Jacqueline Hebert</u>, Craig Chapman, Albert Vette, Patrick Pilarski University of Alberta, Edmonton, Canada

### **BACKGROUND**

One goal of new prosthesis technology is to improve function and movement quality, while lessening reliance on visual attention. We developed a Gaze and Movement Assessment to quantify the visuomotor behaviour of prosthesis users. This metric has test-retest reliability in the non-disabled population, with a normative database for hand function,[1] angular joint kinematics [2] and eye gaze metrics.[3] Applying this assessment could quantify the visuomotor compensations of typical prosthesis users to create a benchmark of performance for standard of care prosthesis.

#### Δ I IV/I

The goal of this study was to quantify the visuomotor behaviours of typical prosthesis users compared to nondisabled gaze and movement behaviour during goal-directed object interaction tasks.

### METHOD

Nine upper limb prostheses users (8 male; 5 transradial, 4 transhumeral) and 16 non-disabled individuals (8 male, 8 female) were recruited. Participants performed two standardized goal-oriented tasks (Cups Task and Pasta Task) with simultaneous motion and eye tracking data recording. Kinematic and eye gaze data were segmented into Reach, Grasp, Transport, and Release phases and time-normalized. Metrics included performance time, phase duration, hand trajectory, angular joint kinematics for the upper limb and trunk, and eye fixation metrics (percentage of time spent fixating on the current (upcoming) target of action compared to the relative time of gaze fixation to the hand/terminal device). Prosthesis user results were compared to normative performance.

### **RESULTS**

The prosthesis users had significantly longer total task and phase durations across both tasks compared to normative, however, the grasp and release phases were relatively more prolonged for the Cups Task (p<0.01). Prosthesis users showed less fixation to the current target and more fixations to the hand in transport for both tasks compared to non-disabled (p<0.01); but significantly more fixation to hand in the Cups Task, likely due to having to monitor the compliance of the cups during transport. For kinematic strategies, all prosthesis users showed similar compensations with increased trunk motion and generally less shoulder and elbow motion than non-disabled. Trends indicated that skill level may be associated with less visual attention to the prosthesis, although the task demands impacted the compensations seen across users.

### **DISCUSSION AND CONCLUSION**

Prosthesis users spend a disproportionate amount of time grasping objects during goal-directed tasks, and visual attention to the prosthesis is most prominent when transporting objects requiring greater dexterity. These findings indicate the importance of using tasks requiring object interactions for training and evaluation. All prosthesis users showed less shoulder motion with mostly trunk compensation. Precise quantification of visuomotor behaviour in prosthesis users can illustrate differences in individual compensatory strategies that provide valuable insights into advantages and limitations of prosthesis performance.

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## **ACKNOWLEDGEMENTS**

Funding: Defense Advanced Research Projects Agency (DARPA) BTO (Dr. Doug Weber and Dr. Al Emondi program manager); Contract No. N66001-15-C-4015.



## 3.1.5.e Bionic Hands - Benefit and Use

<u>Cathrine Widehammar</u><sup>1</sup>, Ayako Hiyoshi<sup>2</sup>, Kajsa Lidström Holmqvist<sup>1</sup>, Helen Lindner<sup>3</sup>, Liselotte Hermansson<sup>1,4</sup>

<sup>1</sup>University Health Care Research Centre, Faculty of medicine and health, Örebro, Sweden. <sup>2</sup>Clinical Epidemiology and Biostatistics, School of Medical Sciences, Örebro, Sweden. <sup>3</sup>School of Health Sciences, Örebro University, Örebro, Sweden. <sup>4</sup>Dept of Prosthetics and Orthotics, Faculty of Medicine and Health, Örebro, Sweden

### **BACKGROUND**

Prosthetic hands with advanced technology making it possible to perform different grasps and positions are expensive and their usefulness has been questioned. Therefore, the benefit of the new hands needs to be studied. Multiple choices of grasps and positions may be useful, but are the patients able to shift between grasps in a timely manner when performing tasks and what grasps are most useful and mostly used?

#### $\Delta IM$

Compare advanced prosthetic hands with conventional myoelectric hands regarding usefulness in daily activities.

Additionally, to study shifting between grasps and what grasps are preferred and most used by the patients.

### **METHOD**

A single case experimental design was used. Inclusion criterions were: age

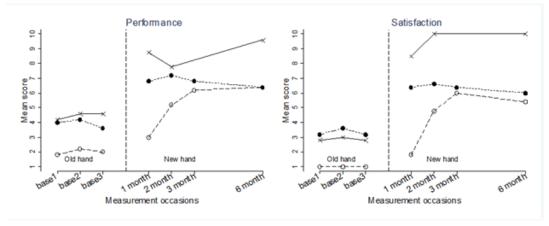


Figure 1. Visual demonstration of quality of performance and satisfaction with performance as measured with Canadian Occupational Performance Measure (COPM), higher scores indicate higher performance and satisfaction.

>18 years, congenital or acquired amputation, previous users of a conventional myoelectric prosthetic hand. Three persons participated, 2 with unilateral congenital amputation and 1 with quadrilateral amputation caused by sepsis. Participants were assessed 3 times before fitting and maximum of 6 times after fitting during treatment and follow up. Outcome measures were: Canadian Occupational Performance Measure (COPM), Modified Southampton Hand Assessment Protocol (SHAP), Assessment of Capacity for Myoelectric Control (ACMC), and a study specific questionnaire investigating the grasps usefulness and use. Visual analysis of baseline and intervention was made.

### **RESULTS**

The occupational performance and satisfaction scores (COPM) increased for all individually chosen activities by using the advanced hand (Figure 1). The modified SHAP test showed that the mean time for switching between grasps improved, for the light objects (n=2) decrease by 14 seconds and for the heavy objects (n=3) decrease by 48 seconds. The ACMC scores at baseline, 1 month, 6 months after fitting were 56.3, 53.7, 54.5 (patient #1), 51.5, 54.5, 43.8 (patient #2), and 87.8, 79.7, 87.8 (patient #3). On average 8 out of 11 possible grasps/positions were used. Most useful grasps were: power, tripod and key-pinch.

### **DISCUSSION AND CONCLUSION**

The advanced hand was more useful than the conventional hand for the individual chosen activities. The participants were able to learn shifting between grasps in a timely manner and used several possible grasps. One participant succeeded to get the same capacity to control the new hand as the conventional hand. A successful fitting is always a combination of the product and the training to learn how to use it.

### **ACKNOWLEDGEMENTS**

This study was supported by the Research Committee at Region Örebro County, Sweden.



### 3.1.5.f

## **Functional Measures of Dexterous Fingertip Prosthesis**

<u>Carlos Martinez-Luna</u>, Todd Farrell, Todd Roberts, Carlton King, Thane Hunt, Brianna Rozell Liberating Technologies, Inc., Holliston, USA

### **BACKGROUND**

Pointdexter, a dexterous fingertip terminal device, was designed to optimally combine the functions of prosthetic hands and hooks in a single upper-limb terminal device. Pointdexter adds an additional, selectable, dexterous grasp option focused on manipulating small objects. The current design is a two-tonged add-on to existing multi-articulating hands. The pointer finger on the hand is replaced with dexterous tonged end-effector in the fingertip and is driven with standard control signals

### **AIM**

Pointdexter adds dexterous function within the form and aesthetics of multi-articulating hands, where appearance is just as important as function in adoption of the prosthesis by the user.[1]

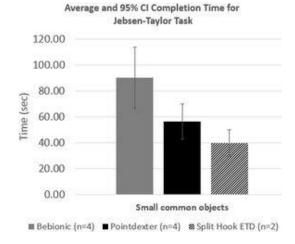
### **METHOD**

LTI conducted an initial clinical evaluation of functional outcome measures to compare Pointdexter, a Bebionic hand, and a powered split-hook ETD. IRB approval and participant informed consent was obtained. Four persons (2 male, 2 female) participated in the study. Two with transradial limb absence and two using a prosthesis simulator. Subjects were trained users of myoelectrically controlled anthropomorphic hands. Subjects conducted functional measures consisting of the Jebsen-Taylor Hand Function tasks. The order of the three

conditions (Bebionic hand, Pointdexter, ETD) were randomized for each subject.

### **RESULTS**

Timed trials of the functional outcome measures were conducted with: Bebionic hand (Otto Bock), Hand with Pointdexter (LTI), and split-hook ETD (Motion Control). Participants practiced with each device accommodate learning effects associated with the administered tests. Subjects conducted multiple timed trials of each of the sub-tasks. The data (Figure 1) summarizes completion times for subjects manipulating small common objects. In these tasks, the hand was generally the slowest and the ETD the fastest, with the Pointdexter being faster than the hand. The ETD performed best across all tasks and users; it is generally considered the most functional device tested. Pointdexter was able to emulate



the precision of the ETD in manipulating small objects and improved the performance when compared to the standard hand. Variability was high and sample size too small for statistical analysis, so further testing will be required.

## **DISCUSSION AND CONCLUSION**

Initial functional tests with the device are encouraging. Anecdotal feedback from users highlighted a desire for more precise, secure, and strong grip patterns in the multi-articulating hand. More design work is needed to improve strength and security of grasp in order to gain more split-hook functionality while still retaining the form-factor of a hand.

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### **ACKNOWLEDGEMENTS**

Supported by the NIH NICHD award R43HD090800. The content is solely the responsibility of the authors.



### 3.1.5.q

## Myoelectric Interfaces and Control Methods: Preliminary Evidence of a RCT

Matthew Wernke<sup>1</sup>, Brian Kaluf<sup>2</sup>, Laura Katzenberger<sup>3</sup>, Glenn Schrober<sup>4</sup>, James Colvin<sup>1</sup>
WillowWood, Mt. Sterling, USA. <sup>2</sup>Ability P&O, Exton, USA. <sup>3</sup>Handspring, Middletown, USA. <sup>4</sup>Optimus Prosthetics, Dayton, USA

### **BACKGROUND**

Traditional myoelectric systems have relied on threshold based control methods. Pattern recognition control changed this paradigm by incorporating machine learning algorithms to determine user intent. Both traditional (direct) and pattern recognition control methods rely on consistent and noise-free information from the surface electrode locations within the socket, a task that is complicated by continually changing residual limb shapes, movement of the arm, and interaction with the environment. To address this issue, a liner with embedded electrodes (myoliner) was developed.

#### $\Delta IM$

Quantitatively compare the functional performance and satisfaction with various control methodologies and interface designs of myoelectric devices.

### METHOD

To date, 14 of an expected 20 transradial subjects have been recruited and participated in the randomized study. The Activities Measure for Upper Limb Amputees (AMULA) and elbow range of motion are used to assess functional performance with the various study conditions. The Orthotics and Prosthetics User Survey (OPUS) section are used to capture subjective data from the subjects. Each condition is worn for a 6-week at home period, with objective and subjective data collected at the beginning and end of each condition period. Subjects are given adequate training for each interface and control methodology.

### **RESULTS**

Initial results indicate that the AMULA scores are higher when subject use the myoliner and pattern recognition, particularly for tasks that require the subject to reach above their head or toward their feet. Responses on the OPUS sections indicate this improvement may be through better fit and contact of the electrodes. Donning of the system and comfort were also improved with the myoliner. Pattern recognition with or without the myoliner improved AMULA scores and subjective responses compared to the direct control condition.

### **DISCUSSION AND CONCLUSION**

The AMULA is proving to be an effective objective test based on the correlation to subjective data because the tasks represent daily activities. The myoliner and pattern recognition may provide a significant improvement to the current standard of myoelectric interface and control methodology that increases the acceptance and usability of these advanced prosthetic devices. The evidence of this study will indicate the significance of any improvements and may help secure reimbursement for such advanced technologies.

## **ACKNOWLEDGEMENTS**

This work is funded by the United States Department of Defense (W81XWH-17-1-0431).



# Free Paper Session Psychosocial Issues / Quality of Life – Community Participation

### 3.1.6.a

## Using the ICF to Understand Barriers and Enablers that Amputees Experience when Walking in the Community.

Heather Batten<sup>1,2,3</sup>, Suzanne Kuys<sup>4</sup>, Robyn Lamont<sup>2</sup>, Steven McPhail<sup>5,6</sup>, Allison Mandrusiak<sup>7</sup>

<sup>1</sup>Princess Alexandra Hospital, Brisbane, Australia. <sup>2</sup>The University of Queensland, Brisbane, Australia. <sup>3</sup>Griffith University, Gold Coast, Australia. <sup>4</sup>Australian Catholic University, Brisbane, Australia. <sup>5</sup>Metro South Health, Brisbane, Australia. <sup>6</sup>Queensland University of Technology, Brisbane, Australia. <sup>7</sup>The University of Queensland, Brisbane, Bahamas

### **BACKGROUND**

Community walking is important for social, recreational and leisure activities that improve quality of life and reduce social isolation. Little is known about the barriers and enablers that people with lower limb amputation may experience when walking in the community. Additionally, much of the prior research has been limited to European settings.

### **AIM**

To understand barriers and enablers that amputees perceive when walking in the community with a lower limb prosthesis.

### **METHOD**

A qualitative study, involving three focus groups (n=14 participants), using purposive sampling, was conducted with people with lower limb amputation who used a prosthesis to walk in the community (age range 32-71 years; K level 1-4; 4-24 months since amputation; 6 Minute Walk Test 50-505m; 9 males; 2 bilateral amputations; 1 person lived rurally). Three investigators analysed transcripts using thematic content analysis.

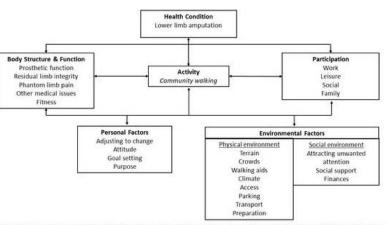


Figure 1: ICF model representation of barriers and enablers related to community walking reported by people with lower limb amputation. Direction of each factor is identified by B= barrier or E= enabler.

## **RESULTS**

Themes aligned with the International Classification of Functioning, Disability and Health domains. Barriers related to body function and structure included prosthetic function, residual limb integrity, phantom limb pain and other medical issues, with optimal prosthetic function and adequate fitness identified as enablers. Personal barriers included challenges adjusting to change, whereas personal enablers included being able to adjust to change, having a positive attitude, goal setting and a purpose for community walking. Environmental barriers included physical (e.g. terrain, crowds, climate, access, parking) and social (e.g. unwanted attention and finances). Environmental enablers included aids, transport, preparation, social support and finances. Community walking was essential to participation in work, leisure, social activities and family roles.

### **DISCUSSION AND CONCLUSION**

Although rehabilitation for people with lower limb amputation should optimise body function and structure to prepare for walking in the community, environmental and personal factors should also be considered. Optimising personal enablers are important and may facilitate community walking. Enhancing environmental (physical and social) enablers and minimising barriers to walking may be possible through environmental planning, social awareness and education. Improved understanding of these factors should inform service delivery to assist lower limb amputees for walking in the community.

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### 3.1.6.b

# Activity-Specific Balance Confidence in Orthosis Users – Preliminary Results

### Helena Burger

University Rehabiltation Institute, Republic of Slovenia, Ljubljana, Slovenia. University of Ljubljana, Faculty of Medicine, Ljubljana, Slovenia

### **BACKGROUND**

Orthosis can improve postural responses and dynamic stability [1] and improve balance. We found no study about patients balance confidence with orthosis.

#### $\Delta IM$

The aim of our study was to find out whether lower limb orthosis improves activity-specific balance confidence in patients who use the orthosis for at least one year.

### **METHOD**

We included all patients who visited our outpatient clinic for lower limb orthotics between September and December 2018 and were willing to participate. We asked them to fill in a questionnaire about falls in the last 6 months and the Activity-Specific Balance Confidence Scale (ABC; [2]) twice – referring to not using the orthosis and to using the orthosis. The study was approved by the Research Ethics Committee of our Institute.

### **RESULTS**

We included 28 subjects (16 men). Four did not have reading glasses with them and were not able to fill in the questionnaires, so we present data on 24 subjects (12 men), 24-83 years old (mean 59, median 64 years). Eight had impairment in the central nervous system, 16 in the peripheral nervous system. Two used ankle orthosis, 19 used various ankle-foot orthoses and three used knee-ankle-foot orthoses. The orthosis significantly improved balance confidence in all ABC activities (except standing on a chair and reaching, p=0.660; p for all others ≤0.022) and the overall ABC score (mean without orthosis 26%, with orthosis 57%, p<0.001). In eight patients the ABC score increased with orthosis over 67%, which is the cut-off point for fall.[3] The difference between both ABC scores was smaller than 13% (minimal detectable change; 3) in seven patients.

### **DISCUSSION AND CONCLUSION**

In the majority of the included subjects orthosis significantly improved balance confidence according to the ABC score. Clinically it is important that the patient feels the difference and increases activity accordingly. Improvements depend on the type of orthosis. The main limitation of the study is the small number of included subjects with very different diagnoses and different orthoses. A larger study is needed to confirm our results.

# **REFERENCES**

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[2] Powell LE, Myers AM. J Gerontol A Biol Sci Med Sci 1995.

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### 3.1.6.c

# Correlation Between Mobility and Quality of Life for People with Lower Limb Amputation

<u>Kazuki Fujimoto</u><sup>1</sup>, Isao Ojima<sup>2</sup>, Taichi Sano<sup>1</sup>, Katsuhiro Konishi<sup>1</sup>

Sawamura Prosthetics and Orthotics Service Co., Ltd, Kobe, Japan. <sup>2</sup>Kobe Gakuin University, Kobe, Japan

### **BACKGROUND**

For lower limb amputee a lot of scales were used to measure physical function, mobility, balance and more. Our private research showed Medicare Functional Classification (MFCL) 3-4 lower limb amputee got high score at almost scales. We could confirm mobility, but we didn't know which factor has influence on quality of life (QOL). To check lower limb amputee and their prosthesis, it is necessary to make clear correlation between mobility and quality of life.

#### ΔIM

To assess correlation between mobility and QOL and which factor has influence on QOL for people with lower limb amputation (LLA).

### METHOD

This study was examined using correlations between participants' measures of physical function, mobility, and balance. It's including 10m-walk test (10MWT), 6 min walk test (6MWT), Timed Up and Go test (TUG), PLUS-M, Socket Comfort Score (SCS) and Prosthesis Evaluation Questionnaire (PEQ) [1,2]. PEQ was used as PEQ-MS and 8 scale (Appearance (AP), Frustration (FR), Perceived Response (PR), Residual Limb Health (RL), Social Burden (SB), Sounds (SO), Utility (UT) and Well Being (WB)). 15 lower limb prosthesis users (TT: 10 cases, TF: 5 cases, age 48±27y, men 93.3%, lateral amputee: 100%, MFCL Level 2: 1 case, MFCL3: 12 cases, MFCL4: 2 cases) were measured at the end of Feb 2019.

### **RESULTS**

The outcome of measures were 10MW (normal speed): 5.5±1.1, 10MW (fast speed): mean 5.5±1, TUG: 8.1±1.3, 6MWT: 463.4±51.1, SCS score (0-10): 8±2.4, PLUS-M (12-60): 57.9± 4.43 and PEQ-MS (0-48): 47±3. PEQ`s FR, RL, WB and SO were lower than AP, PR, SB and UT. In classifying TT and TF on RL scale, 1-T.(Over the past four weeks, rate any rash (es) that you got on your residual limb.) and 1-U (Over the past four weeks, rate any ingrown hairs (pimples) that were on your residual limb.) might influence to PEQ score.

### **DISCUSSION AND CONCLUSION**

This study showed correlation between mobility score including PEQ-MS and almost PEQ score. That means MFCL3 and 4 patient's mobility hardly influence their QOL. But QOL might be influenced by Residual Limb Health. Therefore if patients want to get high level QOL, we should care such as residual limb health in checking prosthesis as maintenance. We will maintain conducting this research to increase subjects and establish validity.

# **REFERENCES**

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### 3.1.6.d

### **Balance Confidence in Lower Limb Prosthesis Users**

Tahmineh Rezaeian<sup>1</sup>, <u>Mahboobeh Mehdikhani</u><sup>2</sup>, Neil Messenger <sup>1</sup>, Daniella Strauss<sup>1</sup>, Maryam Jalali<sup>3</sup>, Parviz Mojgani<sup>4</sup>

<sup>1</sup>School of Biomedical Sciences, University of Leeds, Leeds, United Kingdom. <sup>2</sup>Institute for Health and Sports, Victoria University, Melbourne, Australia. <sup>3</sup>Iran University of Medical Sciences, Tehran, Islamic Republic of Iran. <sup>4</sup>Iran Helal institute of Applied Sciences and Technology affiliated to the Red Crescent Society of Iran, Tehran, Islamic Republic of Iran

### **BACKGROUND**

Balance is a challenging task during daily activities for lower limb amputees (LLAs). It is due to the musculoskeletal and somatosensory systems deficiencies of the amputated side and limitation of a prosthesis in comparison to the natural limb. Activities-Specific Balance Confidence (ABC) Scale questionnaire evaluates functional level during performing 16 different daily activities via the score chosen by a person for balance confidence [1] which will be presented for LLAs in this paper.

### **AIM**

To investigate functional confidence of LLAs around the world during different daily activities.

### METHOD

A self-reported survey composed of three standard questionnaires (including part of Prosthesis Evaluation Questionnaire, complete ABC questionnaire, and Oswestry Disability Index) was designed and published on-line in English and Persian languages. It was publicized by different amputees' support groups and related Facebook pages. The inclusion criteria were over 18 year-old age, more than 6 months after lower limb amputation surgery and having experience of prosthetic device use. Only the results of ABC scale will be presented in this paper. Spearman's correlation and Kruskal-Wallis tests were utilized for statistical analysis with the level of significance set at  $p \le 0.05$ .

### **RESULTS**

One hundred fifty-five respondents from various countries (61.9% male, mostly from UK, Iran, Australia and USA, aged  $54.7\pm12.1$  year-old) participated in the survey. As it is seen in Table 1, along with the high rate of phantom/stump/intact limb pain, falling experience (last 12-months), walking aid usage, worried about falling and lower back pain (LBP) among the participants, there are significant relations between lower ABC scores and present of these issues ( $p \le 0.05$ ). The total mean ABC score was in lower border of moderate functioning level

Table 1. Relation between ABC score and participants issues

(55.24), while 21.9%, 39.4% and 38.7% of participants had in turn a high, moderate and low level of functioning. Majority of participants (121 persons~78% of participants) needed intervention to improve their balance. In addition, 62% of participants

Phantom Intact limb Falling history Worried about LBP Stump pain Walking aid falling (last 12 mos.) pain pain No No No Yes No Yes Yes No Yes No Yes Yes no Yes 50.42 (106)\* 65.66 52.5 64.12 53.26 67.01 50.33 63.23 44.4 70.66 47.26 75.37 51.51 66.73 Mean ABC (117)\* (117)(91) (44)(n) (49)(36)(99)\* (37)(96)(59)(64)(111)(38)M. M-M M М ARF ARF ARF ARF function | ARF | A ARF ARF ARF ARF A score of <67 suggests being at risk of future falling (ARF) and score <80 shows need to intervention for improving balance.

were at risk of future falling (score <67).

### **DISCUSSION AND CONCLUSION**

The results of this study indicate majority of the participants had deficient balance which was associated with presence of other problems. It suggests that the balance of amputees besides other physical problems must regularly be monitored and tailoring balance exercises might be required. Interestingly, using new technologies such as videogames,[2] and computerized dynamic posturography systems [3] are effective in balance improvement of LLAs. In addition, balance aspects should be included in improving prosthetic fabrication technologies and rehabilitation procedures.

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# **ACKNOWLEDGEMENTS**

The authors gratefully acknowledge all respondents participation in the survey.



### 3.1.6.e

# A Systematic Review of Factors Influencing Return to Work after Lower Limb Amputation

<u>Sarah Anderson</u>, Anthony Francis, Michael Dillon La Trobe University, Melbourne, Australia

### **BACKGROUND**

Work is an integral part of many people lives and is often reported to give purpose and meaning to life.[1] Returning to work following lower limb amputation is considered an important factor in rehabilitation programs. Identification of factors which most influence work participation will enable further research and the development of targeted return to work programs for people with lower limb amputation.

### AIM

The purpose of this review is to identify which factors most influence return to work after lower limb amputation.

### **METHOD**

A search strategy was developed, tested, and a search of a range of databases was undertaken. Findings from the searches were exported into Endnote x9 and duplicates removed. The Endnote database was exported into excel where two reviewers independently vetted studies and selected for inclusion or exclusion. Where disagreements existed a third reviewer reviewed the case and discussion occurred until consensus was reached.

### **RESULTS**

Following data extraction 1037 articles were identified. Following vetting 10 articles were to found to meet the inclusion criteria. 5 studies were cross sectional, three retrospective, one prospective and one qualitative narrative study.

Studies were of a low quality, with poor reporting of basic demographic data, a lack of clarity of return to work and poor reporting of statistical methodologies and results made comparison across studies difficult.

A mild to moderate influence was found in education level, age, gender, residuum pain, wearing comfort and psychosocial factors. Whilst these factors were all found to influence RTW by varying degrees, confidence in the results is diminished due to restrictive definitions of RTW, lack of gender diversity in the studies and often poorly reported statistical techniques

### **DISCUSSION AND CONCLUSION**

The studied cohorts did not represent the general population living with limb loss nor was it representative in terms of gender, outcome measures or the definition of work. The definitions of work were very narrow and there was little agreement in what constituted work. Few conclusive factors were found to predict RTW and future studies should carefully consider a broader work definition, include psychosocial factors and carefully select population cohorts

### **REFERENCES**

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### 3.1.6.f

# Daily Activities and Participation: Perspectives of Persons with Lower-Limb Amputation in Singapore

Nani Adilla Zailani<sup>1</sup>, <u>Maggie Donovan-Hall</u><sup>2</sup>
<sup>1</sup>Tan Tock Seng Hospital, Singapore, Singapore. <sup>2</sup>School of Health Sciences, Univeristy of Southampton, Southampton, United Kingdom

### **BACKGROUND**

People with lower-limb amputations continue to face difficulties in daily activities and participation after discharge from hospital. International research, however, have vastly focused on the veterans population as well as specific contexts of prosthetic mobility and sports. In Singapore, the majority of lower-limb amputations are vascular-related.

### **AIM**

The objective of this study is to explore the experiences of persons with lower-limb amputation in the community. It aims to identify barriers and facilitators from a broad activities and participation point of view.

### **METHOD**

A qualitative study design was used. Twelve participants (mean age 56.8 years) with recent major lower-limb amputation were recruited through convenience sampling. Individual semi-structured interviews were conducted and digitally recorded. The data was transcribed verbatim and analysed by means of a thematic analysis approach.

### **RESULTS**

Six themes were identified during analysis.

- Life goes on
- Working in expensive Singapore
- Expectations of life with prosthesis
- The difficult outdoors
- A community of support and learning
- · Going back to an existing world.

Findings showed that participants valued returning to previous meaningful life roles and activities. Personal attitudes and person-environment interactions shaped adaptations and participation.

# **DISCUSSION AND CONCLUSION**

The exploration of perceived barriers and facilitators could aid in the understanding of needs and well-being of the amputee population in Singapore. Occupational therapists could work towards advocating, addressing or capitalising on these factors in rehabilitation to optimise activities and participation.



### 3.1.6.g

# Community Participation After Lower Limb Rehabilitation: A Descriptive and Longitudinal Perspective.

Richard Lombard-Vance<sup>1</sup>, Deirdre Desmond<sup>2</sup>, Fiadhnait O'Keeffe<sup>3</sup>, Nicola Ryall<sup>4</sup>, <u>Pamela Gallagher</u><sup>1</sup>
<sup>1</sup>Dublin City University, Dublin, Ireland. <sup>2</sup>Maynooth University, Maynooth, Ireland. <sup>3</sup>St Vincent's University Hospital, Dublin, Ireland. <sup>4</sup>National Rehabilitation Hospital, Dublin, Ireland

### **BACKGROUND**

People with a physical disability often face barriers to participation, but there has been little investigation of community participation in people with lower limb amputations. In particular, participation enfranchisement (importance and meaning of participation, and control over participation) and participation engagement (activity frequency, activity importance and whether it is felt that enough of that activity is being undertaken) have yet to be assessed. Knowledge of variation in these variables over time is also lacking.

#### ΔIM

The aim of this paper is to investigate community participation (enfranchisement and engagement) in people with lower limb amputation for the first time.

### **METHOD**

As part of a prospective cohort study, a subset of participants with lower limb amputation completed the importance and meaning of participation, control over participation, and engagement sections of the Community Participation Indicators at six (n=40) and twelve (n=30) months post-discharge from rehabilitation.

### **RESULTS**

Regarding participation engagement, activities both important to people and that were most frequently 'performed enough' included: family/friend interaction and communication, household activities, and religious or spiritual activities. Activities that were both important to people and least frequently performed enough were often those that required participation outside the home and/or with persons other than close relatives, and active/sports recreation. Neither importance and meaning nor control over participation changed significantly between six and twelve months.

### **DISCUSSION AND CONCLUSION**

Community participation is an important and multifaceted outcome for people with lower limb amputation. Weighting frequency of activity participation by whether the person wants to participate in certain activities at each time point provides valuable information in assessing rehabilitation outcomes.



# Basic IC Paediatrics

## 3.1.7

# **Outcome Measures in Rehabilitation of Child Amputees**

Özlem Ülger, Ali İmran Yalçın, Nilgün Bek Hacettepe University, Ankara, Turkey

### Abstract

Prosthesis, training and rehabilitation of children amputees take shorter and are made easier, by paying the normal motor development circuits attention. The success of rehabilitation increases with the participation of the patient and the family.

In physiotherapy-rehabilitation, the goal is to track the normal development of the child, to minimize the functional disabilities, to support the use of prosthetics and to provide the motivation for social activities.

Amputation rehabilitation is a long and difficult process. When the amputee is a child, the situation is even more complicated. The rehabilitation program should be planned according to the child. In particular, the disappearence of the child's body image, the obligation to continue to live later as an amputee, the problems in coping with the difficulties, the effects of this situation in the child, family and social environment should be taken into consideration while planning a rehabilitation program.

Functional evaluation of the child amputee is extremely important for rehabilitation success. The fact that the measurement methods used are specific to children's amputees is valuable for demonstrating the effectiveness of prosthesis and rehabilitation.

Regardless of the level and the cause, amputation is a situation that requires unique rehabilitation. It is especially necessary for the children who were amputated at a very young age or was born without an extremity, to recieve prosthesis and prosthesis training, to be directed to sports or recreational activities and to determine how functional it can be with prosthesis at an early stage.

# Statement of the objective / learning objectives

The success of rehabilitation increases with the participation of the child amputee and the family. Functional evaluation of the child amputee is extremely important for rehabilitation success.



# Free Paper Session Education

### 3.1.8.a

# **Developing an Online Qualification for Orthotic & Prosthetic Technicians**

### Ian Adam

British Association of Prosthetists & Orthotists, Glasgow, United Kingdom

### **BACKGROUND**

Over the years the average age of Technicians working within Orthotics and Prostetics in the UK had increased and there was a requirement to recruit new staff. No nationally accredited qualification existed, this has been seen as a hinderance when trying to recruit the right type of candidate. Also, employers did not want to lose their Technicians from the workplace while training along with the associated costs.

### AIM

To produce an accredited qualification that would provide employers with trained Orthotic & Prosthetic Technicians for the future.

### **METHOD**

As I am based in Scotland, I first contacted Scottish Qualifications Authority (SQA) to gain a full understanding of the Scottish Qualifications Framework and which type of qualifications would be suitable for Technicians working in O&P. I also did some research into methods of delivery of qualifications and which colleges had experience in these different types of delivery. I also spoke to the British Healthcare Trades Association (BHTA) to understand what the employers training needs were.

### **RESULTS**

Working with Scottish Qualifications Authority (SQA) we developed a 7 unit Personal Development Award (PDA) once this award had been approved we worked with Glasgow Clyde College (GCC) using their existing Virtual Learning Environment (VLE) model to design a teaching package for the qualification. Due to the nature of the VLE this allows the candidates to undertake the qualification from their workplace location without having to travel to a central location. The candidate completes 5 mandatory units submitting their assessments via the VLE direct to the college and receive feedback when required and assessment results. The candidate then choses 2 workplace units from a library of 12, the units are chosen depending on their employers' requirements. Workplace assessors are used to assess the chosen units. All assessments are also checked by an external verifier.

### **DISCUSSION AND CONCLUSION**

We launched the qualification in 2018 and to date we have 3 cohorts of Technicians, a total of 45 candidates, undertaking the qualification. The qualification takes approximately 18 - 24 months to complete. We would also hope to offer the qualification internationally through GCC as the VLE format is suitable for international candidates and SQA award their qualifications internationally.

## **ACKNOWLEDGEMENTS**

This qualification received financial support from Glasgow Clyde College Foundation, British Association of Prosthetists & Orthotists and British Healthcare Trade Association.



### 3.1.8.b

# Human Study Online Application for Abbreviations in O&P and Related Topics

Youssef Salam

Human Study, Nurenburg, Germany

### **BACKGROUND**

Readers of O&P articles and publications may encounter some abbreviations that are new to them. Students and Researchers may also face the same situation during their searches. Thus, an online application may aid them in quickly finding what the abbreviation stands for in a O&P context.

#### ΔIM

To launch an expandable online application to find the expansion of abbreviations encountered in O&P and related topics; as well as some information that may be helpful in making use of the abbreviation.

#### METHOD

To gather as many abbreviations that are published in O&P articles, books, publications, etc. Then to find the expansion of these abbreviations and some related information such as the source of the abbreviation, links to additional information related to that abbreviation...etc. Then to make the list available online for easy access for the viewers who would just enter the abbreviation and the result/s appear automatically along with some other information.

### **RESULTS**

Over 1200 O&P and related abbreviations are already gathered and listed in this online application. Readers and viewers are urged to contact us to add new abbreviations or to add information to an existing entry.

### **DISCUSSION AND CONCLUSION**

Practitioners, researchers and students in the O&P field and other rehabilitation professionals may need more information on abbreviations or to know their source. In this online expandable document we try to include as much information as possible including source of some abbreviations, email addresses of some O&P organizations, etc. This document also serves as a common reference for authors to know what abbreviation has already been used to avoid making multiple abbreviations for the same terms or words.

### **REFERENCES**

Several O&P books, articles and publications, including ISPO publication "Prosthetics and Orthotics International".

### **ACKNOWLEDGEMENTS**

The author thanks Human Study team and IT department for making this application possible.



### 3.1.8.c

# Establishing a P&O School in Sanaà Yemen by the International Committee of the Red Cross

Aziz Ahmad, Rowan English ICRC, Sanaa, Yemen

### **BACKGROUND**

Since 2002, the ICRC supports 05 PRP centres in Yemen. The armed conflict and the ongoing war since 2015, has added to the need of the P&O service in the country and so the need of trained HR. In this regard the ICRC signed MoU with the partner organization in 2014. As a result a P&O Department been established at the High Institute of the Health Sciences (HIHS) in Sana'a.

### AIM

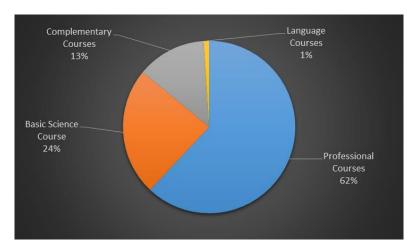
To establish a P&O Training Institute having National and International Recognition.

### METHOD

The P&O department was established based on the needs of trained HR to handle the growing need of P&O services in Yemen, under the MoU signed by the ICRC and HIHS (MoPHP) in Dec: 2014. The students were enrolled in 2018 after following the admission criteria as laid down in the curriculum. The Diploma level course was launched in September 2018.

### **RESULTS**

The ongoing war in Yemen, tribal hostilities and conflicts has added alarmingly to the number of disabled population. During 2016 and 17, over 43000 patients have received services in the 5 PRCs supported by ICRC. Presently only 19 trained (ISPO Cat II) professionals, being trained abroad, are available whereas 500 are needed to cope with the 15% disabled persons of a country with 30 million people. Curriculum development and approval from MoPHP, building renovation, installation of appropriate MEQs and selection of candidates to the course are the major steps being taken. The three years training has been started from September 2018, leading to a diploma in P&O, followed by 01 year of internship. 40% of the selected candidates for the course are female. The contact hours for the 3 years Diploma program are elaborated in the graph below.



## **DISCUSSION AND CONCLUSION**

Due to the deteriorated security situation and the armed conflict in the country, the training was put on hold since 2016. The P&O School in Yemen will provide trained HR to serve people with physical disabilities, with much improved quality. Additionally it will serve as a platform to have an improved quality of life of people with disabilities.

## **REFERENCES**

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# **ACKNOWLEDGEMENTS**

ICRC, ICRC Yemen Delegation, HIHS (MoPHP) Yemen.



### 3.1.8.d

# ICRC Support to O&P Education in the Arabic Speaking world

Gregory Halford<sup>1</sup>, Mohammad Sobuh<sup>2</sup>, Bashar Al Qaroot<sup>3</sup>

International Committee of the Red Cross, Amman, Jordan. <sup>2</sup>University of Jordan, Amman, Jordan. <sup>3</sup>University of Jordan, Amman, Jordan

### **BACKGROUND**

The needs for orthotic and prosthetic (O&P) services in the Eastern Mediterranean region and wider Arabic speaking world are enormous with both conflict and non-communicable disease [1] exacerbating widespread shortages of services. Hence workforce planning for O&P and a scaling up of affordable services to meet the region wide needs are critical.

### AIM

In order to offer sustainable high quality O&P education for the region, ICRC is supporting the University of Jordan Orthotics and Prosthetics teaching program as well as Al Bashir Hospital O&P department.

### METHOD

ICRC's new and innovative program in Jordan will be explained, including the pedagogical methods being encouraged and the alignment of the support to the ISPO education standards. The evolving nature of O&P education will be touched on to highlight the expected graduate competencies ICRC is working to develop in partnership with the University of Jordan and Al Bashir hospital.

Some teaching examples from both orthotics and prosthetics will be used to highlight how understanding is fostered within the learning experience whilst balancing the constraints of limited resources and time, something now common to many universities.

### **RESULTS**

Examples of innovative practices that have been developed through these partnerships will be shared. This includes magnet paper used to teach contracture accommodation in lower limb prosthetics and orthotic alignment. Another example is orthotic force system planning that allows the skill of lower limb orthosis prescription forming to be taught, practiced and examined in a highly efficient manner. Yet another example is of self-directed learning worksheets allowing students to self-critique key elements of the production process such as casting or rectification. The focus of the curriculum reform that acknowledges the regional epidemiological needs will also be explained.

### **DISCUSSION AND CONCLUSION**

Learning methodologies employed at the UJ encourage key concepts to be conveyed through innovative methods that are cheap and time efficient. This approach helps ensure high quality education despite the financial and time constraints preventing large numbers of devices being manufactured. Improvements at the UJ will help address the large scale regional needs for O&P practitioners and will help support people with disabilities through sustainable service provision.

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### 3.1.8.e

# Development of an International Online Professional Learning Community Between Prosthetic and Orthotic Schools in Ghana and the United States

<u>Eric Gaba</u><sup>1</sup>, Ann Yamane<sup>2</sup>, Sue Spaulding<sup>2</sup>, Cody McDonald<sup>2</sup>, Karen Freisem<sup>2</sup>, Kofi Awua-Peasah<sup>1</sup>, Prudence Petio<sup>1</sup>, Henry Larbi<sup>1</sup>, Rebecca Dordunu<sup>1</sup>

<sup>1</sup>Br. Tarcisius Prosthetics and Orthotics Training College, Nsawam, Ghana. <sup>2</sup>University of Washington, Seattle, USA

### **BACKGROUND**

A professional learning community (PLC) with Brother Tarcisius Prosthetics and Orthotics Training College (BTPOTC) and University of Washington (UW) started in January 2017. Members had a shared goal to enhance faculty professional development and promote student learning by sharing evidence-based practices for teaching and learning. We created the PLC based on these essential features: reflective dialogue, deprivatized practice, collaboration or shared work and shared values focused on student learning.[1]

#### AIM

The aim of this study was to explore the development of an international online professional learning community and the impact the learning community had on teaching practices.

### **METHOD**

We conducted a cross-sectional survey of professional learning community members from two prosthetic and orthotic (P&O) educational programs in Ghana and the United States. An online survey was administered to all PLC members in January 2019. The survey included 6 Likert-type and 10 open-ended questions. Likert-type response options ranged from 0-5 and descriptive statistics were calculated. A grounded theory qualitative approach [2] was used to develop a theoretical understanding of the social process. Two researchers independently coded open-ended responses and a third researcher mediated discrepancies. Open coding was used to establish initial codes, followed by focused coding to identify themes.

### **RESULTS**

All PLC members (n=10) involved in teaching in a P&O curriculum completed the survey for a response rate of 100%. The participants highlighted the value of developing a PLC with cultural and professional diversity. The sharing of knowledge amongst colleagues provided an opportunity for professional development related to course development and instructional methods with 7 of 10 respondents citing the PLC helped to improve their teaching practice. The greatest benefit occurred in syllabus design. In addition, sharing with colleagues offered an avenue for discussion regarding teaching challenges and facilitated professional growth. Members reported that while regular meetings facilitated the development of an international PLC, unreliable internet facility hindered productivity. Overall, members rated the learning community as very helpful.

### **DISCUSSION AND CONCLUSION**

An international PLC of P&O educators was developed through videoconferencing. The regularity of meetings and shared goals were key in enhancing professional development related to course development and instructional methods. However, unreliable internet capabilities reduced the productivity of the meetings. This work has culminated into building relationships with a sense of community and a focus on best teaching practices with hopes to facilitate student learning.

### **REFERENCES**

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### 3.1.8.f

# Achievement of ISPO Examination (former Category I) in Japan 2014-2019

Shin Sasaki, Kenta Tonai

Kobe College of Medical Welfare Sanda Campus, Kobe, Japan

### **BACKGROUND**

There is ONLY ISPO recognized school in Japan, which is Kobe College of Medical Welfare (KCMW) Sanda Campus among 17 ISPO Category I recognized school around world. KCMW organizes ISPO examination for individuals whom willing to be examined apart from school recognition. The 1st ISPO examination was held in 2014 and KCMW has 5 years experience since the 1st time. There were 10 individuals already qualified as complete ISPO Prosthetist & Orthotist in 5 years.

### AIM

To identify how many examines faced to ISPO examinations including how many passed/failed examination. Also to identify what are the benefits of having ISPO Prosthetist & Orthotist certificates before having it.

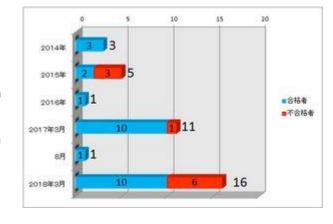
#### METHOD

We looked into a number whom be examined each year from 2014 - 2019, and identified how many passed/failed. We also looked into a number of examinees whether they are still working in the field regardless of passed/failed.

As the Japanese recognition system may differ from other countries, that completion of recognition is given minimum 15 months post graduate clinical experience (with 5 case reports submisson) is essential so that there were more than 30 graduates awaiting for the official recognition so that we also asked perspective of whom passed ISPO examination ONLY yet not fully recognized.

### **RESULTS**

- 1) There were 3 examinees and all passed in 2014.
- 2) There were 5 examinees and 2 passed but 3 failed in 2015
- 3) There were 1 examinee and 1 passed in 2016
- 4) There were 11 examinees and 10 passed but 1 failed in March 2017.
- 5) There were 1 examinee and 1 passed in August 2017.
- 6) There were 16 examinees and 10 passed but 6 failed in March 2018.
- 7) There were 3 examinees and all passed in December 2018.
- 8) There were 9 examinees and result is unknown (04.03.2019)



The feedback from former 10 individuals whom received ISPO Prosthetist & Orthotist certificate were very positive of having ISPO certificates that many benefits on their work. Perspectives of more than 30 awaiting individuals for ISPO certificate were also positive.

### **DISCUSSION AND CONCLUSION**

It should be pointed that having ISPO Prosthetist & Orthotist certificate will increase not only quality of professional services, but also individual motivation towards work as Prosthetist & Orthotist. As there is ONLY 1 school recognized by ISPO in Japan at this moment (04.03.2019), yet it is really needed and essential having more ISPO recognized school inside country so that quality of professional services will increase. There is also required more understanding and support from existing P&O companies to enhance education.



# Symposium Sports & Physical Activity

### 3.2.1

# Prostheses and Sports for Individuals with Lower Limb Amputation

<u>Hiroaki Hobara</u><sup>1</sup>, <u>Thomas Schmalz</u><sup>2</sup>, <u>Wolfgang Potthast</u><sup>3</sup>, <u>Hiroaki Kato</u><sup>4</sup>

<sup>1</sup>National Institute of Advanced Industrial Science and Technology, Tokyo, Japan. <sup>2</sup>Ottobock SE & Co. KGaA, Göttingen, Germany. <sup>3</sup>German Sport University Cologne, Cologne, Germany. <sup>4</sup>Komono Kosei Hospital, Komono, Japan

### **Abstract**

Recent developments in carbon fiber running-specific prostheses (RSPs) have allowed individuals with lower limb amputation to regain the functional capability of running and sport activities. Development of improved rehabilitation techniques and prosthesis designs to promote running within this population requires a detailed understanding of running biomechanics and the biomechanical function of prostheses during this activity. However, due to the lack of running studies in individuals with lower limb amputation and the dearth of information on RSPs, quantification of biomechanical parameters during running using the RSPs is scarce. Therefore, this symposium will review and report cutting-edge researches on prosthetic leg and active rehabilitation including sports from viewpoints of biomechanics, engineering and rehabilitation medicine. Firstly, the history of RSP development and neuromechanical principle of running gait in individuals with lower limb amputation will be presented. Secondly, development of prosthetic knee joints for RSP and the following consequences for transfemoral amputee's running and sprinting in para- and leisure sports will be introduced. Thirdly, assessment of athletic performance in individuals with lower limb amputation using RSP, especially, biomechanical differences of elite long jumpers with and without lower limb amputation will be discussed. Finally, clinical problems and challenges for social implementations on running rehabilitations and para-sports team building for individuals with lower limb amputation will be discussed. We believe that this symposium will be of interest to prosthetists, physiotherapists, biomechanists, engineers, and coaches.

### Statement of the objective / learning objectives

Attendees will gain a detailed understanding of running biomechanics in individuals with lower limb amputation to improve training/rehabilitation regimes and prosthetic designs for promoting running activities within this population.



# Free Paper Session Orthotics: Lower Limb Neurological - Gait

### 3.2.2.a

# Surplus Value of Implanted Peroneal Functional Electrical Stimulation over Ankle-Foot Orthosis for Gait Adaptability in People with Drop-foot after Stroke

<u>Jasper den Boer</u><sup>1</sup>, Frank Berenpas<sup>1</sup>, Alexander Geurts<sup>1</sup>, Vivian Weerdesteyn <sup>1</sup>, Frans Nollet<sup>2</sup>
<sup>1</sup>Radboud University Medical Center, Nijmegen, Netherlands. <sup>2</sup>Amsterdam UMC, University of Amsterdam, Amsterdam, Netherlands

### **BACKGROUND**

Implanted peroneal functional electrical stimulation (FES) is an effective alternative treatment to ankle-foot orthosis (AFO) in people with drop foot after stroke. With FES no constraints on ankle mobility are imposed which might particularly be exploited in challenging walking environments that require adaptations of the gait pattern to environmental disturbances.

### AIM

Is gait adaptability, by means of the capacity to avoid sudden obstacles while walking on a treadmill, superior with implanted FES compared to AFO in people with drop foot after stroke?

### **METHOD**

A 4-channel peroneal nerve stimulator (ActiGait®) was implanted in 22 persons with stroke (>6 months) who regularly used an AFO. Gait adaptability was tested with an obstacle avoidance task on an instrumented treadmill up to 26 weeks (n=10) or 52 weeks (n=12) after FES-system activation. At assessments, 30 trials, in which obstacles were suddenly dropped onto the treadmill, were recorded with each device (FES / AFO). Trials were grouped by available response times (ART) and success rates were calculated. The effect of device, ART and follow up time on success rates was tested using generalized estimated equations. Nonparametric correlations were calculated to associate changes in success rates with clinimetrics.

### **RESULTS**

Success rates of obstacle avoidance were higher when participants used their FES system compared to AFO ( $\Delta 4.7\%$ , p=0.03), which effect was largest for longest ARTs ( $\Delta 15\%$ , p=0.03). Participants with greater motor impairment of the paretic leg showed greater benefit from FES ( $r_s$ =-0.49, p=0.04).

### **DISCUSSION AND CONCLUSION**

FES has been found equally effective as AFO in improving walking speed of people with drop foot after stroke. We now present superior walking performance in a complex walking environment for implanted peroneal FES compared to AFO. These findings underline the importance of using gait assessments that require interplay with the environment, besides assessment of stationary walking, in community ambulators.

## **ACKNOWLEDGEMENTS**

The first study (group I) was funded by the Otto Bock Group and the TWIN Institute for Neuromodulation.



### 3.2.2.b

# Design and Development of an Active AFO to Assist Drop Foot

Carlos Galván-Duque<sup>1,2</sup>, <u>Valentina Rojo</u><sup>2</sup>, José Jesús Hernández-Gloria<sup>2</sup>, Emilio Menditea<sup>2</sup>

<sup>1</sup>Applied Research and Technology Institute, Universidad Iberoamericana, Mexico City, Mexico. <sup>2</sup>Department of Engineering Studies for Innovation, Universidad Iberoamericana, Mexico City, Mexico

### **BACKGROUND**

'Drop foot' refers to lack of dorsiflexion caused by weakness/paralysis of the anterior muscles of the lower leg.[1] Standard practice to correct drop foot is the use of an ankle foot orthosis (AFO).[2] Long-term use of AFOs may lead to disuse muscle atrophy;[3] moreover, the ankle joint contributes most to walking, thus by fixing it to a position, gait patterns are affected.[4]

### AIM

Design and develop an active AFO (AAFO) to improve gait patterns in people with drop foot. The device will allow free ankle movement during stance phase and assist dorsiflexion during swing phase.

### **METHOD**

An AAFO which allows free ankle movement during stance phase and achieves plantarflexion (PF) 15° to assist push-off during pre-swing and then dorsiflexion (DF) 10° during swing phase, was developed. Said device is composed of two force-resistive sensors, a servomotor, a thyristor, a microcontroller and a DC battery. The sensors allow the identification of user's current gait phase. The thyristor works as a switch to control powering of the servomotor, allowing free movement during stance phase and assisting PF/DF during swing phase. DF and PF are controlled by the microcontroller and achieved by the servomotor.

### **RESULTS**

The developed AAFO was made with carbon fibre and had a weight of 0.5 kg (Figure 1). Knee/ankle angles (figure 2,3) were measured in three gait conditions: normal, foot drop and foot drop + AAFO (Vicon Motion Systems®). Said angles were normalized to one gait cycle and average and standard deviation of 10 tests for each condition were calculated (Matlab 2018b). Ankle movement during stance phase with AAFO was similar to normal with a reduction in PF. DF was assisted during swing phase, improving drop foot patient's gait. Knee flexion during swing phase was reduced.

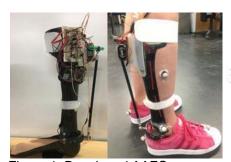


Figure 1. Developed AAFO.

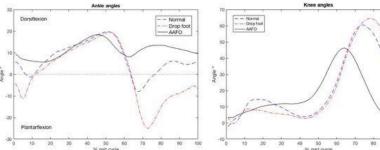


Figure 2. Ankle angles during normal, Figure 3. Knee angles during drop foot and AAFO gait. rormal, drop foot and AAFO gait.

### **DISCUSSION AND CONCLUSION**

The AAFO developed had a lower weight than similar devices published previously (0.5 kg vs. 2.6 kg [5]) and managed to assist DF during swing phase. To avoid reduction in knee flexion, subjects should be allowed an adaptation period with the AAFO. Future work includes testing the device with drop foot patients in various activities and conditions; moreover, the duration of the battery should be tested.

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### **ACKNOWLEDGEMENTS**

The development of this project was partially funded by Jet Central and Applied Research and Technology Institute, Universidad Iberoamericana.



### 3.2.2.c

# A Development of an Ankle Joint for Orthosis using an Electronic Motion Tracking Device

Isamu Bessho<sup>1</sup>, Hiroki Tomiyama<sup>1</sup>, Hirokazu Sugiyama<sup>1</sup>, Yutaka Okada<sup>2</sup>

Hashimoto Artificial Limb Manufacture Co., Ltd., Okayama, Japan. Kawasaki Junior College of Rehabilitation, Kurashiki, Japan

### **BACKGROUND**

Bracing therapy on CVA patients is known to be effective for re-obtaining the walking method. Lower-limb orthoses have functions that joint movement is partially blocked or mobile direction on the joint is restricted. Required levels of functions differ depending on the cases yet there aren't satisfied ankle joints in the market that work the best on all the cases.

#### AIM

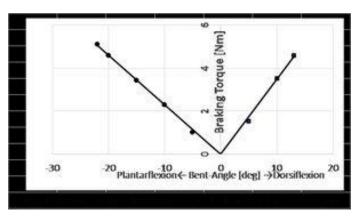
To develop a new ankle joint which was necessary for CVA patient's walking assistance, according to the data collected by wearing AFO installing an electronically controlled hydraulic damper, MR-AFO,[1] we have developed.

### **METHOD**

- A) A development of the joint: Desired braking torque on dorsi and plantar flexions for the new joint were evaluated through a process of data collecting from MR-AFO during walking in a CVA case. Finite element method lead us results that to adopt Titanium as a material and 3D-printer for metal molding.
- B) Gait Measurement: Gait data of a healthy person was collected from MR-AFO's electronic controller [2] that is attached to the AFO carrying the new joint. The electronic controller contained a 6-axis motion tracking sensor, an ankle joint goniometer, and a torque sensor on the joint.

### **RESULTS**

A) Each braking torque at different joint angles was shown in Figure 1. The braking torque was almost proportional to the bent-angle. The springs could be pre-loaded independently for dorsiflexion and plantarflexion. The maximum braking torque at dorsiflexion and plantarflexion were 4.6 Nm and 5.1 Nm, respectively, under springs without pre-loading. An increase of pre-loading brought out the translational shift of the graph-plots towards Y-axis, and the intercept meant the initial braking torque corresponding to the pre-loading.



B) As increasing the pre-loading on the springs, the braking torque of the joint increased. Especially, when the spring at plantarflexion was pre-loaded more, an elongation of time was observed during the time from a moment to make a contact on the ground to the foot-flat.

### **DISCUSSION AND CONCLUSION**

As one of the methods to develop a new ankle joint, designing and trial production were successfully carried out through the data collected by MR-AFO, an orthosis carrying an electronically controlled hydraulic damper. This method allowed us to evaluate the decent levels of objective gait data measured by the motion tracking sensor and utilize 3D-CAD and 3D printer. While valid evidences of the bracing therapy is demanded, this method can be useful on orthoses developments.

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### 3.2.2.d

# Development of an Electronically Controlled Ankle-Foot Orthosis Carrying a Gait Measurement Feature

<u>Dai Nishino</u><sup>1</sup>, Hiroki Tomiyama<sup>1</sup>, Shoji Morimoto<sup>2</sup>, Yutaka Okada<sup>3</sup>, Akio Tsubahara<sup>4</sup>

Thashimoto Artificial Limb Manufacture Co., Ltd., Okayama, Japan. Osaka Electro-Communication University, Osaka, Japan. Kawasaki Junior College of Rehabilitation, Kurashiki, Japan. Kawasaki University of Medical Welfare, Kurashiki, Japan

### **BACKGROUND**

In a process of a rehabilitation on CVA patients, it is preferred to adjust AFO's functions on ankle joints depending on the recovering stage yet the conventional AFOs are not capable enough to handle various cases. Additionally, majority of evaluations on rehabilitation effects is done by an observation with a therapist visually or time measurement with a stopwatch in convenience. The observations still face a limitation in variety and quantitativity of data acquisitions.

### **AIM**

To develop an AFO which allows an instantaneous setup in its functions on the joint as well as gait measurement and analysis, by combining an electronically controlled hydraulic damper with a motion tracking sensor, MR-AFO [1] for the rest.

### **METHOD**

The development was on a new hydraulic damper at first place. Magnetorheological fluid, a fluid which changes its viscosity instantly depending on the magnetic field around, was applied within the damper, and an original electronic controller [2] carrying a six-axis tracking motion sensor, an ankle joint goniometer, and a torque sensor would control the damper. MR-AFO is connected to an associated tablet PC via Bluetooth, which allows to set up joint braking torques and to obtain gait data. Videos recorded by built-in camera in the tablet PC would be synchronized with the gait data and display them along with each other.

The new hydraulic damper can produce



### **RESULTS**

Fig. 1 An outlook of a data collecting software screen from MR-AFO.

a range of 2.5Nm~16Nm of braking torques instantly depending on the magnetic field around. Also, dividing one gait cycle into five phases referred to the data collected from the sensors, eight levels of braking torques can be set up on both dorsal and plantar flexion actions. MR-AFO not just allows emulating other AFO's functions but also trying out non-existing patterns of braking torques in the conventional AFOs. Figure 1 shows an overview of a data collecting software screen from MR-AFO system. Pre-setting of braking torques, recording of gait data, comparisons of the recorded data can be manipulated on a touch screen intuitively.

### **DISCUSSION AND CONCLUSION**

MR-AFO, an AFO carrying an electronically controlled damper of the ankle joint, is developed, where an adjustment of AFO joint functions and an evaluation on gait data can easily be systemized during rehabilitation, compared with how the observations used to be done.[3] Moreover, a contribution of evidences utilizing AFO in the rehabilitation is demanded, MR-AFO can hopefully promote more effective rehabilitation process and its quantitativity to medical fields.

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### 3.2.2.e

# Energy Expenditure, Walking Speed and Satisfaction of the Tamarack Flexure Joint and Meridian Joint AFO in Charcot-Marie-Tooth: Case Study

<u>Aruna Maduranga</u>, <u>Mathurin Rairat</u>, Jutwan Changsaluk, Putri Amelia, Saowaphak Harasuk Sirindhorn School of Prosthetics and Orthotics, Bangkok, Thailand

### **BACKGROUND**

Charcot-Marie-Tooth (CMT) disease is one of the common diseases with signs of chronic non-progressive motor-sensory neuropathy that damage the peripheral nerve which is characterized by symmetric muscle atrophy and weakness of the distal portion of lower extremities. Ankle foot orthoses with different orthotic joint mechanism are used to provide stability due to affect by CMT. Tamarack flexure and meridian joints are common orthotic ankle joints to allow different function in ankle joint.

### AIM

The aim of this study was to compare outcome measurements of AFO with tamarack flexure and Meridian joints in patient's walking speed, patient's metabolic cost and satisfaction toward each of the devices.

### **METHOD**

male participant age 42 with CMT used AFO - tamarack flexor joints was evaluated and fit with both custom AFO - Tamarack joints and AFO - Meridian joints. Outcome measures were administered after patient had accommodated to both types of

AFOs. Measures: 10-meterwalking test (10MWT) 3 trials averaged of comfortable and fast walking speeds (CWS,FWS), metabolic cost while ascending/descending fourteen stairs for three-minutes, with thirty minutes rest between tests. Cortex Metamax 3B (Cortex, Germany) collected gas exchange and resting metabolic cost of 3.5 ml/kg/min was subtracted from gross metabolic cost to determine net metabolic cost. Lastly. satisfaction questions from the orthotic and prosthetic user survey



Figure 1. Questionnaire (Orthotic prosthetic user survey)

(Thai-OPUS) instrument were administered.

### **RESULTS**

For the 10MWT the patient showed 1.02 m/s CWS 1.17 m/s FWS for AFO with Tamarack and 0.89 m/s CWS and 1.19 m/s FWS with Meridian joint AFO. Net metabolic cost was 25.5 ml/kg/min for AFO with Tamarack joint and 28.5 ml/kg/min in Meridian joint AFO, energy expenditure (EE) with Tamarack joint was 35.9kJ/h/kg and Meridian 37.2 kJ/h/kg. OPUS questions had varying responses as illustrated in Figure 1.

### **DISCUSSION AND CONCLUSION**

The AFO with Tamarack flexor joint allowed for reduced O2 consumption and faster walking speeds than the Meridian joint AFO, however, the patients' unfamiliarity with the Meridian joint may have affected results. Future research exploring the differences among the two types of joints in this patient population is merited.

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### **ACKNOWLEDGEMENTS**

Study was supervised by Mr. Pitchaya Rayothee and also thank all lecturers who supported for this study in several ways.



# Symposium Education

### 3.2.3

# Orthotist/Prosthetist Competency Assessment using a Portfolio Method: An Exploration of a Novel, Best Practice Approach

Leigh Clarke, Louise Puli

The Australian Orthotic Prosthetic Association, Melbourne, Australia

### **Abstract**

Regulatory organisations, such as the Australian Orthotic Prosthetic Association (AOPA) and the United Kingdom's Health and Care Professions Council (HCPC), have responsibility for certifying Orthotist/Prosthetists to practice. Certification requires practitioners to complete a competency assessment against national, entry-level Competency Standards, which describe the knowledge, skills and attributes required for safe and effective practice.

Whilst written and oral exams are typically used to assess competency, exams measure knowledge only and fail to assess the full range of attributes required for competent practice, such as verbal communication, detailed decision making, and problem solving.

Following development of robust Entry-level Competency Standards for orthotist/prosthetists in Australia, AOPA developed and implemented a novel approach to competency assessment, using a portfolio method, which was endorsed by the Australian Government for the purpose of Orthotist/Prosthetist immigration.

This method requires submission of a reflective portfolio of evidence against all competencies described in the

Competency Standards and assesses both knowledge and attributes. A reflective portfolio includes a collection of evidence accompanied by specific justifications detailing the way in which the evidence demonstrates competence. A team of trained Assessors use rigorous guidelines and procedures to support the assessment and decisionmaking process. This includes an evidence assessment rubric to support assessment of the evidence quality and iustification for each competency (figure one).

This symposium will outline the portfolio method for competency assessment, including the functions of Assessors and the decision-making processes. The benefit of the portfolio method will be explored, including current work to evaluate assessment reliability.

JUSTIFICATION QUALITY

	Strong	Weak	Unsatisfactory		
High	Evidence was clear, comprehensive and directly related to the performance indicators. The accompanying justification was accurate and suitably detailed.	Evidence was clear, comprehensive and directly related to the performance indicators. The accompanying justification was partially accurate and/or may be missing some detail.	The evidence was clear, comprehensive and directly related to the performance indicators. The accompanying justification was inaccurate and/or incomplete.		
Low	Evidence lacked clarity and/or comprehensiveness and may not be directly related to the performance in ators. The accompanying justification was accurate and suitably detailed.	Evidence lacked clarity and/or comprehensiveness and may not be directly related to the performance indicators. The accompanying justification was partially accurate and/or missing some detail.	Evidence lacked clarity and/or comprehensiveness and may not be directly related to the performance indicators. The accompanying justification was inaccurate and/or incomplete.		
Insufficient	The evidence was grossly	sly insufficient and/or did not relate to the performance indicators.			
Concern	The evidence	ence and/or justification is below entry level competence.			
Accepta	able classifications of evidence	Unacceptable classific	ations of evidence		
SH	Evidence approved	Any evidence classified as insufficient unsatisfactory	or Resubmission		
SL, WH	Evidence approved subject to assessor judgement	Any evidence classified as concern	Resubmission with explanation		

Figure 1. Rubric for the assessment of evidence against the competency standards

# Statement of the objective / learning objectives

Attendees will learn about a novel and best practice approach to assessing practitioner competency, including how to establish the portfolio method, train and support Assessor teams and implement rigorous portfolio assessment methods.



# **Free Paper Session**

# **Prosthetics: Lower Limb Transtibial - Rehabilitation**

### 3.2.4.a

# The Difference in Perceived Workload Between Individuals with and without Transtibial Amputation During Split-Belt Treadmill Walking

Edward Syrett<sup>1</sup>, Brad Hendershot<sup>2,3</sup>, Benjamin Darter<sup>1,4</sup>

<sup>1</sup>Virginia Commonwealth University, Richmond, USA. <sup>2</sup>DoD-VA Extremity Trauma and Amputation Center of Excellence, Bethesda, USA. <sup>3</sup>Walter Reed National Military Medical Center, Bethesda, USA. <sup>4</sup>Hunter Holmes McGuire Veteran Affairs Medical Center, Richmond, USA

### **BACKGROUND**

Walking on a split-belt treadmill with the belts at different speeds creates a perturbation well suited for examining locomotor adaptability.[1] Unlike other populations with neurological injuries, locomotor adaptability for persons with transtibial amputation (TTA) was comparable to individuals without TTA.[2,3] However, persons with TTA generally display increased physiological effort [4] and report a greater attentional focus on walking, especially when perturbed.[5] To this point, the perceived physical and mental workload for split-belt walking has not been evaluated in persons with amputation.

### AIM

To determine the differences in physical and mental workload as measured by the NASA-TLX between those with and without TTA during a split-belt

treadmill walking task.

### **METHOD**

Seventeen participants (9 with TTA, 8 without TTA) completed a single session of walking on a split-belt treadmill according to established testing procedures.[2] The limb with longer step lengths during treadmill acclimation was assigned to the slow belt in persons with TTA, while belt assignment was randomized in those without TTA. An

NASA-TLX Subscale	TTA	Without TTA	Difference	p-value
Effort	53.8±21.9	40.63±26.2	13.2	0.27
Performance	22.7±13.7	15.6±11.7	7.1	0.27
Mental Demand	36.1±24.5	33.7±17.8	2.3	0.82
Physical Demand	54.4±21.8	28.1±17.9	26.3	0.01*
Frustration	25.0±24.8	23.1±24.4	1.8	0.87
Temporal Demand	32.7±25.1	31.2±18.8	1.5	0.89

Table 1. Mean (SD) NASA-TLX subscales and p-values. \* p<.05.

unweighted NASA-TLX was completed immediately after the split-belt condition. Items were scored on a visual analog scale from 0 to 100 (higher values reflect a higher workload). Means for NASA-TLX subscales were calculated and two-sided t-tests were used to compare the groups. Correlations between subscales and the change in step length symmetry during split walking were also calculated.

### **RESULTS**

Only Physical Demand was higher among persons with TTA than persons without TTA (Table 1). Likewise, symmetry improved similarly for both groups during split-belt walking (TTA: 0.16±0.06, without TTA: 0.20±.09). Associations between the change in symmetry and NASA-TLX subscales were r=-.59 with Performance and Frustration in persons with TTA, and between r=-.42 and -.58 for Mental Demand, Temporal Demand, Performance, Effort in persons without TTA. Associations with Physical Demand were r<.25 in both groups.

### **DISCUSSION AND CONCLUSION**

Except for Physical Demand, the perception of workload, like overall adaptability [2], was similar between groups. Furthermore, moderate correlations for changes in symmetry during split-walking and NASA-TLX subscales suggest participants perceived a higher workload when improvement in symmetry was small. As such, perception of task workload (except for Physical Demand) may be influenced by one's adaptability, but not by the presence of a TTA. However, further research needs to evaluate if the perception of workload differs when adaptability is impaired.

### **REFERENCES**

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### **ACKNOWLEDGEMENTS**

Funding: CTSA No. KL2TR000057 from the National Center for Advancing Translational Sciences, and BADER Consortium via CDMRP Award number W81XWH-11-2-0222.



### 3.2.4.b

# Safety of Osseointegrated Implants for Transtibial Amputees: a Two-Center Prospective Proofof-Concept Study

Robin Atallah<sup>1</sup>, William Lu<sup>2</sup>, Jiao Jiao Li<sup>3</sup>, Ruud Leijendekkers<sup>1</sup>, Jan Paul Frolke<sup>1</sup>, Munjed Al Muderis<sup>2</sup>
Radboud University Medical Centre, Nijmegen, Netherlands. <sup>2</sup>Northwest Private Hospital, Sydney, Australia. <sup>3</sup>The University of Sydney, Sydney, Australia

### **BACKGROUND**

Osseointegration is a potential treatment option for transfemoral amputees experiencing socket-related problems such as pain, poor fit, pistoning, decreased quality of life and decreased walking distance. Up to this date, there is little data assessing the feasibility and advantages of osseointegration in individuals with transtibial amputations.

### AIM

The aim of this study was to look into the feasibility, safety and functional outcomes of transtibial osseointegration.

### **METHOD**

We prospectively followed 36 patients undergoing transtibial osseointegration after non-vascular amputation at two centers for a minimum of 24 months. Adverse events were monitored including infection, periprosthetic fracture, implant breakage, aseptic loosening, need for revision surgery/additional amputation and death. Functional outcomes were measured using the Questionnaire of persons with a Trans-femoral amputation (Q-TFA) and mobility level was assessed using the Six Minute Walking Test (6MWT) and Timed Up and Go (TUG).

### **RESULTS**

Soft tissue infection was the most frequently encountered complication, occurring in 20 patients (56%) in 29 events, mostly treated successfully with antibiotic. Four patients (11%) developed septic implant infection resulting in explantation. Aseptic loosening occurred in one patient (3%) and one experienced failure of osseointegration as a result of a periprosthetic fracture. There was a significant increase in the Q-TFA global score and the 6MWT at 1-year follow-up (p<0.05). Conclusion: Transtibial osseointegration results in 23 improved functional outcomes after amputation. Complication rates of septic implant 24 infection are greater than compared to transfemoral osseointegration><0.05)

### **DISCUSSION AND CONCLUSION**

Transtibial osseointegration results in 23 improved functional outcomes after amputation. Complication rates of septic implant 24 infection are greater than compared to transfemoral osseointegration.



### 3.2.4.c

# Benefits of Implementing a New Amputation Program for TT-Amputees

Jenny Utbult<sup>1</sup>, Lina Sjödin<sup>2</sup>

<sup>1</sup>TeamOlmed, Saltsjö-Boo, Sweden. <sup>2</sup>Södersjukhuset, Stockholm, Sweden

### **BACKGROUND**

A discussion in one of Stockholm's larges clinics for amputations, regarding transforming more amputees into walkers resulted in a new amputee care program including updated technique for transtibial amputation, early post-operative treatment of the stump, and in suitable cases, early prosthetic fitting. These joint activities should also be controlled by an "amputation coordinator". The ampute care program was based on the results from previous studies.[1, 2]

### AIM

The aim was to improve the rehabilitation and increase the number of prosthetic ambulators among the survivors, 3 months after amputation. To minimize muscle loss and motivation, the aim was also to shorten the time from amputation to prosthetic fitting.

### **METHOD**

In present study a baseline was recorded 2015, to document the number of amputees fitted with a prosthesis, number of ambulators and finally rehabilitation time from amputation to successful prosthetic fitting. The same recording was performed 2016 after the intervention with an amputation care program controlled by an amputation coordinator. The study was conducted by extracting data from the surgical planning system and by following the medical record at the P&O clinic at Södersjukhuset, Stockholm. Additional variables were the patient age, type of surgical incision and affected side. Patients were totally anonymized in the data sheets.

### **RESULTS**

The patient population following the new care program with [mainly] sagittal incision followed by a rigid dressing and compression treatment of the stump, did in 51% of the surviving cases after 3 months become ambulatory. In the baseline population, 39% of the 3 months survivors became ambulatory. The average time from amputation to prosthetic fitting decreased from 140 days to 69 days. A median comparison shows 214 days 2015 and 54 days 2018. The median age of the populations was nearly the same, 77 years 2015 and 79 years 2018.

	2015	2018
Number of amputees TT-level		81
Age [average, yrs]		79
Age [median, yrs]	80	84
Days to prosthetic fitting [average]	140	69
Days to prosthetic fitting [median]	214	54
Proportion of ambulators 3-month survival		51%

Figure 1. Number of days to prosthetic fitting and ambulators

# **DISCUSSION AND CONCLUSION**

that more elderly amputees were rehabilitated to ambulators in a shorter time. The amputation method was standardized to sagittal incision and the post-operative treatment included rigid dressing followed by compression therapy. This resulted also in improved wound healing and preparation of shape and form of the amputation stump to facilitate early prosthetic fitting. In conclusion, the routine of the new amputation care program is successful in reaching the aim, to rehabilitate more amputees to become ambulators in a shorter time.

# **REFERENCES**

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### **ACKNOWLEDGEMENTS**

Magnus Lilja, CPO, PhD; Anton Johannesson, CPO, PhD



### 3.2.4.d

# A Systematic Review of Varicose Hyperplasia in Lower Limb Amputation

Gregory Halford<sup>1</sup>, Kevin Murray<sup>2</sup>

International Committee of the Red Cross, Amman, Jordan. <sup>2</sup>Strathclyde University, Glasgow, United Kingdom

### **BACKGROUND**

In low income countries (LICs) varicose hyperplasia (VH) is relatively common in people with lower limb amputations. It is observed when lower limb prosthetic sockets with distal gaping are used. This may be because of more basic technology being employed, the challenging nature of residual limbs or the educational background of treating prosthetists. In order to develop an evidence based educational resource with the aim of improving the quality of care in LICs, a systematic review of available literature was undertaken.

#### ΔIM

To systematically review published papers relevant to VH in people with lower limb amputations and to establish the state of the current evidence influencing this condition.

### METHOD

A comprehensive review of the literature was undertaken using key word searches of relevant data bases in English until Dec 2018. Twenty seven (27) published papers were included after application of inclusion and exclusion criteria. SIGN grading was applied to all included publications.

### **RESULTS**

Reported incidence of VH was 1.4% to 8.9% in the reviewed literature. Descriptions of aetiology are consistent, showing good consensus for a vascular origin as a result of poor prosthetic socket fit. Poor fittings are characterised by high pressure proximally and distal gaping within the socket. There is good consensus that the recommended treatment method includes resolving the prosthetic fitting problems and treating the medical complications. An over reliance on expert opinion was shown with much of the opinion directly or indirectly citing SW Levy.[1] The work of pioneering South African physician Loewenthal,[2] also showed great insight into the treatment of VH and this will be included in this presentation.

### **DISCUSSION AND CONCLUSION**

This systematic review shows good agreement regarding aetiology, clinical presentation and treatment of VH, but weak quality evidence (SIGN grades 3 & 4) with only case studies and expert opinion addressing VH directly. A case series or case control study would be useful to determine the factors present during onset of VH and the efficiency and average healing time related to the proposed treatments. This review has led to the development of an evidence based educational package for practitioners.

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### 3.2.4.e

# **Contributing Factors To Trips And Falls In Lower Limb Amputees**

Alison Stenson<sup>1</sup>, Jane McLean<sup>2</sup>, Ramesh Munjal<sup>2</sup>, Michael McGrath<sup>1</sup>, Beata Rek<sup>1</sup>, Saeed Zahedi<sup>1</sup>, David Moser<sup>1</sup>
Blatchford, Basingstoke, United Kingdom. <sup>2</sup>Sheffield Teaching Hospitals, Sheffield, United Kingdom

### **BACKGROUND**

The risk of falls and fear of falling affect the everyday lives of lower limb amputees.[1] The use of regression analyses on large data samples has been used to investigate causes of amputee falling previously.[2] In a study of elderly people without amputations, tripping and stumbling was reported as contributing to nearly a third of all reported falls.[3] Tripping should also be considered when studying falls prevalence and factors.

### AIM

Investigate the prevalence and contributing factors of tripping and stumbling. Investigate events and patient behaviour following a fall.

### **METHOD**

A bespoke questionnaire was developed to collect data about patient demographics, their rates of tripping and falling, and the events following a fall.

Multiple regression analyses were performed. Firstly, the number of trips was taken as the dependent variable. Secondly, number of falls was taken as the dependent variable, with number of trips added as a factor.

For fallers, a third regression, with 'likelihood of injury' as the dependent variable, considered all patient demographics and the location of the fall as factors. A fourth regression used 'likelihood of reporting a fall' as the dependent variable, with gender, age, time since amputation and K level as factors.

### **RESULTS**

The final analyses were performed on a dataset of 421 respondents (79% male, with 278 below knee and 147 above knee amputations).

Factors significantly related to tripping were having an above knee amputation, taking medication that may cause dizziness, being a primary amputee (<12 months), and using a walking stick. Being 60-79 years old was protective against tripping.

Factors significantly related to falling were having an above knee amputation, having type 1 diabetes, using a walking stick, using a crutch, tripping 1-5 times a month and tripping more than 5 times a month.

Injuries from falls were related to falling outdoors and falling both indoors and outdoors. Using a walking stick or two crutches were both protective against injuries.

The final analysis indicated that women were more likely to report a fall to a member of their rehabilitation team.

### **DISCUSSION AND CONCLUSION**

As this study has confirmed, there are many contributing factors to the risk of falls but highlighting the main causes can help identify those most at risk and actions can be taken to protect against it.

### **REFERENCES**

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# Free Paper Session Orthotics: Spinal

### 3.2.5.a

# An Intelligent Automatic Pressure-Adjustable System to Enhance Orthosis Wearing Quality for Patients with Adolescent Idiopathic Scoliosis

Yangmin Lin<sup>1</sup>, Edmond H. M. Lou<sup>2</sup>, Tsz Ping Lam<sup>3</sup>, Jack Chun Yiu Cheng<sup>3</sup>, Sai Wing Sin<sup>4</sup>, Wing Kwan Kwok<sup>4</sup>, Man Sang Wong<sup>1</sup>

<sup>1</sup>The Hong Kong Polytechnic University, Kowloon, Hong Kong. <sup>2</sup>University of Alberta, Alberta, Canada. <sup>3</sup>The Chinese University, New Territories, Hong Kong. <sup>4</sup>Prince of Wales Hospital, New Territories, Hong Kong

### **BACKGROUND**

Though orthosis is commonly considered as an effective treatment for AIS, its effectiveness can be influenced by many factors such as patient's wearing compliance. However, it is difficult to control the wearing compliance by education only in the current clinical practice. An intelligent automated pressure-adjustable orthosis has been developed aiming to maintain a more consistent biomechanical interfacial environment for correction enhancement. Clinical evaluation is needed to confirm the clinical effectiveness of this innovative orthosis.

### AIM

This study aimed to compare the clinical effectiveness of the automated pressure-adjustable orthosis with the conventional orthosis for patients with AIS.

### **METHOD**

A bi-center randomized controlled study of 24 subjects (selected according to the Scoliosis Research Society criteria) was conducted. Equal number of subjects were assigned in the PO group (pressure-adjustable orthoses, with mean age 12.4 and Cobb 26.2°) or the CO group (conventional orthoses, with mean age 12.6 and Cobb 27.4°). The pressure-adjustable system was embedded in the PO group and set to automatically adjust the interfacial pressure as prescribed while compliance sensor was installed in the CO group. The questionnaires of SRS-22, BrQ and SAQ were used to assess the subject's quality of life. The baseline, immediate in-orthosis and 1-year out of orthosis X-rays were used for correction analysis.

## **RESULTS**

One subject dropped out in the PO group. Significant immediate in-orthosis correction was observed in the PO group (11.0°, 42.0%, p<0.001) and the CO group (10.3°, 37.6%, p<0.001). At the 1-year follow up, no subject had curve progression in the PO group while 2 subjects in the CO group had curve progression > 5°. The out of orthosis X-ray showed that the mean Cobb was reduced by 3.8° (13.9%) in the PO group and 0.5° (3.6%) in the CO group. The daily wearing hour was 1.1 longer in the PO group as compared with the CO group (15.4 vs 14.3 hrs). However, the wearing duration with prescribed pressure level was 5.4 hrs significantly longer in the PO group (8.7 vs 3.3 hrs, p<0.001). No significant difference was observed in all the aspects of quality of life assessments between the 2 groups.

# **DISCUSSION AND CONCLUSION**

In this study, the automated pressure-adjustable orthosis was demonstrated being able to enhance the wearing quality as compared with the conventional one, and it tended to offer better correctional effect in this relatively short-term study and doing no harm to the subjects' quality of life. However, to verify this preliminary finding, more subjects with longer study time are deserved.



### 3.2.5.b

# Does Integration of Ultrasound Imaging and Purpose-Design Frame Facilitate Orthotic Treatment for Adolescent Idiopathic Scoliosis?

Babak Hassan Beygi<sup>1</sup>, Wing Kwan Kwok<sup>2</sup>, Sai Wing Sin<sup>2</sup>, Ho Man Kee<sup>2</sup>, Choi Kam Au Yang<sup>2</sup>, Wing Yiu Yip<sup>2</sup>, Edmond Lou<sup>3</sup>, Man Sang Wong<sup>1</sup>

<sup>1</sup>The Hong Kong Polytechnic University, Kowloon, Hong Kong. <sup>2</sup>Prince of Wales Hospital, Shatin, Hong Kong. <sup>3</sup>University of Alberta, Edmonton, Canada

### **BACKGROUND**

Moderate adolescent idiopathic scoliosis (AIS) is generally managed with spinal orthosis while its effectiveness could be reflected from strategic force application and patient's compliance. The pre-orthotic radiographs and clinician's judgment are the main inputs currently for orthotic design. The non-ionizing properties of 3-D ultrasound (US) and feasibility of acquiring the images of the posterior vertebral features could largely increase the possibility of utilizing this modality to orthotic design that has been shown in recent studies.[1-7]

### **AIM**

The objective of this study was to evaluate whether an integrated method of customized assessment frame and clinical US could enhance the orthotic treatment of AIS as compared to the conventional approach.

### **METHOD**

Twenty-six subjects with AIS were recruited and assigned equally into either control or experimental group (n=13). The conventional method of measurement and fabrication was implemented in the control group while the subjects in experimental group were arranged to sit inside a purpose-design frame and the corrective pads were applied and adjusted with the guidance of real-time reconstructed US images in the coronal, sagittal and transverse planes until a curve reduction of at least 30% could be attained. Upon achievement, the trunk geometry was recorded (via a CAD/CAM system) in the procedure of orthotic fabrication. The pre-orthosis and initial in-orthosis radiographs were used for effectiveness comparison between the two groups.

### **RESULTS**

The mean Cobb angle reduced from  $30.3\pm3.7^\circ$  (pre-orthosis) to  $19.0\pm5.2^\circ$  (in-orthosis) in the experimental group and from  $28.2\pm6.3^\circ$  to  $22.5\pm4.8^\circ$  in the control group. The results showed that the mean Cobb angle in both groups significantly decreased in comparison with the pre-orthosis condition. The correction percentage in the experimental group was significantly (p <0.05) higher than that of the control group. Similar trend for the correction rate was observed. The comparison of the compliance did not reveal any significant difference between two groups as the subjects in both groups were wearing the orthosis less than 60% of the prescribed hours (23 hours) per day.

### **DISCUSSION AND CONCLUSION**

The result of this study showed that the subjects in the experimental group can have better curve correction. This implied that the integrated method may potentially alter the conventional design and fabrication process of orthotic treatment with a well-documented simulated in-orthosis correction during the measurement session. Several limitations should be considered including the shortcoming of US system in assessment of subjects with extremely high or low BMI values, and severe curvature and rotation. Further enhancement of the system is ongoing.

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# **ACKNOWLEDGEMENTS**

We would like to acknowledge all participants and their families for their precious time and kind cooperation within this study.



# 3.2.5.c

# Scoliosis Brace Design from Several Scans for Hypercorrection

Sophie Pourret<sup>1</sup>, Jean-Loic Rose<sup>2</sup>, De Mauroy Jean-Claude<sup>3</sup>, Lydie Journoud<sup>1</sup> Lecante, Lyon, France. <sup>2</sup>Proteor, Lyon, France. <sup>3</sup>Clinic du Parc-Lyon, Lyon, France

### **BACKGROUND**

Brace treatment has been reported to be an effective approach to reduce or moderate idiopathic adolescent scoliosis. Braces aim to reduce the deviations of the spine in 3 planes of space. Thus, it restores the patient's physiological balance and maintains those reductions until stabilizing. Usually, the mechanical principles of correction of scoliosis braces consist to apply thrust and thrust against areas. However, many searches attempt to design a rotating treatment of the spine with rehabilitation [1] or brace [2,3,4].

### AIM

This study consists to propose a brace design method from several patient's scans. This approach allows a real hypercorrection of each scoliotic curvature without deleterious impact on sagittal plane, and on costal deformation.

### **METHOD**

The method consists to design brace per layer obtained from different scans of patient in specific positions. Each layer is segmented and assembled by superposition. Thus, the patient will be pulled and not pushed towards the reduction of curvatures. Scapular and pelvic are maintained on

the median vertical axis.

To apply this method, we have proposed to use three positions. The first shape capture is a self-active-axial elongation posture and a balance between pelvic and scapular belts. The second and third shape capture are the maximum reduction of lumbar and thoracic deviations respectively. For six years, this protocol was applied on 2,000 patients with scoliosis.

### **RESULTS**

The following results were obtained from three centers (France, Italy and Hong-Kong). The adolescent's idiopathic scoliosis that meet the SRS criteria has an average Cobb angle reduction of 70% and there is a flat back's decrease of about 9°. The appearance of the rectified shape feels like a twist of the spine

in the opposite direction of scoliosis (figure 1), without real disharmonious and unbalanced impact of body (figure 2). Brace survey showed that these braces have no localized pressure (70% of patients) and thus improve wearing comfort than others braces.

# **DISCUSSION AND CONCLUSION**

Used of multiple scans improves and simplifies brace design with CAD. The simplification is due to the hypercorrection postural position reproduced by the patient himself. Moreover, the method allows to assess clinical reduction with the hypercorrection posture and to use it in brace design. One limit is obtained when a patient cannot stay in required position. In these cases (adults), previous physical therapy would be necessary to relax stiff spine.

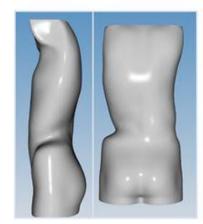


Figure 1. Rectification step for brace with our method and multiple scans

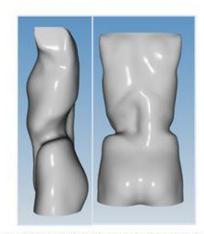


Figure 2. Rectification step for brace with classic method

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### 3.2.5.d

# CAD/CAM Technology and M. Rigo Classification as a Base for Orthotic Treatment Of Idiopathic Scoliosis

<u>Grigorii Lein</u>, Ivan Pavlov Scoliologic.ru, Saint-Petersburg, Russian Federation

### **BACKGROUND**

Idiopathic scoliosis is one of the most common problem of pediatric orthopedics. At the moment, the only evidencebasad effective method of conservative treatment of idiopathic scoliosis is a combination of Cheneau type brace specific corrective exercises. At the same time, the main problem is the complexity of modeling braces, the lack of real manufacturing standards and, as a consequence, the actual impossibility of making multi-central randomized studies. In fact, each particular specialist creates his own model of the corrective brace.

#### AIM

To make a standard of modeling corrective Cheneau type brace to increase effectiveness of treatment of IS.

## **METHOD**

We analyzed results of 2000 braces for 1000 patients. The braces were made by 7 doctors from our team, who had more then 3 years experience of bracing, three of them had more then 10 year experience. The results were evaluated in patients whose first brace was made before the introduction of the new method and the second after the introduction of the proposed standard. There were 320 hand-made braces and 680 CAD/CAM before implementation of standard, since that moment all braces were made by CAD/CAM. We used X-ray and 3D scan method for analysis the results.

### **RESULTS**

Analysis of the treatment results showed that the differences in-brace correction between braces made by CAD Cam technology and hand-made before the introduction of the standard are not statistically significant, but the period of use of braces made by CAD/CAM technology was higher by an average of 3-4 months. In 20% of cases the primary model was not chosen correctly. After the introduction of the standard in-brace correction increased by 24% while the number of incorrectly selected models decreased to 5%. Cosmetic results were analyzed by 3d scan and after implementation of the standard symmetry of the trunk increased.

# **DISCUSSION AND CONCLUSION**

We can tell that CAD/CAM technology is only tool, but in combination with a M. Rigo classification it allow us to make a standard of modeling of corrective Cheneau type braces. New standard allow to make the knowledge of best experienced employees available to any new doctor and increase the effectiveness of all team. Beside this new standard can be used as a base for multi central randomized control trial studies.



### 3.2.5.e

# **Scoliosis Electronic Monitoring Brace for Forces Distribution Measurements**

Massimo Pulin<sup>1</sup>, Giorgia Sartorato<sup>1</sup>, <u>Piero Schiavuta</u><sup>2</sup>, Roberto Pierobon<sup>2</sup>, Giorgio Marinaro<sup>2</sup>, Massimo Balsano<sup>3</sup> Orthomedica srl, Padova, Italy. <sup>2</sup>Protolab srl, Padova, Italy. <sup>3</sup>AOUI Azienda Ospedaliera Universitaria Integrata, Verona, Italy

### **BACKGROUND**

About 2% of European teenagers are affected by idiopathic scoliosis and need custom brace treatment longer than one year and up to 23 hour per day to counteract the evolution of scoliotic curve by applying a mechanical stress against the body and favoring the correct posture of rachis. Despite the demand of recording acting forces inside the brace,[1] currently no devices in the market are able to quantitatively measure them and the wearing time.

### AIM

This work aimed at developing an innovative plug and play wearable sensor kit for monitoring the pressure inside scoliosis braces, to improve the compliance to medical prescriptions [2] and the active patient participation.

### **METHOD**

Miniaturized force sensors have been inserted in the scoliotic braces in the position of apexes of the scoliotic curve to gather data of corrective forces applied to the body. A prototype system was developed where data were transferred to a single electronic board and communicated via Bluetooth to a dedicated smartphone app for representation and further with medical specialists. Digitalization of data boosts the development of automated analyses to frequently check treatment progresses, while the availability of gathered data allows the use of predictive algorithms to favor rapid intervention in case of wrong treatment trend.

### **RESULTS**

Twenty patients affected by idiopathic scoliosis tried in vivo the brace modified with force sensors. They were asked to perform body movements following an agreed protocol and sensor data were recorded with the aim to prove the correlation among the motion, the joint angles over time and the applied brace pressure in the relevant positions. Several exercises performed for 30 seconds gave the output pressure values consistent with the sensor position along the scoliotic curve (lumbar and dorsal). Data are stored in a database, analyzed and shown on the graphical user interface designed for the medical personnel. On the other hand, the patient can check through an app installed on the smart phone the average time of brace use (daily, weekly or monthly), and the compliance with the precepted treatment.

Task 1 - standing with normal breathing

0.45
0.4
0.35
0.35
0.25
0.25
0.15
0.11
0.05
0
0
5
10
15
20
25
30
time [s]





### **DISCUSSION AND CONCLUSION**

Trials with patients served as proof of concept of the sensor customized brace deploying sensors, digital acquisition, analysis and predictive methods. We trust that the proposed technological system can be a powerful tool in the hands of expert operators moving orthopedic physicians and physiotherapists towards quantitative measures and practices by means of predictive trends based on increasing amounts of collected data.[3] Sensors are not invasive and well accepted by patients that, ultimately, are actively involved to therapy success.

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### **ACKNOWLEDGEMENTS**

Embrace Project funded by Veneto Region - Italy (POR FESR Action 1.1.4 DGR 889 13/06/2017).



# Free Paper Session Psychosocial Issues / Quality of Life - Prosthetics

### 3.2.6.a

# Japanese Design Influences on Nuance and Ownership in Hands of X

<u>Graham Pullin</u><sup>1</sup>, Andrew Cook<sup>1</sup>, Jo Gooding<sup>2</sup>

<sup>1</sup>University of Dundee, Dundee, United Kingdom. <sup>2</sup>Kingston School of Art, Kingston upon Thames, United Kingdom

### **BACKGROUND**

Despite increased choices in prosthetic hands, many wearers do not feel that their attitudes are represented. This can result in prostheses being rejected or abandoned.[1] Hands that imitate human flesh may seem uncanny [2] and imply an intention to 'pass' that fewer disabled people share.[3] Bionic hands can imply overcoming disability, whereas many disabled people resent this expectation. "We wish to evolve unremarkably" says disability activist Liz Jackson.

### AIM

This study explores how prosthetics hands might be unashamedly artificial, yet understated and approachable. And how a feeling of ownership might be engendered, to counter many wearers' feelings that their prosthesis is not *theirs*.

### **METHOD**

Our methods were both participatory and design-led.[4] We involved wearers, designers and makers in participatory workshops that were the source of our detailed designs. And the direction was profoundly

influenced by industrial and fashion design and in particular Japanese design: concepts of *hari* and *sabi*; nuanced choice of materials such as woods and leathers that age,[5] reflecting and engendering a deeper relationship with their wearer; Naoto Fukasawa's notion of *super normal* led us to abstract historical prosthetic hands in search of a timeless design that deferred to the wearer's everyday life;[6] MUJI's products inspired a palette of domestic materials that were familiar and approachable.[7]



# **RESULTS**

The outcome was an installation in an eyewear retailer (embodying the change in perspective from a medical to a social model of disability). We prototyped the wearer's experience of a service in which they would be offered a choice of materials from which their hand was made. The results included the deeper reflections on a lack of a feeling of ownership or design in current services: our participating wearers became our mentors. One output (which would be shown at ISPO) is a documentary film showing the *Hands of X* service and interviews with wearers.

# **DISCUSSION AND CONCLUSION**

Hands of X has provoked new discussions in the UK and US (exhibited at the Smithsonian). Our conclusion is that *sabi* and *super normal* resonate with many wearers. Pullin now has a Senior Fellowship with The Healthcare Improvement Studies Institute to explore co-design and a sense of ownership, including reinventing the Prosthesis Evaluation Questionnaire to assess and evidence just such psychosocial issues. Speaking at ISPO is an invaluable opportunity to introduce international—not least further Japanese—perspectives.

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# **ACKNOWLEDGEMENTS**

Hands of X (Co-I Miodownik, UCL) supported by EPSRC; Gooding's Fellowship by AHRC LDoc Network; Pullin's Senior Fellowship by THIS.Institute.



### 3.2.6.b

# Evaluation of Quality of Life in Patients with Lower Limb Amputation and in use of Prosthesis, in a Rehabilitation Hospital

<u>Denise Matos</u><sup>1,2</sup>, Tereza Araujo<sup>2</sup>

Sarah Network Rehabilitation Hospitals, Brasilia, Brazil. <sup>2</sup>Brasilia University, Brasilia, Brazil

### **BACKGROUND**

Quality of life is often recognized as an important outcome of rehabilitation programs for people with amputation. It is a consensus that these patients present impoverished quality of life compared to their healthy peers. Despite the importance of the theme, the number of studies focusing on the multiplicity of factors influencing it is still limited. In addition, quality of life measures are increasingly required in clinical trials to demonstrate changes related to intervention over time.

### AIM

The study aims to evaluate the quality of life of people with amputation of lower limbs and in use of prosthesis, in a rehabilitation hospital.

## **METHOD**

A cross-sectional study was performed with the instruments SF-36 and TAPES-R for the evaluation of quality of life. Data regarding sociodemographic characterization and amputation were obtained in electronic medical records. The inclusions criterions adopted were a patient with lower limb amputation of more than six months and being in use of prostheses. The data were collected in an orthopedic workshop of a rehabilitation hospital. Comparative evaluations were carried out by gender, type of amputation with and among the instruments used.

### **RESULTS**

The sample consisted of 116 individuals with a mean age 35.9 years (SD = 12) and the women presented lower mean age (p = 0.016). In the SF-36, the most affected domains were functional capacity, vitality and the physical component; the social aspect presented the highest average. There is a worse perception of quality of life among women, in amputations above the knee and due to traumatic causes. In the analysis by TAPES-R, patients with amputations above the knee present greater functional difficulty, worse adjustment and less functional satisfaction with the prosthesis. There is a negative association between time of use of the prosthesis and adjustment to the limitation: use of the prosthesis less than 10 hours / day is associated with worse adjustment, limitation of activity, and dissatisfaction with the functionality of the prosthesis.

n	%
116	100,0
68	58,6
48	41,4
44	37,9
29	25,0
26	22,4
17	14,7
48	41,4
60	51,7
8	6,9
37	31,9
79	68,1
42	36,2
67	57,8
7	6,0
43	37,1
36	31,0
23	19,8
14	12,1
	116 68 48 44 29 26 17 48 60 8 37 79 42 67 7

## **DISCUSSION AND CONCLUSION**

The correlation between the instruments TAPES-R and the SF-36 shows coherence between them and their domains, which indicates the evaluating character of the instruments. With a suitable rehabilitation program, a satisfactory rehabilitation result with prosthesis can be expected, not only in terms of adherence or successful use, but also in terms of psychosocial rehabilitation, social and labor reintegration and as high quality of life as possible.



### 3.2.6.c

# Quantifying the Improvement in Perceived Quality of Life after Prescription of Micro-Processor Knees

<u>Fraser Dunlop</u><sup>1</sup>, Laura Murray<sup>1</sup>, Ramesh Munjal<sup>2</sup>

University of Strathclyde, Glasgow, United Kingdom. <sup>2</sup>Sheffield University Teaching Hospital, Sheffield, United Kingdom

### **BACKGROUND**

It is assumed that a micro-processor knee (MPK) improves the quality of life of a user when compared to a non-MPK. Existing research generally focuses on objective outcome measures. Using both subjective and objective outcome measures this study covers multiple aspects of daily life to quantify the change in functional ability of a prosthetic user.

### AIM

To quantify the anecdotal evidence that MPKs improve quality of life by analysing data collected during routine care of amputees in the UK.

### **METHOD**

This study is a retrospective analysis of data that was collected during the routine trial protocol for patients who had been prescribed an MPK prosthesis at a hospital in the UK. Patients were included for trial if they met eligibility criteria set out by NHS England. Each patient completed multiple outcome measures including the PEQ and six-minute walk test as a baseline using their current prosthesis, 4 weeks after supply of the MPK, and 6 months after supply. The data from these outcome measures was then analysed for change over time.

### **RESULTS**

27 patients were included in the final analysis. The mean reduction in reported trips and stumbles was 90% during the first 4 weeks using an MPK, and this improvement was maintained at the 6-month outcome measures (Table 1). Statistically significant (p<0.05) improvements in the 6MWT and TUG test were also made and maintained throughout the study period. The average self-reported quality of life improved significantly in the Reintegration to Normal Living Index, and self-perceived well-being improved in over 90% of patients.

# Self-reported Trips & Stumbles during four weeks prior to appointment

	N	Mean	Std. Deviation	Minimum	Maximum
Trips & Stumbles baseline	27	7.33	4.455	2	20
Trips & Stumbles at 4 weeks	27	.70	1.382	0	5
Trips & Stumbles at 6	27	.70	1.031	0	4
months					

### **DISCUSSION AND CONCLUSION**

An MPK is beneficial to patients in improving physical function but also in improving psychological well-being. With results from the PHQ-9, 4 of the 5 patients who were classed as depressed at baseline showed an improvement to a level at which they would no longer be classed as depressed.

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### **ACKNOWLEDGEMENTS**

The Prosthetic department at Sheffield Teaching Hospital.



### 3.2.6.d

# The Lived Experience of Sequential Partial Foot and Transtibial Amputation

Sarah Anderson<sup>1</sup>, Michael Dillon<sup>1</sup>, Emily Duke<sup>2</sup>, Hannah Ozturk<sup>3</sup>, Rwth Stuckey<sup>1</sup>
La Trobe University, Bundoora, Australia. <sup>2</sup>St Vincent's Hostpital, Melbourne, Australia. <sup>3</sup>Northern Hospital, Epping, Australia

### **BACKGROUND**

Given the large proportion of people that will experience serious complications and reamputation following an *initial* PFA [1], it is important to illuminate the unique experiences of people who have undergone *sequential* PFA and TTA. Learnings about the lived-experience could inform the content of condition-specific, pre-amputation education materials that can support meaningful conversations between health professionals, patients, and their loved ones. These conversations are important for informed decision-making and to establish realistic expectations that can help minimize negative experiences.

### **AIM**

The purpose of this investigation was to describe the lived experience of people who have undergone sequential PFA and TTA.

### **METHOD**

Using a narrative inquiry approach, adults with experience of sequential partial foot amputation and transtibial amputation on the same limb agreed to participate in semi-structured, face-to-face interviews. These were transcribed verbatim and conducted until data saturation. Each interview was read, coded and a thematic summary with quotes was returned to each participant for verification. Data were triangulated through independent coding and analysis.

### **RESULTS**

The lived experiences of the 10 participants were characterized by three themes: enduring complications eventually resolved, health and wellbeing improved with knowledge, and advice from the lived experience. The foot complications that led to partial foot amputation often endured until after transtibial amputation, where participants reported being able to get on with their life. At the point of partial foot amputation, participants had little knowledge about the surgical procedure, likely outcomes or common risks. In the lead up to transtibial amputation, structured systems provided access to peer support and conversations with healthcare professionals. As participants' knowledge improved, many people were able to exercise control over their healthcare decisions.

### **DISCUSSION AND CONCLUSION**

The lived experience highlights the importance of high-quality information and meaningful conversations to inform decision making and prepare people for life with limb loss.

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### 3.2.6.e

# Prefrontal Cortical Activation during Challenging Walking Situations in Persons with Lower Limb Amputation - An fNIRS Observational Study. Preliminary Results

<u>Jette Schack</u>, Peyman Mirtaheri, Harald Steen, Terje Gjøvaag Oslo Metropolitan University, Oslo, Norway

# **BACKGROUND**

Persons with lower limb amputation (LLA) report the need of increased attention and concentration when walking.[1] It is, therefore, important to understand better the interaction between mobility and cognitive control mechanisms during mobility. The prefrontal cortex (PFC) plays a key role in cognitive control of mobility and becomes activated when compensatory strategies are necessary during walking and when the execution of walking is not automated.

### AIM

To assess prefrontal cortical activity in persons with and without lower limb amputation during different walking conditions

### **METHOD**

Thirty-nine persons with LLA and thirty-three controls participated in the study. Persons with LLA had a non-vascular reason of amputation. The majority had a transtibial amputation (n=20), followed by transfemoral (n=11) and kneedisarticulation (n=8). Three walking conditions in a Figure-of 8-walk-test was assessed: 1) walking with self-selected walking speed, 2): carrying a tray with two cups of water and 3) walking on uneven terrain. Cortical activity was assessed using functional near infrared spectroscopy (fNIRS), a portable neuroimaging technique.[2] A linear-mixed model was used to detect changes between groups and between walking-conditions within each group.

### **RESULTS**

A systematic increased PFC activity was observed during all three conditions in persons with lower limb amputation compared with able-bodied controls and a significant increased activation was observed in condition 1 and 3 (p < .05), respectively. Between-walking condition comparisons showed a significant different PFC activation between condition 3 compared with condition 1 and condition 2 (p < .05) in both groups. However, the effect of walking condition on PFC activity was not modified by group, the interaction term group x condition was non-significant (P > 0.1), suggesting that persons with LLA had the same PFC increase during challenging walking conditions as able-bodied controls.

# **DISCUSSION AND CONCLUSION**

A systematic increased PFC activation during all three walking-conditions was observed for persons with LLA compared with able-bodied controls. However, the activation of PFC seems to depend on the nature and complexity of the task. The results suggest that persons with LLA have to use more cognitive resources during mobility than able-bodied controls. The higher activation in both groups during walking on uneven terrain suggests that prefrontal cortex plays an important role during demanding environments.

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# **ACKNOWLEDGEMENTS**

This work was supported by the foundation "Stiftelsen Sophies Minde" Oslo, Norway.



### 3.2.6.f

# Phantom Pain and Psychosocial Adaptation of Norwegian Lower Limb Prosthetic Users – A Pilot Study

<u>Inger Marie Starholm</u><sup>1</sup>, Gitte Flindt Hilding<sup>2</sup>, Hege Lund<sup>2</sup>, Vegar Hjermundrud<sup>1</sup>, Jette Schack<sup>1</sup>, Mirjam Mellema<sup>1</sup>, Terje Gjøvaag<sup>1</sup>

<sup>1</sup>Oslo Metropolitan University, Oslo, Norway, <sup>2</sup>Unicare Bakke AS, Halden, Norway

### **BACKGROUND**

The impact of a lower limb amputation on phantom pain and psychosocial adaptation to limits imposed by an amputation has never been investigated in Norwegian prosthetic users. Pain may act as a constant "reminder" of perceived restrictions and disabilities and hence affect acceptance and adaptation to limits imposed by the amputation.

### AIM

This study investigated if experiences of phantom pain (PP) affected the participants' General Adaptation (Adapt-Gen), their Social Adaptation (Adapt-Soc) and their Adaptation to Limits (Adapt-Limit), as imposed by the amputation.

### **METHOD**

In an ongoing investigation, 32 experienced prosthetic users (21 males, 11 females) with unilateral lower limb amputation, mean (SD) age 60.2 (12) years, participated. They had in average used their prosthesis for 9.9 (14.3) years and 72 % were amputated of traumatic and 28 % of vascular reasons. The participants' scores on different psycho-social domains were investigated using the Trinity Amputation and Prosthesis Experience Scale-Revised (TAPES-R) questionnaire. Possible differences in sub scores for Adapt-Gen, Adapt-Soc and Adapt-Limit for persons with and without PP were investigated by the Mann-Whitney U test (IBM SPSS statistics, v24).

## **RESULTS**

In this group of prosthetic users, 78% experienced PP and 41% of these persons reported their level of pain to be "distressing". About 37% of the persons reporting PP, experienced this every day of the week. However, 87% of the persons with PP, report no limitation or only limited a little in their capacity to walk more than 500 meters, thus their physical functioning was not severely restricted. Scores for General and Social Adaptation were similar and generally high, for persons with/without PP (Fig 1). This indicates good general and social adaptation to their situation and that occurrence of pain do not influence on this adaptation. However, the Adaptation to Limits score was lower for persons with PP (p < 0.004).

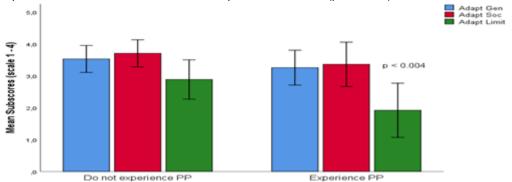


Figure 1. Phantom pain and psychosocial adaptation subscores. Higher scores indicate better adaptation.

### **DISCUSSION AND CONCLUSION**

General and Social Adaptation scores are high, and do not seem influenced by PP. Despite a fairly good level of physical functioning, the low score on the Adaptation to Limits item may indicate that PP possibly acts as a reminder of restrictions imposed by the amputation.[1] In conclusion, PP do not seem to influence General and Social Adaptation. However, PP does seem to affect Adaptation to Limits in this ongoing study.

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# **Basic IC Rehabilitation Medicine & Surgery**

# 3.2.7

# Interdisciplinary Outpatient Clinic for Amputees with Residual Limb Pain (RLP)

Gunther Felmerer<sup>1</sup>, Jennifer Ernst<sup>1</sup>, Eric Andres<sup>2</sup>, Daniela Wüstefeld<sup>2</sup>

Division of Plastic Surgery, Department of Trauma Surgery, Orthopedics and Plastic surgery, University Medicine Goettingen, Georg August University Goettingen, Germany. Patient Care Center Duderstadt/Berlin Ottobock SE & Co. KGaA, Duderstadt, Germany

## **Abstract**

50-95% of amputees suffer from chronic pain after amputation. Causes of pain after amputation include phantom limb pain, residual limb pain (RLP), contralateral limb pain, and back pain (Buchheit et al. 2016; Ephraim et al., 2005). As the etiology of those different pain qualities determines the therapy, a precise medical history and refined diagnostics are required. The cooperation of a multidisciplinary team – **orthopedic surgeons, plastic surgeons, CPO, OTs and engineers** in an outpatient clinic allow for a comprehensive analysis and approach to this complex symptom.

A systematic algorithm based on this **interdisciplinary management** of amputees with chronic pain revealed that revision surgery plays a significant role in the treatment of residual limb pain. The algorithm helps to identify underlying pathologies of residual limb pain.

According to this algorithm surgical revisions are indicated for the treatment of residual limb pain if a clear pathology can be identified and after conservative treatment options have been exhausted. Significant research efforts, following surgical refinements as targeted muscle reinnervation, osseointegration and further innovative microsurgical techniques revealed new options for the treatment of residual limb pain. If there is no obvious pathology, it is advisable to avoid surgical revision of the residual limb and treat diffuse pain similar to phantom limb pain in cooperation with a specialized pain therapist and new technologies as virtual reality.

The comprehensive approach by an interdisciplinary management together with new prosthetic technologies and surgical refinements finally offers new dimensions for the prosthetic fitting and rehabilitation of amputees with residual limb pain.

# Statement of the objective / learning objectives

The IC informs about innovations and treatment options of RLP. An structured algorithm developped by medical doctors, CPOs and OTs gives hands on a interdisciplinary management of RLP.



# Advanced IC Orthotics: Spinal

# 3.2.8

# **Enabling Hand Function and Creating Independence for People with SCI on C4-C6 with Robotics and Active Orthopedic Devices**

Sofie Woge<sup>1</sup>, David Jonsson<sup>2</sup>, Christina E. Wanscher<sup>3</sup>

Tendo AB, Lund, Sweden. <sup>2</sup>Clinic for Spinal Cord Injuries, Hornbæk, Denmark. <sup>3</sup>RoboCluster, Odense, Denmark

# **Abstract**

In Sweden alone, 5.000 people are living with a spinal cord injury (hereon SCI) and the incidence rate is 150 new cases yearly. Between 50-70% of the patients were under the age of 30 at the time of the injury and the impact on the activities of daily living, is often severe. The loss of movement and sensation often leads to limitations which requires continued assistance and it, consequently, leads to a significant loss of independence and quality of life (QOL).

For individuals with e.g. **C4-C6** injuries, aids such as powered wheelchairs, has proven life changing in terms of the mobility and freedom it returns to its user. However, when listing the most important function for QOL, hand function was ranked the highest – this compared to e.g. the ability to walk and bladder and bowel function. Despite this, options that does not include complex surgeries or even amputation to replace the hand with a prosthetic myoelectric hand, is limited. What if robotic technologies, such as **Exoskeletons** and **Active Orthopedic Devices**, could enable the same revolutionary freedom for hand function, as the electronic wheelchair did for mobility?

We will, during the symposium, present a new way of using innovative robotic technologies to give independence and QOL back to C4-C6 patients – to enable an enhanced key-grip which allows them grasp, hold and release object in an intuitive way. We will also highlight the importance and benefits of working in a close collaboration with potential users and display study results.

# Statement of the objective / learning objectives

Ways to create **Independence** and **Hand Function** for **C6-C4** patients by using non-invasive technologies and **Robotics** and how to involve the user in the process.



# **Symposium Prosthetics: Lower Limb Transtibial**

# 3.3.1

# Stepping Forward: Focusing on Research with the Older Prosthesis User

Matthew J. Major<sup>1,2</sup>, Natalie K. Vanicek<sup>3</sup>, William C. Miller<sup>4</sup>

Northwestern University, Chicago, USA. <sup>2</sup>Jesse Brown VA Medical Center, Chicago, USA. <sup>3</sup>University of Hull, Hull, United Kingdom. <sup>4</sup>University of British Columbia, Vancouver, Canada

# **Abstract**

Much of the research with prosthesis users involves people with good levels of function, who are often younger, traumatic amputees. However, in developed countries, the majority of lower-limb amputations are related to nontraumatic aetiologies, such as diabetes and/or vascular disease. Therefore it is vital to conduct research with older prosthesis users, who often suffer from concomitant health issues, demonstrate significant mobility and balance problems, and are likely fitted with more basic prostheses.

In this symposium, we will discuss the experience of three researchers from different countries (Canada, USA, UK) working with older individuals with major lower-limb amputation. The overarching shared aim of our work is to improve function in this patient group through tailored exercise and enhanced prosthetic componentry. Specifically, we will: describe therapeutic interventions involving game-based training; focus on important stability-related sensorimotor factors during walking and postural control tasks; and explore the acceptability to older prosthesis users of the involvement in research with more advanced prostheses. We will discuss differences in functional outcomes between older individuals with and without amputation, as well as adherence to a prospective data collection protocol for measuring fall prevalence. The session will conclude with an interactive discussion between the panel and members of the audience focusing on differences in prosthetics rehabilitation within the context of different healthcare frameworks.

This symposium will consider challenges presented when working with older prosthesis users, and outline the important implications of this research for healthcare provision and influencing guidelines and policies to elevate the quality of evidence-based practice.

# Statement of the objective / learning objectives

This session will focus on the older prosthesis user involved in prosthetics research. We will investigate differences in clinical rehabilitation internationally but with shared priorities related to patient-reported outcomes including mobility, pain, and health-related quality-of-life.



# Free Paper Session Orthotics: Lower Limb Neurological - AFO

# 3.3.2.a

# The Effect of the Plantarflexion Resistance of Oil Damper Ankle-Foot-Orthosis on Trunk and Pelvis in Stroke Gait

# Ling Hua

International University of Health and Welfare, Tokyo, Japan. China Rehabilitation Research Center, Beijing, China

# **BACKGROUND**

The plantarflexion resistance of AFOs can affect the lower limb functions, the effect of different plantarflexion resistance on the thorax and pelvis during gait with stroke has not been clarified.

#### AIM

This study aimed to explore the effect of the plantarflexion resistance of an AFO on the trunk and pelvis in stroke patients, attempt to present a vision from upper body to select the plantarflexion resistance of an AFO.

#### METHOD

The gait of four stroke patients (age: 61~82; onset time since stroke incidence: 20-145 months) in post phase with 3 different amounts of plantarflexion resistance generated by the oil damper(OD) of an AFO named Gait-Solution Design (GSD) were measured by a 3D motion capture system (VICON). So 8 spatial-temporal parameters and 6 parameters of the upper body in the coronal plane and 4 parameters in the sagittal plane were calculated. The Friedman analysis (a non-parametric test) (p<0.05) was performed with SPSS version 22 for the analyses of parameters.

## **RESULTS**

The result of parameters with Friedman analysis did not show significance so this study discusses the change of these parameters in individual separately. Only one participant showed immediate changes with different plantarflexion resistance on the upper body in the sagittal plane. All four participants showed changes of upper body sway in the coronal plane, inappropriate plantarflexion resistance induced the increase in the range of upper body sway and induced more degree of asymmetry of body sway in the bilateral side.

# **DISCUSSION AND CONCLUSION**

One participant showed a negative effect with upper body sagittal motion with inappropriate plantarflexion resistance, suitable plantarflexion resistance decreased upper body lateral movement in all four participants. The plantarflexion resistance function of AFO affected the alignment of the upper body during the gait of stroke patients in the post phase.

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# **ACKNOWLEDGEMENTS**

Thanks to the patients who participated in this study, thanks to Pro. Yamamoto Sumiko, Dr. Nomura Takahiro and Daryabor Aliyeh.



# 3.3.2.b

# Effects of Ankle–Foot Orthoses with Plantar Flexion Stop and Plantar Flexion Resistance using Rocker Sole Shoe on Stroke Gait

Aliyeh Daryabor<sup>1,2</sup>, Mokhtar Arazpour<sup>3</sup>, Gholamreza Aminian<sup>3</sup>, Mina Baniasad<sup>4</sup>, Sumiko Yamamoto<sup>5</sup>

Student Researcher in International University of Health and Welfare, Tokyo, Japan. <sup>2</sup>University of Social Welfare and Rehabilitation Science, PhD student, Tehran, Islamic Republic of Iran. <sup>3</sup>University of Social Welfare and Rehabilitation Science, Tehran, Islamic Republic of Iran. <sup>4</sup>Mechanical Engineering Department, Sharif University of Technology, Tehran, Islamic Republic of Iran. <sup>5</sup>International University of Health and Welfare, Tokyo, Japan

# **BACKGROUND**

Following hemiplegia, all three gait rockers are seriously damaged. Previous studies conducted on the influence of ankle foot orthoses (AFOs) with plantarflexion resistance (AFO-PR) compared with AFO with plantarflexion-stop (AFO-PS) have reported that AFO-PR improve heel and ankle rockers during walking; however, improvement of the (third rocker) push-off was insufficient. It was also demonstrated that rocker soles shoes could result in improving rollover foot function and consequently, facilitating transferring weight from one limb to another.

# AIM

To evaluate the effect of two AFOs and comparison between two AFOs, AFO-PS and AFO-RS, when wearing standard shoe (SS) and wearing rocker sole shoe (RS) in a randomized controlled trial.

## **METHOD**

20 stroke subjects in chronic phase were randomized to each AFO group (AFO-PS group:10 and AFO-PR group: 20). The gait of each group under three conditions (1) only SS (without AFOs) before training and then (2) with AFOs using SS (AFO-SS) and (3) AFOs using toe-only RS (AFO-RS) after 2 weeks gait training were measured by three-dimensional motion analysis. Comparisons within groups for each group were, at first, done in three conditions mentioned. Comparisons between two groups were done between AFO-PS and AFO-PR wearing SS, as well as, between AFO-PS and AFO-PR wearing RS.

# **RESULTS**

Comparing gait without AFOs (only SS) with AFOs-SS, both AFOs significantly improved walking speed, double support time, center of mass displacement and knee flexion in initial contact (p<0.05). After 2 weeks of AFO-PR use wearing SS or RS compared with only SS, cadence, step time, ankle angle in loading response and single support, knee extension in single support, backward component of ground reaction force (GRF). However, these changes were not observed in the AFO-PS group. Both AFOs groups wearing RS compared with AFOs wearing SS did not improved third rocker parameters including power generation, forward component of GRF, plantar flexion moment in terminal stance and pre-swing time (p>0.05). Concerning the comparison between two groups when wearing AFOs with SS or RS, there were no significant differences in the all gait parameters (p>0.05).

# **DISCUSSION AND CONCLUSION**

Findings of the present study showed that orthotics effect of AFO-PR was larger than AFO-PS for improving gait parameters in chronic hemiplegic patients which could be due to the AFO function in sagittal plantar flexion resistance. This result is in agreement with that of a previous study.[1] On the other hand, when patients using AFOs wore rocker shoes, their push-off ability did not improved.

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# **ACKNOWLEDGEMENTS**

This study was supported by the Iran National Science Foundation, Grant Number 95849762.



# 3.3.2.c

# A Pilot Study Investigating Effect of Ankle-Foot Orthosis (AFO) Stiffness on Walking Patterns of Patients with Ankle Impairment

<u>Peeraya Ruthiraphong</u>, Stephanos Solomonidis University of Strathclyde, Glasgow, United Kingdom

## **BACKGROUND**

Ankle-foot orthoses (AFO) is a standard treatment to improve gait pattern and balance in stroke patients.[1] However, evidence based practice on benefits (walking speed and balance) are still low (grade C) and insufficient data in kinematics, kinetics, long term effects.[2] The reason could be lack of well understanding in their mechanical properties leads to variety design. To determine AFO moment during gait cycle by using strain gauges may explain matching of stiffness degree suitable with individual impairment.

## AIM

To demonstrate the effect of commonly used AFOs stiffness, which are solid reinforced (SOR), solid (SOL) and posterior leaf spring (PLS) and the biomechanics results on the lower extremities during the gait cycle.

# **METHOD**

Strain gauges were attached to each AFO at ankle level to allow the measurement of the moment generated by the orthosis in the sagittal plane. The subject, wearing each instrumented AFO walked in the gait analysis laboratory where kinematic and kinetic data were acquired. This method allows the contribution of the AFOs during walking to be determined, and this information (orthosis moment) in conjunction with the kinematic and kinetic data from gait analysis (Vicon), the anatomical moments, can be calculated by using MATLAB program.

# **RESULTS**

Static calibration and orthosis moment during walking shows the most to least stiffness from solid, solid-reinforced (SOR) and PLS. Ankle DF increased most during loading response (13.5+/-0.7) and reduced peak DF most (late stance) in the stiffest AFO. The moment however showed correlation of decreased external peak PF

(early stance) and decreased knee flexion moment, correspondingly. Peak DF moment during terminal stance phase were increased most with the stiffest AFO (SOR) and only this type increased peak external knee extension moment. The data in swing phase are similar in all AFOs. Even though in static calibration, SOR AFO resisted DF more than solid AFO only 10Nm. The moment effect to the knee was shown only in SOR. These values were closed to control in PLS. There was anatomical moment working against both solid orthoses, while this does not occur in PLS.

	Peak knee flexion moment during loading response		Peak knee extension moment-terminal stance phase		Peak plantar fler moment during le response		Peak dorsiflexion moment- terminal stance phase	
	Mean+/- SD(Nm)	RMSE	Mean+/- SD(Nm)	RMSE	Mean+/-SD(Nm)	RMSE	Mean+/-SD(Nm)	RMSE
Normal	62.6+-	0	-13.0+/-3.3	0	-26.92+-2.8	0	108.9+-2.4	0
PLS	629+/-3.1	0.3	0.3+/-1.7	133	-38.52+/-2.8	11.6	101.56+-3.7	7.34
Solid	40.5+/-2.5	22.1	-13.0+/-5.9	0	-19.2+-0.7	7.72	118.5+-2.5	9.6
Solid reinforced	25.8+/-9.8	36.8	-71.97+/-10.2	58.97	-4.7 <sub>+</sub> -5.3	22.22	128.12+-4.5	19.22

Figure 1. shows knee and ankle moment in subject without AFO, and wearing three different AFOs. PLS: Posterior leaf spring, Solid reinforced is solid AFO with carbon fiber insert. RMSE: root mean square error- compares the value between left side with each AFO and the left side without orthosis (normal)

# **DISCUSSION AND CONCLUSION**

The results imply that AFO that is stiffer than the optimal requirement could lead to restriction of ankle motion and have an indirect effect on the knee moment. The anatomical moment worked against the stiffer one, which could be the reason for AFO disadvantage if it is too stiff for clinical requirement- Early stance: too stiff AFO obstruct ankle peak PF and affected peak knee flexion moment. Late stance: too stiff AFO increased peak DF moment and affect peak knee extension moment.

# **REFERENCES**

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- [2] Papi et al. J Eng Med 2015; 229(1):40-51.



# 3.3.2.d

# Gait Change in Stroke Patients during the Recovery Phase with Continuous use of an Ankle-Foot Orthosis with Plantar Flexion Resistance

Minoru Murayama<sup>1,2</sup>, Sumiko Yamamoto<sup>2</sup>

Kiseikai Funabashi Municipal Rehabilitation Hospital, Chiba, Japan. <sup>2</sup>Graduate School International University of Health & Welfare, Tokyo, Japan

## **BACKGROUND**

Sustained use of an ankle-foot orthosis (AFO) with a plantarflexion stop (AFO-PS) is thought to decrease the muscle activity of the tibialis anterior (TA), but the effect of using an ankle-foot orthosis with plantar resistance (AFO-PR) has not been examined. The effect of AFO use on hemiplegic patients recovering from stroke during a hospital stay of several months has also not been studied.

# **AIM**

To use kinematic and electromyographic analyses to elucidate the effects of regular use of an AFO-PR on gait changes over 2 months in hemiplegic patients during the recovery phase.

# **METHOD**

Participants were 15 hemiplegic patients during the recovery phase who were prescribed an AFO-PR. We asked them to walk 10 m at a comfortable pace and used goniometers to measure ankle angle and shank tilt angle. We recorded electromyograms of the TA and soleus muscles and measured the walking time and number of steps taken. Initial measurements were taken 2 weeks after delivery of the orthosis, and subsequent measurements were taken 1 and 2 months later. We used the Bonferroni multiple comparison test to compare changes among the initial measurement and 1- and 2-month follow-up measurements.

# **RESULTS**

Figure 1 shows the angles measured and the %EMG waveforms for each muscle in a representative case. The shank tilt angle and TA results showed a greater increase between the 1- and 2-month follow-up measurements

than between the initial and 1-month follow-up measurements. Multiple comparisons of gait parameters in the 15 participants showed a significant overall increase in gait speed and shank tilt angle during single-leg support (SS) phase during both the first and second months after the initial measurement. Although the plantar flexion angle of the ankle during loading response (LR) and the dorsiflexion angle of the ankle during SS phase increased significantly by the 1-month followup, the shank tilt angle during LR and %EMG of the TA had increased significantly by the 2-month follow-up despite the lack of significant change by the first 1-month follow-up.

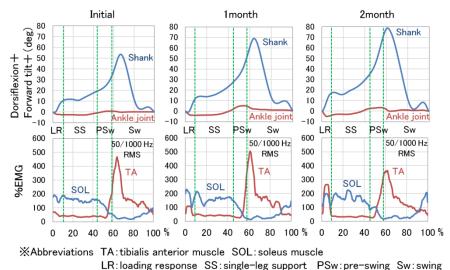


Figure 1. Typical examples of angle and EMG waveform

# **DISCUSSION AND CONCLUSION**

While Hesse et al. suggested that use of an AFO-PS results in disuse atrophy of the TA, our study found a significant increase in the %EMG of the TA during LR in the second month. This discrepancy may be the result of differences between AFO-PS that stop plantar flexion and AFO-PR that permit plantar flexion, suggesting that habitual use of an AFO-PR has a low risk of disuse atrophy of the TA.

# **REFERENCES**

[1] Hesse et al. Stroke 1999; 30:1855–1861.



# 3.3.2.e

# Effect of Gait Training using Ankle-Foot Orthoses with Plantarflexion Resistance and Plantarflexion Stop on Stroke Gait when not Wearing Device

Sumiko Yamamoto<sup>1</sup>, Aliyeh Daryabor<sup>2,3</sup>

<sup>1</sup>International University of Health and Welfare, Tokyo, Japan. <sup>2</sup>Student Researcher in International University of Health and Welfare, Tokyo, Japan. <sup>3</sup>Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Science, Tehran, Islamic Republic of Iran

# **BACKGROUND**

In order to manage functional impairment from stroke, subacute rehabilitation including gait training is crucial. Wearing ankle-foot orthosis (AFO) in associated with gait training within subacute phase can improve the ambulatory function of patients poststroke. On the other hand, wearing an AFO with plantarflexion resistance has been demonstrated to assist gait function of stroke, but the evidences regarding its effect on their gait as well as on the upper body movement during subacute phase when not wearing is limited.

# **AIM**

To determine the effect of uses of an AFO with plantar flexion stop (AFO-PS) and AFO with plantarflexion resistance (AFO-OD) and comparison between two AFOs on the gait of stroke patients when not wearing the ankle–foot orthosis in subacute phase.

#### METHOR

Forty stroke patients within subacute phase were randomized to each AFO group (AFO-PS group: 20 and AFO-OD group: 20) in an unblinded randomized controlled trial. Subjects, wearing the determined type of AFO, took part in 1 hour of gait training sessions by physiotherapists every day for 2 weeks. Shod gait without an AFO before gait training and then without using the AFO after 2 weeks of use were measured by three-dimensional motion analysis. Comparison between walking when wearing AFO before and after gait training in each group is considered as therapeutic effect. Additionally, Comparison of gait without an AFO after gait training between two groups was done.

# **RESULTS**

Significant changes observed on use of the both groups when not wearing AFO were improvements in some gait parameters including the spatiotemporal parameters, shank vertical angle, backward component of floor reaction force, preswing knee angular velocity, and velocity of the COG in the double stance phase. There were not any significant differences in ankle kinematics in both groups. After 2 weeks of AFO-OD use without its using, thorax showed decreased forward tilt at initial contact. However, the pelvis showed forward tilt in the AFO-PS group at this phase. Regarding the comparison between two groups, there was no significant difference between the AFO-PS and AFO-OD groups after gait training wearing AFOs when not using them regarding all parameters.

# **DISCUSSION AND CONCLUSION**

These changes indicated using AFOs in associated gait training can improve walking function during stroke gait within subacute phase. This research and a previous research [1] demonstrated that AFO with the plantar flexion resistance can facilitate better alignment of the upper body, however, this study and previous study [1] are the first studies evaluated the effect of AFOs on the upper body alignment. So, further research is required to prove these results.

# **REFERENCES**

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# **ACKNOWLEDGEMENTS**

This study was financially supported by JSPS KAKENHI Grant Number 26350630.



# 3.3.2.f

# Alignable and Resistance Adjustable Articulated AFO to Reduce Knee Hyperextension Poststroke - A Comparison of Blocked and Controlled Motion Settings

Ana Maria von Corvin<sup>1</sup>, Roy Bowers<sup>2</sup>

<sup>1</sup>Master in Orthotic Rehabilitati, University of Strathclyde, Glasgow, United Kingdom. <sup>2</sup>National Centre for Prosthetics and Orthotics Department of Biomedical Engineering University of Strathclyde, Glasgow, United Kingdom

## **BACKGROUND**

Hemiparetic gait poststroke may be considered a compensatory mechanism to prevent falls. A tuned AFO establishes a biomechanically optimal position of the lower limb and provides stability. Controlled plantar flexion reduces the knee flexion moment at loading response. The repeated movement of the ankle supports physiotherapy, may promote neuroplasticity to restore the motor strategies of gait. Therefore, an AFO with and alignable and a resistance/assistance adjustable ankle joint may provide a better orthotic solution although higher costs are involved.

## AIM

This case series compares the resulting spatiotemporal parameters, symmetry, kinematics, knee moment and preference of setting in poststroke patients after four weeks using the same ankle joint in a blocked and a limited ROM setting with regulated plantar and dorsiflexion.

## **METHOD**

Four poststroke patients with knee hyperextension were tested using an AFO with an alignable, range of motion (ROM) limitation and resistance/assistance-adjustable ankle joint. The tuned AFO was worn with standardized shoes. Three trials were performed in a non-randomized order: baseline with shoes; blocked AFO and the same AFO with a controlled ROM and assistance/resistance of plantar and dorsiflexion. The patients were given four weeks for familiarization in each of the settings before the next trials were performed. 3-D analysis was performed to record the spatiotemporal parameters, symmetry, kinematics and knee moments. The preferred setting was appraised through questionnaires after they had used the AFO in the two conditions.

# **RESULTS**

An increase in velocity and cadence with both AFO settings at a self-selected speed was documented. The stride length increased in three patients in both AFO settings. The mean values for all four patients show very small differences in the symmetry of the steps compared to the baseline data.

The findings regarding the knee flexor moment were diverse but favorable in three patients while wearing the regulated plantar flexion resistance and limited ROM setting compared to a solid ankle.

The L-tests reveal a reduction in the time required for functional activities with the AFO, independent of the setting.

Most subjects felt that both conditions improved balance, swing clearance and loading of the foot. Three subjects preferred a controlled ROM setting and one patient did not favour either AFO configuration but would rather use the AFO instead of not having one.

# **DISCUSSION AND CONCLUSION**

Velocity and cadence increased independent of the AFO setting while the results related to step ratio symmetry and stride length were inconsistent. The knee flexion moment was positively influenced by the controlled plantar flexion resistance at loading response. A tendency to correct the knee and hip flexion in stance was recognized with the tuned AFO in both settings and hip flexion improved in swing with the ROM setting. The patients felt more comfortable with a resistance adjustable ankle joint.

# **ACKNOWLEDGEMENTS**

Fior & Gentz GmbH provided the ankle joints for this case series.



# Advanced IC Education

# 3.3.3

# **Optimizing Strategies for Literature Searching in Prosthetics & Orthotics**

<u>David Rusaw</u><sup>1</sup>, <u>Nerrolyn Ramstrand</u><sup>1</sup>, <u>Elisabeth Nylander</u><sup>2</sup>

<sup>1</sup>Jönköping University - School of Health and Welfare, Jönköping, Sweden. <sup>2</sup>Jönköping University - Jönköping University Library, Jönköping, Sweden

# **Abstract**

This instructional course is intended for graduate and post-graduate students, as well as those actively involved in research within the Prosthetics and Orthotics field.

Literature searches are a necessary component of effective research. To identify and access suitable literature, researchers need to understand which databases are most appropriate, how they differ in terms of content and search structure, and how to develop a search strategy which optimizes the proportion of relevant literature sources. Additionally, scholarly journals are increasingly requiring authors to publish utilized search strings to allow duplication of results.

The choice of terms and syntax used to construct searches within literature databases have a major influence on the outcomes of a literature search. If this process is not conducted correctly, it can result in unnecessary identification of inappropriate sources or unintended omission of appropriate literature. This instructional course will be led by academic P&Os and librarians and will equip participants with the tools to develop an advanced search strategy for a prosthetics and orthotics related topic. In addition, the concept of validated search filters, also known as *search hedges*, will be introduced. These can be used to efficiently and accurately filter the evergrowing volume of literature. During the course, participants will be provided with a validated search hedge which has been developed by the instructional team to be utilized when conducting a systematic search for literature within the area of limb prosthetics.

# Statement of the objective / learning objectives

Upon completion, the student will:

- Understand the concept of a search hedge
- Make informed decisions about the selection and use of literature databases
- Independently develop a search strategy for a prosthetics and orthotics related topic



# Free Paper Session Prosthetics: Lower Limb Transfemoral - Osseointegration

#### 3.3.4.a

# Hip Muscles Forces during Walking in Transfemoral Amputees with Osseointegrated Prosthetic Limb

Vahidreza Jafari Harandi, David C. Ackland, Raneem Haddara, <u>Peter Vee Sin Lee</u> The University of Melbourne, Melbourne, Australia

# **BACKGROUND**

Gait asymmetries in transfemoral amputees fitted with an osseointegrated implant have been shown to be lower compared to those of conventional socket fitted prosthesis.[1] Due to the lack of ankle plantarflexors and knee muscles in transfemoral amputees, the remaining musculature in the intact and residual limb must compensate for absent muscles.[2] There is currently little known about muscle compensatory mechanisms in amputees with an osseointegrated prosthetic limb.

# AIM

The purpose of this study was to evaluate intact and residual limb hip muscle forces during the stance phase of walking in osseointegrated transfemoral amputees using 3D musculoskeletal models.

## **METHOD**

Four transfemoral amputees (age, 56±3.5yrs; mass, 80.4±12.5kg; height, 1.8±0.1m) participated in the study. Lower extremity joint angles were calculated using retro-reflective marker trajectories measured via Vicon cameras during self-selected speed. Ground reaction forces were obtained using 3 imbedded force-plates. Low pass Butterworth filter was used to filter motion and force data with cut-off frequency of 6 and 20Hz, respectively. A 3D musculoskeletal model comprised 10 rigid body segments with 23 degrees-of-freedom, actuated by 76 Hill-

type muscle-tendon units was developed in Opensim. The prosthesis' mass center and moment of inertia were computed from a Solidworks model. Joint moments were calculated by inverse dynamics, then decomposed into discrete muscle loads using static optimization.

# **RESULTS**

Hip flexion motion in the intact limb was slightly greater at contralateral toe-off than that of the residual limb (mean difference: 2.01°). The knee flexed more in the intact limb than the residual limb at contralateral toe-off and at contralateral heel-strike (mean difference: 2.20° and 3.63°, respectively). The hip moment of the intact limb demonstrated greater flexion at the early and late-stance than that of the residual limb. Peak forces of the gluteus medius in the intact limb was higher than that in the residual limb (mean difference:4.05N/kg (Fig 1).

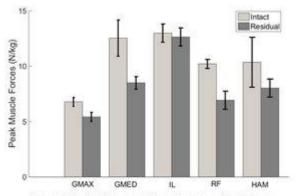


Figure 1. Peak of hip muscle forces in stance. Symbols are GMAX: gluteus maximus; GMED: gluteus medius; IL: iliopsoas; RF: rectus femoris; HAM: hamstrings

# **DISCUSSION AND CONCLUSION**

Peak hip muscles forces in the residual limb of transfemoral amputees with an osseointegrated prosthesis were lower than those in the intact limb during walking. Differences in the forces produced by the hip muscles between the two limbs may be related to differences in the hip flexion and step length. The reduced step length of the residual limb resulted in reduced hip extension, which lead to smaller muscle forces in the residual limb relative to those in the intact limb.

# **REFERENCES**

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- [2] Lim YP. Muscle function during walking. Gait Posture 2013.



# 3.3.4.b

# Safety and Performance of Osseointegrated Bone-Anchored Prostheses in Transfemoral Amputees: A 5 Year Follow-up Study

<u>David Reetz</u>, Robin Atallah, Jamal Mohamed, Henk van de Meent, <u>Ruud Leijendekkers</u>, Jan Paul Frölke Radboudumc, Nijmegen, Netherlands

## **BACKGROUND**

Despite advances in the prosthetic socket technology, the performance of prosthetic sockets is often reported as unsatisfactory. Since almost 30 years, osseointegration implant surgery offers an alternative solution by attaching the artificial limb directly to the femoral residuum. Osseointegration implant surgery has been introduced in our center in 2009. Over the years, we prospectively followed our patients. Recently a first cohort has completed 5 years of follow-up.

# AIM

The aim of this study is to report the 5-years follow-up safety, prosthesis wearing time, and quality of life outcomes of a cohort of patients with femoral osseointegration implant.

# **METHOD**

Patients who underwent implantation of a press-fit osseointegration implant with a follow-up of 60 months were asked for informed consent. Implantation of the intramedullary component was performed in stage one, the transcutaneous adapter was mounted with creation of a stoma in stage two. Infections were registered retrospectively using an earlier developed classification system (see reference) out of the patient records and general practitioner contacts. In addition, we looked at implant breakage and surgical refashioning. Prosthesis-wearing-time and quality-of-life were prospectively measured with the Questionnaire for persons with a transfemoral amputation (Q-TFA) prosthetic use score (PUS) and global score (GS), respectively. Changes over time were analyzed with the Wilcoxon signed-rank test.

# **RESULTS**

In total, 35 out of 37 patients were included in our analysis.

Twenty-seven patients (77%) presented with some kind of infection (146 events in total) with 138 events classified as grade I-II infections (94.5%). There were eight events classified grade III in four patients. There were four individuals in which 57 events of infectious complications occurred (39% of all infectious events).

The intramedullary part of the device showed breakage in two cases.

In total soft tissue refashioning had to be done 25 times in 12 patients. One patient underwent 9 out of the 25 refashionings.

The Q-TFA PUS increased from median 71 [interquartile range (IQR) 30-90] to 100 [IQR 90-100] with p<0.001. The Q-TFA GS improved from median 42 [IQR 25-50] to 71 [IQR 52-83] with p<0.001.

# **DISCUSSION AND CONCLUSION**

Grade I and II infections were frequent complications and could most of the time be treated with conservative measures. Despite the adverse events the quality of life improved significantly, this indicates that the benefits of this treatment possibly outweigh the disadvantages. Current developments focus on reduction of the infectious complications and prevention of implant breakages.

# **REFERENCES**

[1] Al Muderis et al. J Bone Joint Surg Am. 2016; 98(11):900-9.



# 3.3.4.c

# Femoral Curvature Influence for Above Knee Bone Anchored Prosthesis Alignment. Cadaveric Study

Oskars Gainutdinovs<sup>1,2</sup>, Peteris Studers<sup>1,2</sup>, Oleg Gaynutdinov<sup>1</sup>, Kristaps Knokenfelds<sup>2</sup>
<sup>1</sup>Riga Stradins University, Joint Laboratory of Orthoapedic and Traumatology, Riga, Latvia. <sup>2</sup>Hospital for Traumatology and Orthopaedics, Riga, Latvia

## **BACKGROUND**

The bone anchored prosthetic devices have been investigated in the present study, because of certain disadvantages of socket suspension prosthesis worsening the quality of life of amputees. There is a standard alignment for socket suspension prosthesis. Osseointegrated prosthetic alignment has to be realized at the same principles, taking into account some features regarding intramedullary stem fixation and femoral shift anatomy.

#### AIM

- 1. Study of the femoral shift canal axis and mechanical axis orientation.
- 2. Experimental research of intramedullary stem position for the bone anchored prosthesis.
- 3. Study result evaluation for the bone anchored prosthesis alignment.

# **METHOD**

Thirty-one Caucasian cadaver femurs were used (13 females, 18 males, 11 left, 20 right). The X-ray was performed for all steps of standard anterior and lateral view.

- 1. Femur main anatomical points were marked by 3 mm metal loads to improve measurements.
- 2. Femur was amputated in the middle shift, custom made stem was implanted.
- 3. Same Femur was reamputated 7 cm below trochanter minor, custom made stem was implanted. All X-ray images were analysed graphically. Femur canal axis was divided for 20 segments. Angles between femor mechanical axis and femoral canal axis and between femoral stem axis and mechanical axis were found.

# **RESULTS**

Analysis of a native femur revealed the following: 1. According to anterior X-ray view, femoral canal has almost constant angle between femoral canal axis and femur mechanical axis 5-7 degrees. 2. In lateral images angle is variable. In proximal 1/3 of femur it almost constant 7-9 degrees, then it decreases, becomes neutral in 55-60% of femoral length and distally turns negative - minus 3-4 degrees. Implanted femoral stem orientation showed correlation with native femur measurements. The angle after first and second amputation in frontal view was constant 5-7 degrees. The lateral view angle was variable as for a native femor 8-9 degrees flexion angle proximally and 6-8 degrees in the middle part.

# **DISCUSSION AND CONCLUSION**

The study shows that bone anchored prosthesis alignment features for a transfemoral amputee are inducted by intramedullary fixation and femur shift curvature. The residual femor in neutral position has angles with load line in frontal and sagittal plane. Straight femoral stem anchored prosthesis needs posterior placement of the knee joint. Posterior placement for bone anchored prosthesis is necessary as for a socket one. Posterior position of the knee joint could provide posteriorly curved femoral stem or/and specific prosthetic components.

# **ACKNOWLEDGEMENTS**

Medical ethics committee has allowed conducting this study accordingly to Latvian legislation. Riga Stradins University supported study financially.



# 3.3.4.d

# Biomechanical Evaluation of Vibrotactil Feedback for Bone Anchored Prosthesis

Oskars Gainutdinovs<sup>1,2</sup>, Peteris Studers<sup>1,2</sup>, Oleg Gaynutdinov<sup>2</sup>, Vladislavs Jevstignejevs<sup>3</sup>

Hospital for Traumatology and Orthopaedics, Riga, Latvia. <sup>2</sup>Riga Stradins University, Joint Laboratory of Orthoapedic and Traumatology, Riga, Latvia. <sup>3</sup>Riga Technical University, Riga, Latvia

# **BACKGROUND**

Vibrotactil feedback is one of the way how humans receive information about body and other subject condition. There are numbers of mechanisms providing sensation of vibration, including lamellar bodies. Osseoperception phenomenon is well known from oral implantation experience. The nature of osseoperception is still unclear. However, only few studies can be found in literature regarding osseoperception in osseointegrated prosthesis and the rule of vibration in this process.

## AIM

Biomechanical options of using vibratory oscillation of rehabilitation devices for biological feedback. Main purpose of the study is investigation of oscillations in the parts of the bone anchored prosthesis and their influence on intramedullary implant and residual bone.

# **METHOD**

Ten proximal femurs were used. Intramedullar stem to anchor above knee prosthesis was implanted. All samples got cemented fixation. The system residual femur, intramedullar stem, above knee prosthesis were created. All samples were tested in load machine. 10, 20... 80 kg of vertical loading was provided. During the loading prosthesis got vibration stimulation with a help of a standard mini-shaker (type 4810). Stimulation range was from 5Hz to 500Hz (0.5Hz step). Feet and knee joint got vibration stimulation separately. Vibration measurement was performed by 3D laser vibrometer. Vibration was measured on multiple points: bone surface, uncovered stem surface, prosthetic surface.

#### **RESULTS**

Oscillation resonances were detected for all samples. Range of resonances was form 30Hz – 80Hz. The lowest frequencies were found for minimum loading. Increase of prosthesis loading increases frequency of resonance. Amplitude of oscillations show revert correlation. Maximum amplitude of oscillation corresponds to minimum load. Increase of loading decreases amplitude.

Vibrational stimulation of prosthetic foot reduces amplitude of oscillation and works as a shock absorber in comparison with stimulation of knee joint.

No other significant resonances were found on the level of 200Hz - 300Hz. Amplitude has not changed significantly by load increasing. The above mentioned frequencies correspond to sensitiveness of lamellar bodies.

# **DISCUSSION AND CONCLUSION**

Vibrational oscillations of the prosthesis are spread on residual femur surface. Oscillation amplitude is sufficient for inducting action potential of mechanical receptors. Natural frequency of above knee prosthesis is between 30 – 80 Hz. Range of frequency 200Hz – 300Hz does not have evident maximum of oscillations. This is an optimal range of sensitiveness of lamellar bodies. It may be used for artificial generated vibration for improving rehabilitation devices feedback.

# **ACKNOWLEDGEMENTS**

Founded by ERDF-1.1.1.1/16/A/147 "Research and Development of Electrical, Information and Material Technologies for Low Speed Rehabilitation Vehicles for Disabled People".



# 3.3.4.e

# Mobility Differences in Transfemoral Amputees with Osseointegration versus Traditional Prosthetic Sockets

Robert Gailey<sup>1,2</sup>, Anat Kristal<sup>3</sup>, Munjed Al Murderis<sup>4</sup>, Jennifer Lucarevic<sup>1</sup>, Sheila Clemens<sup>1</sup>, Brooks Applegate<sup>5</sup>, Brad Isaacson<sup>2</sup>, Ignacio Gaunaurd<sup>1,6</sup>

<sup>1</sup>University of Miami Miller School of Medicine, Department of Physical Therapy, Coral Gables, USA. <sup>2</sup>Uniformed Services University Department of Physical Medicine & Rehabilitation, Bethesda, MD, USA. <sup>3</sup>University of Miami Miller School of Medicine, Department of Physical Therapy, Coral Gables, FL, USA. <sup>4</sup>2The Australian School of Advanced Medicine, Macquarie University, North Ryde, Australia, Australia. <sup>5</sup>University of Western Michigan, Department of Educational Leadership, Research & Tech, Kalamazoo, MI, USA. <sup>6</sup>Miami Veterans Affairs Health Care System, Miami, FL, USA

# **BACKGROUND**

The Osseointegration (OI) limb reconstruction surgical procedure for people with lower limb amputations (LLA) has been performed in numerous countries. Presently, there are variations with the two-stage surgical procedure. Published outcomes for people who have had OI reconstruction report improvements within subjects when comparing pre to post-surgical mobility or quality of life.[1,2,3] To date no studies have compared prosthetic mobility in people with LLAs who use an osseointegration prosthesis (OIP) to a traditional socket prosthesis (TSP).

## AIM

The purpose of this study was to determine the differences in mobility of TTA and TFA fit with a osseointegration prosthesis versus a traditional socket prosthesis.

## **METHOD**

Subjects: Two groups of TFAs: one using an OIP (N=11; mean age ± SD, 44±14.9 years; mean Residual Limb (RL) length± SD, 68%±15.9); another group using a TSP (N=11; mean age ± SD, 49.6±16.0 years; mean residual limb length± SD, 81%±13.9) (p > 0.06). Table 1. Procedures: Subjects competed Prosthetic Limb Users Survey of Mobility™ (PLUS-M) short form, 12 questions. In addition, subjects performed 2 trials of the 10 meter walk test (10MWT), component Timed Up and Go (cTUG) test at self-selected and

Table 1. Descriptive characteristics of study sample						
	OIP (N=11)	TSP (N=11)	p-value			
Age (years)	44.7±14.9	49.6±16.0	0.48			
Time since amputation (month)	86.7±102.3	149.7±193.8	0.35			
Waist/height (ratio)	0.58±0.11	0.58±.07	0.93			
Residual limb length (%)	68.2±15.9	80.9±13.9	0.07			

osseointegration prosthesis (OIP), traditional socket prosthesis (TSP)

Table 2.Temporal-spatial gait parameters derived from 10-MWT

NEW XCC 1	OIP(N=11)	TSP(N=11)	p-value
Walk Time (sec)	7.56±1.56	6.52±1.44	0.12
Gait Speed (m/sec)	0.81±0.13	0.96±0.22	0.07
Prosthetic SLS2 (%) Sound SLS (%) Prosthetic DLS3 (%)	.31±0.18 .36±0.03 .17±.04	.31±0.44 .33±0.06 .18±.06	0.95 0.18 0.57
Sound DLS (%) DLS (%)	.16±.02 0.33±0.04	.19±.03 0.37±0.09	0.04 0.23

fast walking speeds. Data analysis: Paired t-tests was performed to compare differences in group performance.

# RESULTS

There were no significant differences between the two TFA groups in prosthetic mobility as measured by performance-based measures cTUG and 10-MWT. This dependent variable set was comprised of six separate measure of temporal-spatial gait derived from the 10-MWT, see Table 2. for descriptive statistics. A multiplicity adjusted p-value was set at .05/6 = .0083 for this family of outcomes. As can be seen from Table 2, none of the observed differences reached the multiplicity adjusted p-value of 0.0083 suggesting little to no differences exist between the OIP and TSP groups among the 10-MWT gait measures. Self-report measures PLUS-M (59.2±5.3) versus (53.5±7.2) and ABC (94.3±6.5) versus (85.5±12.3) OIP versus TSP respectively, were significantly different (p<0.05) between groups.

# **DISCUSSION AND CONCLUSION**

This study found that people with TFA who use OIP are able to demonstrate similar prosthetic mobility compared to TFA using a TSP and had improved perceived balance and mobility. Therefore, suggesting that OI reconstruction surgical procedure provides a successful solution for this group of people with TFA who cannot use a TSP. Further research with a larger sample and other measures of prosthetic mobility would further determine the similarities and differences between prosthetic options.

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# 3.3.4.f

# Implant Breakage in Patients with Osseointegration Prosthesis after Transfemoral Amputation

<u>Jamal Mohamed</u>, David Reetz, Jan-Paul Frölke Radboud University Medical Center, Nijmegen, Netherlands

# **BACKGROUND**

Sudden breakage of implant can result in falling and may cause injury to the patient. The incidence is low but it may be considered as serious complication. Surgical implant revision is required to remove the broken component and replace it. This study is designed to identify possible risk factors for implant breakage.

# **AIM**

The aim of this study is to identify possible risk factors associated with implant breakage after osseointegration prosthesis to prevent breakages in the future.

## **METHOD**

This retrospective cohort study includes all patients with transfemoral amputation who underwent implantation of osseointegration prosthesis and were followed up after one, two and five years. The data were analyzed by determining the following variables as possible risk factors: gender, age, body mass-index, degree of bone resorption (less than 10 mm, 11 to 20 mm and more than 21 mm), stem diameter of implant and infectious events. To determine degree of bone resorption, we used standard conventional radiographs of the femur taken directly after implantation as well as after every follow-up time.

# **RESULTS**

The total population included 142 participants of which 102 (71.8%) were male. Reasons for amputation: 55.6% trauma, 12% tumor, 9.9% vascular, 14.1% infection, 2.1% congenital and 6.3% other reasons. Mean age at implantation was 54.2 ± 13.8 years (range 19.9 - 85.9). The mean BMI of this group was 26.13  $\pm$  4.24 kg/m<sup>2</sup>. There were six (4.2%) patients with implant breakage. The mean BMI of these patients was 26.02 ± 3.74 kg/m<sup>2</sup>(range 19.41 -29.86) with a mean age of

# Variables in the Equation 8 S€ Wald of Sig.

							NOTING CLIDE EXD(B)	
	8	SE	Wald	df	Sig	Exp(B)	Lower	Upper
Gender	-5.230	5.129	1.040	1	.308	.005	.000	124.163
BMI	1.307	1.902	.472	1	.492	3.694	.089	153.478
Bone resorption 1-year follow-up	-10.533	11.414	.852	1	.356	.000	.000	138394.776
Bone resorption 2-years follow-up	5.303	9.529	.310	1	.578	200.923	.000	2.596E+10
Bone resorption 5-years follow-up			=	0*	- 3			
Infection 1-year follow-up			- 3	0*	- 4			
Infection 2-years follow- up				0.				
Infection 5-years follow- up	2.732	3.964	.475	.1	.491	15.368	.006	36405.918
Stem width implant			- 34	0*				
Age at implantation				0*				

a. Degree of freedom reduced because of constant or linearly dependent covariates

 $45.5 \pm 13.0$ -years (range 22.9 - 57.0). A Cox regression analysis showed no correlation between the risk factors and implant breakage, as none of the risk factors had a p-value below 0.05 (see table).

# **DISCUSSION AND CONCLUSION**

Breakage of the intramedullary component after osseointegration prosthesis for patients with transfemoral amputation occurred in 6/142 or 4,2%. We were unable to identify a possible correlation between the predetermined risk factors and the event. Long term survival of osseointegration implants is currently unknown due to the lack of large patient series with long follow-up. Implant development highly depends on these data. International registration of data therefore is mandatory.



# 3.3.4.g

# Revision Surgery after Failed Press-Fit Osseointegration Implants for Transfemoral Amputees

Jan Paul Frölke<sup>1</sup>, Ruud Leijendekkers<sup>2</sup>, Henk Van de Meent<sup>3</sup>

Radboudumc Dept of Surgery, Nijmegen, Netherlands. <sup>2</sup>Radboudumc Dept of Orthopaedics, Nijmegen, Netherlands.

<sup>3</sup>Radboudumc Dept of Rehabilitation, Nijmegen, Netherlands

# **BACKGROUND**

Press-fit osseointegration implants for patient with above knee amputation are now an established alternative for prosthetic attachment to the human body. Despite promising results, the transcutaneous attachment of an artificial leg might fail as a result of breakage or (a-) septic implant loosening.[1] There is a need for developing revision surgery in case of implant failure.

#### AIM

Our aim is to describe all cases that underwent revision surgery after failure of a press-fit osseointegration implant in our center and propose a protocol for successful revision surgery.

# **METHOD**

All consecutive patients who underwent implantation of a standard press-fit osseointegration implant were instructed to contact our center in case of implant failure. Patients with loosening or breakage of the implant were scheduled for surgical revision of the intramedullary component in three stages. In stage one the loosened or broken implant was removed from the medullary cavity. After an

Patients	Transfem. amputation	Cause failure	Time to failure (months)	Size (mm)	Interval (months)	Size revision (mm)	Follow-up (months)
Pt #1	Trauma	Breakage	49	14	10	18	35
Pt #2	Trauma	Breakage	57	16	11	21	27
Pt #3	Trauma	Breakage	69	14	8	18	16
Pt #4	Trauma	Breakage	84	15	7	19	13
Pt #5	Trauma	Septic loosening	68	15	33	16	1
Pt #6	Tumor radiation	Septic loosening	30	15	n/a	n/a	n/a
Pt #7	Trauma	Breakage	92	15	scheduled	n/a	n/a







interval for bone healing a new press-fit prosthesis with larger diameter was implanted. Stage three was done 6-8 weeks later with creation of the stoma and mounting of the transcutaneous adapter. Post-surgery rehabilitation protocol was similar to primary press-fit osseointegration treatment.

# **RESULTS**

From May 2009 to March 2019, 232 press-fit osseointegration prosthetic devices were implanted in lower limb amputees in our center. From 161 standard press-fit femoral implants, seven implants were removed because of breakage (n=5) or (a-) septic loosening (n=2) and five out of seven patients underwent replacement of a new implant.

# **DISCUSSION AND CONCLUSION**

From a total of 161 standard press-fit femoral osseointegration implants, 7 implants (6%) failed within the 10 years duration of the study. Most implant revisions were performed because of implant breakage. Implants revision was successful in 5 out of 7 cases. This study shows that implant failure occurs in standard press-fit osseointegration implants and revision is successful with our three stage surgical protocol. The aim is to prevent implant breakages with improved implant design and materials.

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# Free Paper Session Orthotics: Spinal

# 3.3.5.a

# The Clinical Effectiveness of 3D-Printed Brace vs Conventional Brace for Adolescent Idiopathic Scoliosis (AIS)

Yangmin Lin<sup>1</sup>, Chi Kwan Chan<sup>2</sup>, Jason Pui Yin Cheung<sup>3</sup>, Kenneth Man Chee Cheung<sup>3</sup>, Man Sang Wong<sup>1</sup>

The Hong Kong Polytechnic University, Kowloon, Hong Kong. <sup>2</sup>The Duchess of Kent Children's Hospital, HK Island, Hong Kong. <sup>3</sup>The University of Hong Kong, HK Island, Hong Kong

# **BACKGROUND**

Bracing is generally prescribed to manage moderate AIS (Cobb 25- 45°). With the continuous development of computer-aided design and manufacture, more versatile fabrication of spinal braces can be achieved, such as reduction in brace thickness and weight by application of 3D printing. This may improve the patient's wearing compliance and its subsequent treatment outcome. However, 3D printing in the brace for AIS is still at its embryonic stage and further investigations are needed to confirm its clinical value.

#### AIM

This study aimed to investigate the clinical effectiveness of 3D-printed brace comparing to the conventional brace for the patients with AIS.

## **METHOD**

A randomized controlled study of 30 subjects was conducted, who were selected according to the Scoliosis Research Society bracing criteria. Subjects were evenly assigned to the 3B group (3D-printed brace, with mean age 12.3 and Cobb 32.7°) or the CB group (conventional brace, with mean age 12.5 and Cobb 29.6°). The questionnaires of Scoliosis Research Society-22 (SRS-22), Trunk Appearance Perception Scale (TAPS) and Brace Questionnaire (BrQ) were used to assess the subjects' quality of life and temperature sensors were embedded into the braces for compliance measurement. The in-brace X-rays were used for correction analysis. Assessments were conducted at the baseline, 1<sup>st</sup> month and 3<sup>rd</sup> month of bracing.

# **RESULTS**

All the subjects completed 3 months of follow-up. Compared with the CB group, the 3B group was significantly lighter in weight (p<0.01) by 0.3kg. Effective in-brace correction was observed in both the 3B group (12.2°, 36.8%, p<0.01) and CB group (13.1°, 44.7%, p=0.01) at the 1<sup>st</sup> month follow-up. Comparable results were observed at the 3rd month follow-up between the 3B group (10.5°, 32.0%, p<0.01) and the CB group (8.3°, 27.6%, p<0.01). The results of school activity in BrQ was significantly better in the 3O group at the 1<sup>st</sup> month follow-up (88.0 vs. 77.6, p<0.05). Daily wearing hours was slightly longer in the 3O group (17.2 vs 16.9 hrs, p>0.05). However, no significant difference between two groups in all the aspects of SRS-22, nor TAPS was observed at the 1<sup>st</sup> month and 3<sup>rd</sup> month follow-ups.

# **DISCUSSION AND CONCLUSION**

The results of this study demonstrated that no significant differences in the patient's acceptance and quality of life were observed between the two groups, and the 3D-printed spinal braces (with lighter and thinner design) could provide similar in-brace correction as compared with the conventional spinal braces. Further studies with longer-term and more subjects are deserved for drawing conclusive findings.

# **ACKNOWLEDGEMENTS**

This research was partially supported by the ISPO Hong Kong Research Grant 2018.



# 3.3.5.b

# Whether Acupuncture can Facilitate Orthotic Intervention to Adolescent Idiopathic Scoliosis? A Preliminary Report

<u>Chengfei Gao</u><sup>1,2,3,4</sup>, Yu Zheng<sup>5</sup>, Chengqi He<sup>2,3</sup>, M.S. Wong<sup>1,3</sup>

Department of Biomedical Engineering, The Hong Kong Polytechnic University, Hong Kong, China. <sup>2</sup>Center of Rehabilitation Medicine, West China Hospital, Sichuan University, Chengdu, China. <sup>3</sup>Institute for Disaster Management and Reconstruction, Sichuan University-The Hong Kong Polytechnic University, Chengdu, China. <sup>4</sup>Department of Rehabilitation Medicine, The Affiliated Hospital of Qingdao University, Qingdao, China. <sup>5</sup>Department of Rehabilitation Medicine, The First Affiliated Hospital of Nanjing Medical University, Nanjing, China

## **BACKGROUND**

Orthotic intervention to adolescent idiopathic scoliosis (AIS) has been demonstrated to be effective in reduction of high-risk curves to the threshold for surgery. However, further enhancement of the treatment effectiveness may be possible when incorporated with other physical means such as acupuncture which has been used for centuries in Chinese medical practice to treat musculoskeletal disorders, and some studies suggested that acupuncture can slow down the progression of scoliosis.

# **AIM**

To investigate whether acupuncture combined with orthotic intervention is more effective than orthotic intervention only in preventing curve progression of AIS.

# **METHOD**

A prospective randomized controlled trial was carried out. Patients who fulfilled the Scoliosis Research Society (SRS) criteria for orthotic intervention were recruited and randomly assigned to the OA group (acupuncture combined with orthotic intervention) or the OI group (orthotic intervention only). All the patients were prescribed with rigid thoracolumbosacral orthosis (TLSO) and acupuncture intervention was performed for the patients in the OA group. Cobb angle, back muscle endurance (Biering-Sorensen test) and spinal flexibility (Fingertip-to-Floor Distance test) of the patients in both groups were measured at baseline and 6-month follow-up. Independent samples t-tests were performed to analyze the data between the two groups after 6-month intervention.

# **RESULTS**

Forty-four patients (21 in the OA group and 23 in the OI group) completed the study protocol with data available for evaluation. No statistically significant difference was found in the comparison of demographic data between the two groups. After 6 months intervention, patients in the OA group showed better Cobb angle correction than those in the OI group (4.1±5.3° vs. 2.1±4.7°, p=0.028). The tests of back muscle endurance and spinal flexibility showed deterioration in the OI group while improvements were found in the OI group. Between-group statistical significance was detected at the 6-month evaluation in back muscle endurance time (146.9±26.2s versus 115.8±21.7s, p<0.001) and fingertip-to-floor distance (24.5±4.4cm versus 31.2±5.0cm, p<0.001).

# **DISCUSSION AND CONCLUSION**

The preliminary data indicated that 6-month acupuncture intervention during bracing period could further increase the Cobb angle correction as compared with bracing only, which may be related to the improvement of back muscle endurance and spinal flexibility of patients with AIS. The current study provided promising results of applying acupuncture in the management of AIS, however, long-term study with larger sample size is needed to further confirm its clinical effectiveness.



# 3.3.5.c

# Assessment of Health-Related Quality of Life in Patients with Adolescent Idiopathic Scoliosis after Conservative Treatment

Badurun Nisa<sup>1</sup>, Faiza Aslam<sup>2</sup>, Rahman Rasool Akhtar<sup>3</sup>, Nadeem Gul<sup>4</sup>
<sup>1</sup>Kobe University Graduate School of Health Sciences, Kobe, Japan. <sup>2</sup>Institute of Psychiatry Benazir Bhutto Hospital, Rawalpindi, Pakistan. <sup>3</sup>Benazir Bhutto Hospital, Rawalpindi, Pakistan. <sup>4</sup>Fauji Foundation Hospital, Rawalpindi, Pakistan

## **BACKGROUND**

This study is an attempt to assess Health-Related Quality of Life (HRQoL) in patients with Adolescent Idiopathic Scoliosis (AIS). AIS is an excessive lateral curvature of the spine among individuals of 10 years or older.[1] There is often a lack of concern about the QoL of patients with disability. Results of this study may lead to a better understanding of factors associated with the HRQoL of a patient with AIS and explain the impact of treatment on the HRQoL.

The aim of the study is to improve the Health-Related Quality of Life (HRQoL) of patients with adolescent idiopathic Scoliosis (AIS).

## **METHOD**

It was a cross-sectional study on 30 patients with Adolescent idiopathic scoliosis by using the non-probability consecutive sampling technique. Patients with AIS using Thoracolumbar Spinal Orthosis for at least 2 months were included in the study. Patients suffering from Osteoid Osteoma of Spine and patients having any spinal surgery done before were excluded from the study. Data was collected by administering the SRS-22 questionnaire. SRS-22 is a reliable, reproducible and valid instrument for AIS patients.[2] Statistical Package for the Social Sciences SPSS version 21 was used to enter and analyze data. For all the categorical variables like age, gender, HRQoL frequencies and percentages were calculated.

#### **RESULTS**

The response rate was 97%. Mean age of the study participants was 15 years (SD  $\pm 3.2$  years). The mean total Scoliosis Research Society SRS-22 score was 2.8 (SD  $\pm 0.37$ ). The maximum and minimum score in each domain is 5 and 1 respectively. The higher score shows a greater patient quality of life.

Function	$2.76 \pm 0.52$
Pain	$2.64 \pm 0.66$
Self-image	$3.13 \pm 0.53$
Mental health	$2.96 \pm 0.52$
Satisfaction/dissatisfaction with management	$2.2 \pm 0.62$
Total	$2.8 \pm 0.37$

Table 1. Mean score for Scoliosis Research Society 22 (SRS-22r) Domains

# **DISCUSSION AND CONCLUSION**

The mean SRS-22 score indicates mediocre Health-related Quality of life. Mean SRS-22r Score was lowest for sub-domain of pain and satisfaction with the management. Domain for Psychosocial well-being was found to have the highest score. A previous study [3] has reported minimal pain and good psychosocial well-being. The Health-related Quality of life of patients with Adolescent idiopathic scoliosis is important to be dealt with in evidence-based health care.

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# 3.3.5.d

# Reliability and Validity Study of a Purpose-Designed Computational Method for Estimation of Plane of Maximum Curvature of Adolescent Idiopathic Scoliosis

Hui-dong Wu<sup>1,2,3</sup>, Cheng-qi He<sup>2,3</sup>, Man Sang Wong<sup>1</sup>

Department of Biomedical Engineering, The Hong Kong Polytechnic University, Hong Kong, China. <sup>2</sup>Department of Rehabilitation Medicine, West China Hospital, Sichuan University, Chengdu, China. <sup>3</sup>Institute for Disaster Management and Reconstruction, Sichuan University-Hong Kong Polytechnic University, Chengdu, China

# **BACKGROUND**

Adolescent idiopathic scoliosis (AIS) is a complex three-dimensional (3D) deformity with lateral curvature and axial rotation. Therefore, the Cobb angle measured from the postero-anterior radiograph could not reflect the actual 3D deformity. The plane of maximum curvature (PMC) was thereby proposed, which refers to a vertical plane that presents the maximum projected spinal curvature. Its parameters include PMC Cobb (the Cobb angle in PMC) and PMC orientation (the angle between PMC and the sagittal plane).

# **AIM**

This study aimed to develop a computational method (CM) for PMC estimation on the patients with AIS and to validate the CM using computed tomography (CT).

# **METHOD**

Twenty-nine patients with AIS and pre-operative CT images (27 females and 2 males; age: 17.8±4.8 years) were recruited. For the CM, the PMC was obtained via identifying the eight points on the superior-/inferior-endplate of upper-/lower-end-vertebra in the coronal and sagittal CT images. For the CT, the PMC was determined by rotating vertical plane along the vertical axis with 5° increment until the maximum Cobb angle was found. Two experienced raters repeated the PMC estimation three times independently with one-week interval for the two methods. Intra-class correlation coefficient (ICC), Pearson correlation coefficient (r) and Bland-Altman method were used for the statistical analyses.

# **RESULTS**

Twenty-seven right thoracic curves (RTs) (mean coronal Cobb: 46.1°±12.4° with ranging from 26.2° to 71.1°) and 23 left thoracolumbar/lumbar (LTLs/LLs) (mean coronal Cobb: 30.6°±11.1° with ranging from 16.4° to 54.2°) were studied. The intra- and inter-rater ICC values were greater than 0.91 and 0.84 in both RTs and LTLs/LLs, respectively, revealing very good intra- and inter-rater reliability of PMCs (PMC Cobb and orientation) obtained from the CM. Furthermore, the PMCs (PMC Cobb and orientation) obtained through the CM were strongly correlated with those obtained from the CT with correlation coefficient from 0.83 to 0.94. Good agreement was also observed between the PMCs (PMC Cobb and orientation) obtained from the two methods with ICC values being > 0.90 and mean difference within 4.7° for both RTs and LTLs/LLs.

# **DISCUSSION AND CONCLUSION**

In this study, the developed computational method provided promising results in estimation of PMCs for the subjects with AIS. Nonetheless, further research is deserved to enhance the computational method via a larger sample size to optimize the PMC estimation accuracy. In the long run, the enhanced computational method could have potential to be used as an alternative for the 3D assessment of AIS in routine clinical practice.



# 3.3.5.e

# Development of an Intelligent Spinal Orthosis for Adolescent Idiopathic Scoliosis (AIS)

<u>Chen He</u><sup>1</sup>, Hong-Liu Yu<sup>1</sup>, Man-Sang Wong<sup>2</sup>

<sup>1</sup>Institute of Rehabilitation Engineering and Technology, University of Shanghai for Science and Technology, Shanghai, China. <sup>2</sup>Department of Biomedical Engineering, Hong Kong, Hong Kong

# **BACKGROUND**

Spinal orthosis is a standard treatment for the patients with moderate adolescent idiopathic scoliosis (AIS). However, owing to inadequate strap tension application or change of body postures in daily activities, the current design of spinal orthosis may not allow the patients to maintain the prescribed tightness for appropriate biomechanical effect during the treatment period.

#### AIM

This study aims to develop and validate an intelligent spinal orthosis system with auto-adjusted tightness during daily activities.

## **METHOD**

This project developed a biomechanical model, an optimizing control method and a prototype. A spine-orthosis coupled model under application of pad pressure and strap tension was built. Fuzzy logic and neural network were applied to seek for an effective control method of the model. Then the prototype was assembled with appropriate type of motor, microprocessor, force transducer and controlled tension unit. For the prototype validation, a Scoliosis Analog Model was custom-made for the measurement of forces and moments corresponding to the applied pads and straps. A randomized controlled trial with 40 subjects (20 subjects with conventional orthoses and 20 subjects with intelligent orthoses) will be conducted to compare their clinical effectiveness.

## **RESULTS**

A pilot study on a subject with moderate AIS (12 years old, Cobb angle  $27.8^{\circ}$ ) showed the mean strap tension and pad pressure in 24 hours were  $47.7 \pm 16.2$  N and  $5.1 \pm 3.7$  KPa respectively and with moderate correlation (R=0.67, P<0.05). The pressure and tension transducers demonstrated good functionality and utility. Based on the data, a spine-orthosis coupled biomechanical model with an effective control method will be built in the next step. Further validation of the intelligent orthosis system will be conducted.

# **DISCUSSION AND CONCLUSION**

The preliminary results verified the feasibility of establishing biomechanical model based on the parameters of strap tension and pad pressure. Further development and validation of the intelligent spinal orthosis system is deserved.



# Free Paper Session Psychosocial Issues / Quality of Life - Amputation

# 3.3.6.a

# Young Adults with Transversal Upper Limb Reduction Deficiency: The Role of the Rehabilitation Center in Supporting Transition to Adulthood

Kim Huurneman<sup>1</sup>, Ilse Lankhorst<sup>1</sup>, Erwin Baars<sup>1</sup>, Iris van Wijk<sup>2</sup>, Corry van der Sluis<sup>3</sup>

Rehabilitation Center Vogellanden, Zwolle, Netherlands. <sup>2</sup>Department of Rehabilitation Medicine, Rehabilitation Center De Hoogstraat, Utrecht, Netherlands. <sup>3</sup>University of Groningen, University Medical Center Groningen, Department of Rehabilitation Medicine, Groningen, Netherlands

## **BACKGROUND**

Young adults with transversal upper limb reduction deficiency (tULRD) experience limitations regarding education, job selection and transportation during transition to adulthood.[1] To overcome these limitations, they could consult a rehabilitation center. However, the role of the rehabilitation center for these young adults during transition to adulthood is reported to be limited.[1] Therefore, the preferable role and accessibility of rehabilitation center should be evaluated to stay connected to the wishes and preferences of these young adults and parents.

# **AIM**

To evaluate 1) opinions of young adults with tULRD, parents and professionals regarding the role and accessibility of the rehabilitation center in addressing limitations during transition to adulthood; 2) their needs and suggestions to improve rehabilitation care.

# **METHOD**

A qualitative study using two online focus groups was performed among young adults with tULRD and parents during 4 consecutive days from 8am-11pm (asynchronous participation) on a secured website. Anonymity was guaranteed by using pseudonyms. Moderators posted questions about experiences with current rehabilitation care and the needs concerning transition domains; education-, job selection, getting a driver's licence. Health care professionals joined a videotaped group discussion, during a national workgroup meeting. A coding framework was designed to overview the collected data. The software program Atlas-Ti (version 8) was used for data analysis.[2] The consolidated criteria for reporting qualitative research (COREQ) were used to ensure transparent reporting.[3]

# RESULTS

16 young adults with tULRD (mean age 19.8 (SD 3.1) years, 5 males), 11 parents (4 males) and 17 health professionals participated. Young adults with tULRD and parents often sought solutions to overcome transition problems themselves. They mainly contacted the rehabilitation center for care regarding stump or prostheses. They were mostly unaware of care facilities regarding transition domains such as education, jobselection or transportation. Professionals indicated that transitional limitations were addressed during periodic appointments. However, young adults with tULRD do not often visit periodic appointments, due to unclear aims or limited benefit. Participants do have a need for reliable information or sharing experiences with peers. To improve rehabilitation care, participants suggested methods for providing relevant information and facilitate peer contact (online tools), dedicated training programs to practice work related tasks, job interviews or to increase self-confidence.

# **DISCUSSION AND CONCLUSION**

The role of the rehabilitation center is often unclear and periodic appointments do not adequately match the needs of young adults with tULRD and parents. There is a challenge to supply reliable information and support demand-driven appointments in order to stay connected and meet the needs. Developing an (online) tool with up-to-date information to overcome transitional limitations, links to dedicated websites, also covering experiences of peers, could be of value to improve rehabilitation care for these young adults.

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# **ACKNOWLEDGEMENTS**

Grant/ research support: ProReva, orthopaedic workshop, Educational budget Rehabilitation Centre Vogellanden, Foundation Beatrixoord Noord Nederland, De Hoogstraat Research foundation.



# 3.3.6.b

# Amputation and Body Image: Perspectives and Challenges for Rehabilitation Psychology

<u>Juliana Naves</u><sup>1,2</sup>, Tereza Araujo<sup>2</sup>

<sup>1</sup>Sarah Networh Rehabilitation Hospitals, Brasilia, Brazil. <sup>2</sup>Brasilia University, Brasilia, Brazil

## **BACKGROUND**

Factors such as the etiology, type of amputation, physical symptoms and psychological disorders, such as feeling of isolation, low self-esteem, anxiety and mood disorders, can influence the perception of the body image and quality of life. Research in the area of body image is associated, in most cases, with the presence of pathologies, with a strong association with eating disorders and few studies about body image in amputees.

## AIM

Understand the psychosocial aspects the experience of amputation, especially body image perception in lower limb amputees.

# **METHOD**

It is a cross-sectional study with patients treated at a Orthopedic Workshop, Brazil. The inclusion criteria in the sample were individuals with amputation of lower limb, aged 18 years or older, from 6 months of amputation, without distinction of gender. The indicators used were: a Portuguese version of the *Amputee Body Scale*, a Brazilian version of *Body Quality of Life* (BIQLI), *Trinity Amputation Scale and Prosthesis* Experience (TAPES), The Hospital Anxiety And Depression Scale (HADS) and sociodemographic data set.

# **RESULTS**

The sample consisted of 42 patients; most were male, aged 26 to 49 years, complete high school, single and had trauma amputation. The BIQLI and ABIS showed scores of 17.6 and 49.1 respectively, indicating a positive perception of body image. TAPES indicated a better general and social adjustment. Statistically significant differences were observed in the general adjustment score in relation to depression (p= 0.026). Functional satisfaction presented better evaluation in relation to aesthetic perception. The domains of the TAPES for general adjustment (p= 0.003), social (p= 0.006) and activity restriction (p= 0.005) showed a significant association with the body image assessment. In relation to the HADS scale, 11.9% presented anxiety symptoms and 7.1% depression.

# **DISCUSSION AND CONCLUSION**

Low level of anxiety and depression is observed in this study. Body image assessment by BIQLI and ABIS indicates a positive body perception. There was correlation between positive body image perception and general adjustment, social adjustment and limitation for activity. Depression appears to be a relevant variable, so it is inversely related to general adjustment and its absence was indicative of better functional satisfaction among patients amputated by trauma.



# 3.3.6.c

# Health-Related Quality of Life and functional Level Twelve Months Following Dysvascular Major Lower Limb Amputation: A Prospective Longitudinal Study

<u>Ulla Riis Madsen</u><sup>1</sup>, Carina Baath<sup>2</sup>, Connie Boettcher Berthelsen<sup>3</sup>, Ami Hommel<sup>4</sup>

<sup>1</sup>Holbaek Hospital, Holbaek, Denmark. <sup>2</sup>Karlstad University, Karlstad, Sweden. <sup>3</sup>Aarhus university, Aarhus, Denmark. <sup>4</sup>Lunds University, Lund, Sweden

## **BACKGROUND**

Little is known about quality of life and functional level after dysvascular major lower limb amputations (tibia, knee or femoral) and there are more challenges in studying health related quality of life (HRQoL) in this population. How to recruite is one. What to compare with is another.

#### ΔIM

To investigate changes over time and among age groups in HRQoL and functional level twelve months following dysvascular major lower limb amputation.

#### METHOD

A prospective cohort study design with assessments at baseline (one month pre-amputation) and follow-up three, six and twelve months post amputation. Data were collected via in-person interviews using Short Form 36 for HRQol, and Barthel Index 100 for functional level. Out of a consecutive sample of 103 patients having dysvascular major lower limb amputation, 38 patients completed the study. Outcome at follow-up was compared with baseline and analyzed in age groups.

# **RESULTS**

All aspects of HRQoL were below population norms one month pre-amputation. At twelve months, significant improvements was achieved in all aspects of HRQoL except physical function, which was not worse. Pain, general health and vitality had improved as soon as after three months. However, psycho-social problems persisted and fluctuated throughout the twelve months in all age groups. Large differences were identified between age groups in functional level with the loss of physical function almost solely evident among the oldest patients (aged 75+).

# **DISCUSSION AND CONCLUSION**

These unique prospective longitudinal data shows that patients who survive twelve months post-amputation gain significant improvements in HRQOL compared with one month pre-amputation. However, patients having dysvascular-amputations constitute a heterogeneous group with widely different functional levels and psychosocial needs and have a range of complex needs of care not always met by healthcare provided. Quality improvements are required in several areas of healthcare to optimize quality of life and functional level, especially among the oldest.

# **REFERENCES**

Data presented has been published in: Madsen UR et.al. Disabil Rehabil, 2018, Epub ahead of print.



# 3.3.6.d

# Comparison of Quality of Life in People with Partial Foot and Transtibial Amputation

Michael Dillon<sup>1</sup>, Matthew Quigley<sup>1</sup>, Sarah Anderson<sup>1</sup>, Phil Stevens<sup>2</sup>
<sup>1</sup>La Trobe University, Melbourne, Australia. <sup>2</sup>Hanger Clinic, Salt Lake City, Utah, USA

#### **BACKGROUND**

Quality of life (QoL) appears to be comparable in cohorts with partial foot (PFA) or transtibial amputation (TTA).[1] Factors that most influenced QoL include: older age, time living with diabetes, and the presence of comorbid conditions such as retinopathy. Research in a larger sample is required to be confident that amputation at either the PFA or TTA does not influence QoL, and to identify factors that most influence QoL.

## AIM

To determine if amputation at the PFA or TTA level explained a significant part of the variance in QoL, and identify which demographic and health factors significantly influence QoL.

# **METHOD**

Community dwelling adults over 18 years of age with unilateral PFA or TTA completed a SurveyMonkey questionnaire including a modified demographic section of the Trinity Amputation and Prosthesis Experience Scales-Revised (TAPES-R), Medical Outcome Short form (SF-36v2) and the Patient Reported Outcomes Measurement Information System 29 (PROMIS-29). Multivariate linear regression models were developed in IBM SPSS Statistics 22 to explain which demographic, amputation and health factors explained significant variance in the SF-36v2 Physical (PCS) and Mental Component Summary (MCS) scores.

#### **RESULTS**

Complete data were available for 125 persons: 68% male, mean age 55 (22-83 years), 34% amputation due to trauma or cancer, 18% retinopathy, 30% neuropathy, 15% nephropathy, 65% TTA. The regression model explained a large proportion of the variance in the PCS (73%,  $R^2$  = 0.736) and MCS (64%,  $R^2$  = 0.646) scores which was statistically significant ( $F_{15,41}$  p<0.001). Amputation level explained a small proportion of the PCS (3%,  $R^2$  = 0.034) and MCS (<1%,  $R^2$  = 0.004) scores which was not statistically significant (p>0.05). Factors that significantly influenced the PCS or MCS scores included: time since amputation as well as the PROMIS Physical Function, anxiety and depression scores. When stratified by amputation level, time living with diabetes and the presence of nephropathy also influenced the PCS scores in the PFA cohort.

# **DISCUSSION AND CONCLUSION**

Consistent with previous research,[1] this study found that amputation at either the PFA or TTA level was not a significance influence on QoL. As such, QoL after amputation need not be a factor influencing the choice of PFA or TTA. There are opportunities for clinicians to improve QoL in people living PFA or TTA by focusing attention on the modifiable factors of: depression, anxiety and physical function.

# **REFERENCES**

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# 3.3.6.e

# The Views and Experiences of how Peoples' Quality of Life has been Influenced after Lower Extremity Amputation (LEA)

<u>Fiona Davie-Smith</u><sup>1</sup>, Lorna Paul<sup>2</sup>, Brian Kennon<sup>1</sup>, Sally Wyke<sup>3</sup>, Wesley Stuart<sup>1</sup>

NHS GG&C, Glasgow, United Kingdom. <sup>2</sup>Glasgow Caledonian University, Glasgow, United Kingdom. <sup>3</sup>University of Glasgow, Glasgow, United Kingdom

# **BACKGROUND**

Results from previous studies, demonstrate that being fitted with a prosthesis after LEA is important for functional tasks and to enable a return to usual activities. Although the prosthesis may enhance QoL, no studies have examined the participants' views and experiences of living with a LEA due to Peripheral Arterial Disease. Furthermore, no studies have investigated what other factors may impact QoL.

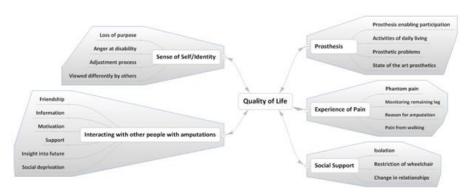
# **AIM**

To investigate the views and experiences of people within the first 12 months of a lower extremity amputation (LEA) and explore the factors influencing their Quality of Life (QoL), through semi structured interviews.

# **METHOD**

A cohort study examining QoL after LEA identified 101 participants who had completed the EQ-5D-5L. Maximum variation sampling selected participants using their QoL scores: Good (0.51 to 1.0); Moderate (0 to 0.49), and Poor (<0). Five participants from each category were interviewed (n=15). Interviews were conducted in participants own homes and recorded digitally with field notes. One Sheet of Paper (OSOP) analysis was

performed and broad themes were identified all of which were guided by questions relating to QoL. Further analysis identified sub themes and these were compared and contrasted with level of LEA. Ethical approval was obtained from the West of Scotland Research Ethics Committee (14/WS/0016) in October 2014.



# **RESULTS**

Five broad themes were identified

as influencing quality of life after LEA (Figure 1). Despite many of the participants having a prosthetic limb, they all talked of the discomfort and difficulty in wearing it for specific tasks, this was more prevalent in those with a Trans-femoral amputation. Social isolation was commonly raised; despite many being surrounded by family they felt isolated due to their change in sense of self and the inability to do the things they wanted to without assistance. Talking to others in the same situation became more difficult to achieve when they were discharged from out patient physiotherapy and became more physically isolated.

# **DISCUSSION AND CONCLUSION**

All participants spoke of the drastic change the LEA had on themselves and their family as many were still struggling to come to terms with their LEA even 6 months afterwards. Many spoke of the physical difficulties encountered despite having a prosthetic limb. The trans-femoral prosthetic limb was highlighted as difficult to use both physically and cognitively. Clinical services need to be designed to consider these factors in order to improve the QoL after an LEA due to PAOD.

# **REFERENCES**

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# **ACKNOWLEDGEMENTS**

Diabetes UK and all of the participants who gave their time to share their experiences of LEA.



# 3.3.6.f

# Rehabilitation Engagement and Cognitive Functioning in People with Lower Limb Amputation.

Richard Lombard-Vance<sup>1</sup>, Deirdre Desmond<sup>2</sup>, Fiadhnait O'Keeffe<sup>3</sup>, Nicola Ryall<sup>4</sup>, <u>Pamela Gallagher</u><sup>1</sup>
<sup>1</sup>Dublin City University, Dublin, Ireland. <sup>2</sup>Maynooth University, Maynooth, Ireland. <sup>3</sup>St Vincent's University Hospital, Dublin, Ireland. <sup>4</sup>National Rehabilitation Hospital, Dublin, Ireland

# **BACKGROUND**

Engagement in the rehabilitation process has been linked to more favourable physical and psychosocial outcomes. However, little is known about the factors associated with rehabilitation engagement and it has yet to be examined in people with lower limb amputation. Evidenced high incidence of impaired cognitive functioning in lower limb amputation may negatively impact on rehabilitation engagement but has yet to be investigated.

#### AIM

This paper examines the relationships between sociodemographic and clinical factors, cognitive functions and rehabilitation engagement.

## **METHOD**

As part of a quantitative, prospective cohort study, 87 adult participants with lower limb amputation were recruited during a lower limb amputation rehabilitation programme at a national rehabilitation hospital. Cognitive functioning was assessed with a battery of neuropsychological assessments during rehabilitation. Clinician-rated rehabilitation engagement was obtained at discharge with the Hopkins Rehabilitation Engagement Rating Scale.

## **RESULTS**

Higher rehabilitation engagement was significantly related to younger age, longer formal education, and fewer comorbidities. Higher rehabilitation engagement was significantly correlated with higher overall cognitive functioning, combined processing speed and attention, delayed memory, and visuospatial construction, but not significantly correlated with either measure of executive functioning (cognitive flexibility or planning).

# **DISCUSSION AND CONCLUSION**

Better cognitive functioning in people with lower limb amputation is associated with better rehabilitation engagement. Understanding relationships between cognitive functioning and rehabilitation engagement, both of which are potentially modifiable, presents opportunities for improvement of engagement and, by extension, outcomes.



# 3.3.6.g

# Factors Predicting Resilience among Persons with Limb Loss

Benjamin Darter<sup>1,2</sup>, Amy Armstrong<sup>1</sup>, Carolyn Hawley<sup>1</sup>

<sup>1</sup>Virginia Commonwealth University, Richmond, USA. <sup>2</sup>Hunter Holmes McGuire Veteran Affairs Medical Center, Richmond, USA

# **BACKGROUND**

Injuries such as limb loss have a significant impact on a person's experiences. One's resilience interplays with these experiences and contributes to well-being and quality of life.[1] Though most people are resilient,[2] factors such as employment are related to higher resilience after traumatic injury.[1] However, specific factors impacting resilience after limb loss are less understood and may differ from other populations.

#### ΔΙΜ

Determine factors and individual characteristics predicting resilience in persons with limb loss.

#### **METHOD**

A survey was made available in hard copy and web-based form to 870 individuals with traumatic limb loss identified through a national health system database. The survey was composed of the 10-item Connor-Davidson Resilience Scale (CD-RISC) [3] as well as items on participant demographics and other characteristics (including, items related to pain, prosthetic use, impact of amputation on quality of life, community activities and ability to work). Unadjusted and adjusted models predicting resilience (total CD-RISC score) were developed using a linear regression. Backward elimination in stepwise regression was used for the adjusted model. All tests were performed at the 0.05 level with the backward elimination threshold set at p=0.15.

Characteristic	Comparison	Diff(SE)	p-value
Employment	Employed-Unemployed	2.19(1.23)	0.07
	Employed-Retired	3.04(1.37)	0.02
	Unemployed-Retired	0.85 (1.39)	0.54
Residual limb pain	Great-Moderate	-2.45 (1.27)	0.05
	Great-Slight	0.33(1.66)	0.84
	Moderate-Slight	2.77(1.58)	0.08
Other pain	Great-Moderate	2.21(1.36)	0.10
	Great-Slight	-2.03(1.62)	0.21
	Moderate-Slight	-4.24(1.56)	0.00
Difficulty social/ community activity	Great-Moderate	-4.79(1.63)	0.00
	Great-Slight	-7.63(1.64)	<0.00
	Moderate-Slight	-2.84(1.35)	0.03
Overall situation	Average-Good	1.53(1.31)	0.24
	Average-Poor	3.53(1.50)	0.02
	Good-Poor	5.06(1.64)	0.00

Table 1. Adjusted models predicting resilience (CD-RISC)

# **RESULTS**

165 responded to the survey (23% response rate). The mean for CD-RISC was 28.2. Several factors were found to predict resilience (Table 1). Specific to employment, individuals who disliked their employment had lower resilience (p=0.02), as did those who thought their employment did not use their skills, strengths and training (p=0.051).

# **DISCUSSION AND CONCLUSION**

Resilience scores were similar to other populations after traumatic injury (20-31 is normal after traumatic injury [4]). Resilience was higher among those with less pain, employment, higher social/community, and better overall situation as a person with limb loss. While causality should not be inferred, supporting employment opportunities, including ones aligned with a person's skills, strengths, and training has the potential to improve overall resilience, well-being and quality of life.

# **REFERENCES**

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# **ACKNOWLEDGEMENTS**

Funding: RRTC grant no. CDF 84.133b-4 from NIDILRR, and CTSA No. KL2TR000057 from the National Center for Advancing Translational Sciences.



# Free Paper Session Rehabilitation Medicine & Surgery - General

# 3.3.7.a

# Role of Mirror Image Therapy for Phantom Limb Pain in Below Knee Amputees

# Poonii Gupta

Teerthanker Mahavir University, Moradabad, India

#### **BACKGROUND**

The pain caused by surgery is usually of transient nature, however perception of pain in amputated limb persists. This prolonged pain, which is often refractory to painkillers, nerve block and surgical treatment may severely affect the patient's quality of life. Phenomenon of phantom limb pain has been investigated using neurological, neurophysiological and psychopathological approaches. However exact cause of phantom limb pain is still mystery. We analysed role of mirror therapy for treatment of phantom limb pain in below knee amputation.

#### AIM

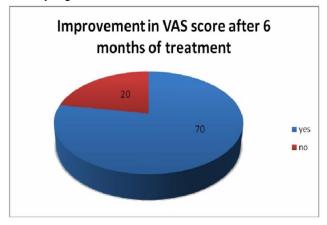
To evaluate the role of mirror therapy in treating phantom limb pain in below knee amputees.

## **METHOD**

96 patients who had phantom limb pain after below knee amputation were included in this study. They had to visit the hospital four times a week for a 15-minute treatment period. In this technique they performed movement of unaffected limb while watching its mirror reflection and thus creating a visual illusion of movement of affected limb. The degree of pain relief was measured on visual analog scale (VAS).

# **RESULTS**

70 patients out of 96 reported an improvement of 4 or more degrees of VAS score after 6 months of the treatment. The result was statistically significant.



Outcome of mirror image therapy in amputees

# **DISCUSSION AND CONCLUSION**

Mirror therapy improves pain sensation of amputated part when other treatment modalities fail. This therapy works on the principle of mirror neuron system. A mirror neuron fires either when a person acts or when a person observes same action performed by another. The mirror image of the normal body part helps reorganize and integrate the mismatch between proprioception and visual feedback of the removed body. This reorganization decreases the sense or emotion of phantom limb pain in the amputated part.

# **REFERENCES**

[1] Kim SY, Kim YY. Korean J Pain. 2012; 25(4):272-4.



# 3.3.7.b

# Influence of Type of Stump Closure on Rehabilitation after Lower Limb Amputation due to Malignancies

#### Poonii Gupta

Teerthanker Mahavir University, Moradabad, Hungary

#### **BACKGROUND**

Lower limb amputation is required in patients with lower limb malignancies in whom no other treatment option is available. Till date there is no consensus as to which surgical closure achieves the maximum rehabilitation potential. We assessed the effects of different types of stump closure on the outcome of lower limb amputation in people with lower limb malignancies. The main focus was to assess the relative merits of skew flap amputation versus Burgess flap (long posterior flap) closure.

# AIM

To compare the rehabilitative outcome of skew flap versus Burgess flap closure in below knee amputation.

# **METHOD**

This was a ten years retrospective and 2 years prospective study. A total of 144 patients were include of which 76 (53%) patients had Burgess closure while 59 (41%) had skew flap closure. 9 patients underwent atypical closure or skin grafting. These groups were compared on the basis of stump healing time, rate of infection, time for prosthetic fitting and compliance with prosthesis with either of the flaps made.

#### **RESULTS**

76% stumps after Burgess closure and 71.4% after Skew flap closure healed well in time which was insignificant (p>0.05). Primary stump healing was 58% for skew flaps and 55% for burgess flap. The result was not significant. Of the total 144 patients, 72.2% had prosthetic fitting. 60% of them underwent prosthetic fitting within 3 months in both the groups after closure. 66.8% of Burgess flap closure patients and 71% of Skew flap closure were happy with their prosthesis which was not significant.

# **DISCUSSION AND CONCLUSION**

Stump healing time, rate of infection, time of prosthetic fitting and prosthetic compliance was similar in both the groups. We thus conclude that there is no benefit of one type of closure over another. The choice of closure can, therefore, be a matter of surgeon preference taking into account factors such as previous experience of a particular technique, the extent of non-viable tissue, and the location of pre-existing surgical scars.

# **REFERENCES**

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# 3.3.7.c

# Assessing the Impact of Prosthetic Socket Fit on Major Lower Limb Amputee Rehabilitation

Shruti Turner, Alison H. McGregor Imperial College London, London, United Kingdom

## **BACKGROUND**

Prosthetic sockets are the point of load transfer from body to prosthesis and are complex interfaces,[1, 2] important for successful rehabilitation and ambulation. Despite extensive literature on medical impacts of ill-fitting sockets,[1, 3, 4] literature is limited on priorities of users and rehabilitation teams regarding fit. Understanding user needs and priorities is important to address these issues.

## AIM

To determine the impact of socket fit on lower limb prosthetic rehabilitation, and how to define "good fit". Secondly, to understand the requirements of a socket fit biofeedback tool.

# **METHOD**

An anonymous survey was developed to identify rehabilitation impactors and frustrations for prothesis wearers and rehabilitation clinicians. Recruitment was through emailing personal contacts, relevant charities and social media. Participants could provide contact details to participate in a telephone interview to gather details behind answers given in the survey and feedback on a new biofeedback technology, which identifies causes and prevents the consequences of ill-fitting sockets. The interview transcriptions were analysed using a framework based on literature of prior knowledge to obtain information to address the research question.

# **RESULTS**

44 clinicians and 50 amputees completed the survey. 75.00% of clinicians and 50.00% of amputees identified socket fit and consequences of ill-fitting sockets, including sores and pain, as the biggest impactor on rehabilitation. The main frustration for 34.09% of clinicians and 40.00% amputee responses was socket fit. "The socket is the only one [prosthetic component] that gives an absolute 'no I can't use the prosthesis." [Prosthetist]

51.11% clinician and 39.44% amputee responses agreed fit was the biggest frustration with the socket itself. "Socket fit is something that's really important, but, of course, not as glamourous, and therefore gets forgotten." [Amputee]

18/18 interviewees recognised the value of the biofeedback technology and agreed it would be most useful for prosthetists during socket fitting.

# **DISCUSSION AND CONCLUSION**

Amputees and clinicians agree socket fit is the biggest frustration with and impactor on rehabilitation. The new biofeedback technology complements clinicians' expertise and does not provide a "solution" to ill-fitting sockets like other available technologies, whose benefit is difficult to measure as socket fit is not defined. The study is a preliminary step to understanding and addressing the impact of socket fit on rehabilitation.

# **REFERENCES**

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# **ACKNOWLEDGEMENTS**

The authors thank The Royal British Legion for their funding.



# 3.3.7.d

# Use it, then lose it. Rehabilitation of Staged Amputations in a Quadrilateral Amputee with Symmetrical Peripheral Gangrene

# Matthew Fuller

Physiotherapy Department, Guys and St Thomas NHS Foundation Trust, London, United Kingdom

## **BACKGROUND**

Peripheral Symmetrical Gangrene is a rare and devastating sequelae of sepsis which can lead to multiple limb loss.[1] There is sparse literature regarding rehabilitation in this cohort. We present the rehabilitation story and outcome of a patient who presented with extensive limb necrosis requiring quadrilateral amputations. The patient waited 94 days for lower limb amputation to allow maximal demarcation and salvage below knee levels (BKA), here we describe the use of his necrotic lower limbs as rehab aids.

# AIM

Promote the novel use of ischeamic/necrotic lower limbs as a therapeutic adjunct, allowing functional rehabilitation, improved physical outcome measures, protect against deconditioning and demonstrate no harm is caused.

#### **METHOD**

Informed consent gained from patient. The patient was admitted via A&E with intractable vomiting, intubated due to worsening agitation in context of hypoxia, transferred to ICU and diagnosed with Pneumococcal septicemia complicated by multiorgan failure and infarction. Although medical condition was stabilised with supportive measures he suffered extensive damage to his peripheries. Upper limbs amputated 33 days after admission due

to wet gangrene. Lower limbs showed extensive damage but as dry, decision was made to manage his condition expectantly. Rehab on ICU and HDU commenced but limited to bed-based exercise. Stepped down to ward and following multidisciplinary discussions weightbearing exercises commenced. Bilateral BKA were performed 94 days after admission.



# **RESULTS**

CPAX[2] measures were taken on ICU, this critical care scoring system measures physical morbidity across 10 areas, each with a 5 point score. Higher scores indicate greater physical abilities. The patient made good progress with scores increasing weekly, Fig.1. Core strength was good but function and progression limited by non-weightbearing. Discussion with the patient and MDT lead to commencement of progressive weightbearing exercises in the gym, transfers, dynamic/static balance in standing and stepping with reducing assistance. After 2 weeks the patient was able to perform 22 Sit to Stands in 30 secs and one week later 23 from a 19" plinth, CPAX at this point was 41 with ceiling of 45 due to inability to measure grip strength. Rehab continued until definitive surgery.

# **DISCUSSION AND CONCLUSION**

The patient made good functional progress with rehabilitation using his necrotic lower extremities as adjuncts to physiotheraputic input. The patient was able to improve range of movement and strength around his hips and knees in preparation for prosthetic rehabilitation. The potential ramifications of prolonged non weightbearing; extensive deconditioning, increased infection risk and possibility of contracture have been avoided. The patient was positively engaged and no major adverse incidents were caused by this rehabilitation program.

# REFERENCES

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# **ACKNOWLEDGEMENTS**

All GSTT Vascular unit staff for their support in the rehabilitation of this gentleman, a truly MDT piece of work.



# 3.3.7.e

# Effectiveness of Mirror Therapy in Phantom Limb Pain of Vascular Amputees

Marlène Lacout 1,2,3, François Genêt2

<sup>1</sup>Insitut Robert Merle d'Aubigné, Valenton, France. <sup>2</sup>Hopital Raymond Poincaré, Garches, France. <sup>3</sup>Hopital Rothschild, Paris, France

## **BACKGROUND**

Given the predictable increase in the prevalence of amputees due to a vascular pathology and the negative impact of phantom pain, it is important to identify effective and less iatrogenic treatments for these frail patients. Mirror therapy is a non-invasive rehabilitation technique whose effectiveness has been widely suggested in small and heterogeneous populations.

#### $\Delta IM$

The aim of the study was to evaluate the effectiveness of mirror therapy on phantom pain of lower limb amputee patients due to a vascular pathology.

# **METHOD**

We conducted the MIR-PHAN randomized controlled trial, a monocentric study, carried out in a fitting rehabilitation center. The primary endpoint for the efficacy of mirror therapy was the intensity of average phantom pain over the past 3 days as assessed by the EVA.

The secondary endpoints were:

- the frequency of episodes of phantom pain;
- the duration of painful episodes;
- the consumption of analgesic pharmacological treatment :
- the SF-12 quality of life score and the mental score and social quality of life SF-12
- Spiegel's sleep disorder score
- possible side effects.

We expected at least 40 patients for statistical analysis.

# **RESULTS**

At intermediate evaluation: 35 patients were included and 30 were randomized: 16 patients in group 1 without mirror therapy and 14 in group 2 with mirror therapy. Both group received Gabapentin, the reference treatment, and usual physical therapy. Of the 35 patients included, almost 26% left the study for medical reasons, not related to the intervention. There is a significant decrease of the intensity of phantom pain after 8 weeks in group 1 (- 28/100 EVA) and group 2 (-40/100 EVA), with no significant difference between the two groups. In group 2, there is a significant decrease of the use of analgesic drug treatment at 8 weeks versus an increase in group 1. There is a significant difference in the evolution of drug analgesic dosage between group 1 and group 2.

# **DISCUSSION AND CONCLUSION**

Mirror therapy combined with a suitable analgesic drug treatment seems to be more effective than analgesic drug alone in the management of phantom pain because the combination of the two treatments allows a dose reduction of the drug treatment. It appears that only a part of this population can use mirror therapy, because of the difficulty of applying this treatment to vascular patients with important comorbidities.

# **REFERENCES**

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# 3.3.7.f

# An Exploration of Specialist Clinicians' Experiences and Beliefs about Inpatient Amputee Rehabilitation as a Pathway Option for Adult Primary Amputees

# J Spyrou

University of Hertfordshire, Hertfordshire, United Kingdom. Guys and St Thomas' NHS Foundation Trust, London, United Kingdom

## **BACKGROUND**

Access to specialist amputee rehabilitation varies throughout the UK, with healthcare inequality evident in this specialist field. NHS England recognises this, launching a review of prosthetic services with the aim of improving and ensuring 'equitable access to high quality care (NHS England, 2018) for amputees. Evidence suggests specialist inpatient amputee rehabilitation units provide accelerated and improved patient outcomes however these are rare in the UK, with the standard model of care delivered via an outpatient pathway.

#### AIM

To explore specialist amputee clinicians' experiences and views about specialist inpatient rehabilitation as a pathway option for adult primary amputees in the UK.

To explore specialist amputee clinicians' perceptions and beliefs about the effects of specialist inpatient amputee rehabilitation.

## **METHOD**

A phenomenological qualitative research study using semi structured interviews. Participants were recruited from specialist amputee networks, and had experience in both specialist inpatient rehabilitation and the outpatient pathway. To ensure data saturation the sample was limited to physiotherapists. 8 interviews were conducted; until data saturation reached. A reflexive diary and audit trail were completed to ensure transparency throughout the research process and demonstrate truthfulness. Member checking of data was completed as a measure of conformability. Interviews were transcribed and inductive codes applied. Inductive Thematic Analysis was used to analyse and interpret data.

# **RESULTS**

Pending, although initial results indicate:

- amputee rehabilitation has an 'out of date' hierarchical approach to service delivery;
- inpatient rehabilitation viewed as the optimal pathway with increased intensity, rapid achievement of goals, and accelerated prosthetic function;
- peer support and comradery enhanced within the inpatient setting with psychological benefits to patient group; inpatient approach suitable for the majority of amputees including the sub groups; borderline trans femoral (for intensive prosthetic assessment), multi-limb loss, upper limb, prosthetic and non-prosthetic candidates;
- enhanced and more efficient working of MDT;
- rapid accessibility to medical care in the sub-acute phase:
- NHS financial constraints is seen as the rationale for minimal access to specialist inpatient rehabilitation in the UK:
- clinical experience correlates to the evidence base in this field; rapid functional and psychological outcomes via an inpatient rehabilitation pathway.

# **DISCUSSION AND CONCLUSION**

Further research is required to include a wider population and to be able to generalise findings nationally. Initial results indicate clinician experiences support the evidence base and feel specialist inpatient rehabilitation should be a more accessible amputee rehabilitation pathway in the UK for primary amputees.

# **ACKNOWLEDGEMENTS**

Dr Catherine Minns-Lowe, University of Hertfordshire, UK; Guys and St Thomas NHS Foundation Trust, UK.



# 3.3.7.g

# In-Home Use of Phantom Motor Execution for the treatment Phantom Limb Pain

Eva Lendaro<sup>1</sup>, Shannon Brown<sup>1</sup>, Alexandra Middleton<sup>2</sup>, <u>Max Ortiz Catalan</u><sup>1</sup>
<sup>1</sup>Chalmers University of Technology, Gothenburg, Sweden. <sup>2</sup>Princeton University, Princeton, USA

## **BACKGROUND**

Phantom Limb Pain (PLP) has been hypothesized as arising from the stochastic entanglement of the pain neurosignature with impaired sensorimotor circuitry.[1] Coherently with the implications of this hypothesis, a myoelectric pattern recognition device has been developed to promote Phantom Motor Execution. Preliminary evidence has been sought through a clinical trials.[2, 3]

## AIM

Here we investigate the use of Phantom Motor Execution as a self-treatment strategy for PLP, aiming to explore the benefits and the translational challenges encountered in the transition from clinic to self-administered home use.

# **METHOD**

Here, we present a series of case studies on the use of Phantom Motor Execution as a self-treatment strategy for PLP. Four limb loss patients (2 upper and 2 lower limb) initially experiencing phantom limb pain participated in this study. All patients were provided with and trained to use a myoelectric pattern recognition and AR/VR device. Patients then took these devices home and used them independently over the course of 12 months. Additionally, a user researcher conducted surveys about the use preferences of the rehabilitation device while an antropologist conducted in depth interviews with the patients in their homes.

# **RESULTS**

We show that home therapy yields efficacious results in pain reduction comparable to findings observed in the clinic, with the advantages of independent use outside of the hospital, as patients adapt the therapy according to their individual preferences and lifestyles.

# **DISCUSSION AND CONCLUSION**

In this study we develop a more holistic understanding of how patients use the device at home and motivate themselves to do the therapy regime. We identify type of users and patterns of usage of the device. From this design recommendations can be drawn for future development of at home-based therapy systems.

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# **ACKNOWLEDGEMENTS**

This work was funded by the Stiftelsen Promobilia, VINNOVA, and European Pain Federation—Grünenthal—Research Grant (E-G-G).



# Free Paper Session Developing Countries

# 3.3.8.a

# Implementation of a Research Protocol to Investigate Quality of Life, Functional Outcomes, and Cost-Effectiveness of Above Knee Prostheses in Tanzania

Alexander Hetherington<sup>1</sup>, Leah Mamseri<sup>2</sup>, Geofrey Mwakasungula<sup>2</sup>, Sravya Challa<sup>1</sup>, Patrick Albright<sup>1</sup>, Syed Ali<sup>1</sup>, Jan Andrysek<sup>3</sup> Billy Haonga<sup>2</sup> Saam Morshed<sup>1</sup> David Shearer<sup>1</sup>

Jan Andrysek<sup>3</sup>, Billy Haonga<sup>2</sup>, Saam Morshed<sup>1</sup>, David Shearer<sup>1</sup>

Department of Orthopaedic Surgery, University of California San Francisco, San Francisco, USA. <sup>2</sup>Muhimbili Orthopaedic Institute, Muhimbili University of Health and Allied Sciences, Dar Es Salaam, United Republic of Tanzania. <sup>3</sup>Holland Bloorview Kids Rehabilitation Hospital, University of Toronto, Toronto, Canada

## **BACKGROUND**

In 2017, the World Health Organization (WHO) released global standards and implementation recommendations to improve orthotic and prosthetic (O&P) services. The WHO suggests that appropriate technology meet user-related, economic, and technical criteria. These standards also recommend that O&P research be conducted at national centers of excellence and academic institutions, engage local personnel, and investigate the effects, costs, and economic impact of assistive technology.

#### **AIM**

This study aims to establish an above knee prosthesis and research protocol in order to measure the impact on quality of life, functional outcomes, and cost-effectiveness of these devices in a low-resource setting.

#### METHOD

This study includes patients older than 18 years of age presenting to Muhimbili Orthopaedic Institute (MOI) who suffered unilateral transfemoral amputation over six months from enrollment date and had no prior experience with prosthetic use. Data collected include EQ-5D, PLUS-M, two minute walk test, physiological cost index, video gait analysis, as well as direct and indirect costs associated with provision of the study prosthesis at 1 month, 6 month, and 1 year follow-up visits. Local well-trained orthopedic technologists and research coordinators conduct all recruitment and data collection.

## **RESULTS**

The study prosthesis utilizes Ottobock socket lamination materials, the LegWorks All-Terrain Knee, stainless steel alignable components and SACH foot from Ortpar Orthopedi, as well as plaster of paris, cosmetic cover textiles, and other fabrication materials from local Tanzanian suppliers. The total cost of the above knee prosthesis is approximately 500 USD. To date, 61 patients have been enrolled, 40 have been fit with the study prosthesis, and baseline metrics have been recorded for all participants. On average, participants were fit with their first prosthesis 496 days from the date of their injury or amputation. Of the participants fit with the study prosthesis, 69% were fit with a quadrilateral socket design and 31% were fit with an ischial containment socket.

#### **DISCUSSION AND CONCLUSION**

With support from academic and industry partners, the MOI team has successfully fit the above knee prosthesis and implemented the research protocol. We hope that the results will help inform and improve existing O&P services, demonstrate the utility and cost-effectiveness of prostheses, and encourage local governments to support rehabilitation and provision of this technology.

# **ACKNOWLEDGEMENTS**

This study is funded by the DKM Foundation.



## 3.3.8.b

# An Innovative Collaboration to Develop an Advanced Prosthetic Foot for Low- and Middle-Income Countries

<u>Grégory Huot</u><sup>1,2</sup>, Mathieu Janier<sup>3</sup>, Rajasundar Chandran<sup>4</sup>, Mathieu Falbriard<sup>5</sup>, Michael Rechsteiner<sup>1</sup>, Marc Zlot<sup>1</sup>

<sup>1</sup>Physical Rehabilitation Programme, International Committee of the Red Cross - ICRC, Geneva, Switzerland. <sup>2</sup>EssentialTech Centre, Ecole Polytechnique Fédérale - EPFL, Lausanne, Switzerland. <sup>3</sup>Laboratory of Applied Mechanics and Reliability Analysis - LMAF, EPFL, Lausanne, Switzerland. <sup>4</sup>Laboratory for Processing of Advanced Composites - LPAC, EPFL, Lausanne, Switzerland. <sup>5</sup>Laboratory of Movement Analysis and Measurement - LMAM, EPFL, Lausanne, Switzerland

#### BACKGROUND

The World Health Organization stated in 2005 that 80% of persons with disabilities were living in developing countries.[1] While technologies and materials used for prosthetic feet in industrialised countries exhibit biomechanics close to the anatomical foot, together with energy storage and return during the gait cycle, the demand for appropriate and affordable advanced prosthetic feet is also growing rapidly in low- and middle-income countries and there are currently very few products available on the market intended to address this need.[2]

#### AIM

This work aimed to develop a low-cost advanced prosthetic foot (targeting K3 users) adapted to the specific contexts of low- and middle-income countries under the lead of a humanitarian international organisation (ICRC) and a Swiss leading research institute (EPFL).

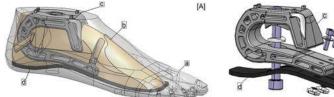


Figure 1. [A] Complete prototype foot showing the cosmetic shell (a), the filling foam (b), the ankle part (c), and the blade (d); [B] Details of the keel assembly.

# **METHOD**

This multidisciplinary research project built an alliance of specialists that brought their experience from their respective fields of work, namely:

- -Physical rehabilitation services in developing and fragile contexts (ICRC)
- -Technologies for development and associated business models (EssentialTech)
- -Applied mechanics and reliability (LMAF laboratory)
- -Processing of advanced composites (LPAC laboratory)
- -Movement analysis and measurement (LMAM laboratory)
- -Affordable prosthetics and orthotics manufacturing (CR Equipements SA)
- -Swiss governmental research funding mechanism (Innosuisse)

The prosthetic foot was designed by considering required biomechanics and performance as well as the specific contexts of use, including the environment and social factors. The targeted manufacturing cost was max. 100 USD.

# **RESULTS**

The developed prosthetic foot (patent pending) comprises a rigid composite keel made of an ankle part and a blade, a lightweight filling foam and a resistant cosmetic shell that protects the internal parts from environmental conditions and has an anatomical shape for an increased user acceptance. The ankle part (injection moulded) and the blade are made of carbon composites. The filling foam and cosmetic shell are made of polyurethane. The mechanical performance was tested under conditions close to ISO 10328:2016 and the prosthetic foot was released for field tests in Vietnam (VIETCOT) with 11 transtibial amputees under the supervision of an ICRC prosthetist. Patients showed a high acceptance rate and satisfaction.

## **DISCUSSION AND CONCLUSION**

This collaboration allowed to numerically design, build, validate, and test the prototype in the field within two years. The chosen materials and the associated manufacturing processes will keep the manufacturing cost below 100 USD after the industrialisation phase. Long-term field tests are required to ensure that the overall performance, durability and look are up to the users' expectations. An approach that aimed to meet the specific needs of low- and middle-income countries was developed during the project.

# **REFERENCES**

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## **ACKNOWLEDGEMENTS**

Innosuisse, the Swiss Innovation Agency, that financially supported the project. The Vietnamese Training Centre for Orthopaedic Technologists (VIETCOT) in Hanoi.



## 3.3.8.c

# Ankle Design of a Prosthetic Foot, a Compromise Between Strength and Stiffness

Mathieu Janier<sup>1</sup>, Gregory Huot<sup>2,3</sup>, Rajasundar Chandran<sup>4</sup>, Mathieu Falbriard<sup>5</sup>, Joël Cugnoni<sup>1</sup>, Michael Rechsteiner<sup>2</sup>, Véronique Michaud<sup>4</sup>, Kamiar Aminian<sup>6</sup>, Klaus Schönenberger<sup>3</sup>, John Botsis<sup>1</sup>

¹Laboratory of Applied Mechanics and Reliability Analysis - LMAF, Ecole Polytechnique Fédérale - EPFL, Lausanne, Switzerland. ²Physical Rehabilitation Program, International Committee of the Red Cross - ICRC, Geneva, Switzerland. ³EssentialTech Centre, EPFL, Lausanne, Switzerland. ⁴Laboratory for Processing of Advanced Composites - LPAC, EPFL, Lausanne, Switzerland. ⁵Laboratory of Movement Analysis and Measurement - LMAM, EPFL, Lausanne, Switzerland. ⁵Laboratory of Movement Analysis and Measurement - LMAM, EPFL, Lausanne, Switzerland.

#### **BACKGROUND**

Advances in thermoplastic composite materials opened an opportunity to develop a new low cost, dynamic prosthetic foot for humanitarian applications that could fit the CRE-SACH foot external envelope currently used by the ICRC. Several studies have shown the requirement for a lightweight, fatigue resistant and psycho-socially acceptable prosthesis.[1-2]

#### AIM

This work presents the design process of a low cost thermoplastic C-shaped keel meeting both the required stiffness to respect a natural stance phase and the strength required to resist the overloads called for by the ISO 10328:2016 standard.

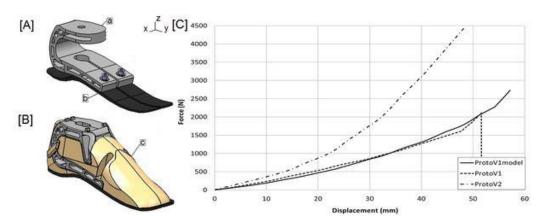


Figure 1: [A] First prototype [B] Second prototype, (a) Ankle (b) Blade (c) Foam [C] Force-deflection curves during forefoot loading at 20 degrees of the two prototypes, and the numerical model

# **METHOD**

A first loop of keel design was performed using two separate parts: A C-shaped ankle part which maximizes the bending performance during the forefoot loading case, and a composite sole blade bolted to the ankle, which works as a beam during forefoot and heel loading cases. A first prototype has been designed using FEA, manufactured and subsequently tested in compression. The obtained measurements were used to calibrate a numerical model, thus allowing a design optimization loop to be carried out. In order to comply with current standards, the ankle was modified to introduce overload protection mechanisms and a third part made of lightweight foam.

#### **RESULTS**

The ankle was injected with a reinforced thermoplastic presenting a measured Young's modulus of 10.5GPa. A good agreement between both measured and simulated vertical displacements could be reached, (Fig (1) [C]). The first prototype, (Fig (1) [A]) failed at 2275 N vertical load, which corresponds to a maximum Von-Mises stress of 295MPa in the ankle part. The final assembly which includes an overload protection mechanism (Fig (1) [B]) present a nonlinear behavior allowing it to sustain loads exceeding 4480N without damage. All the keel parts were symmetric to be fitted in both right or left cosmetic. A targeted price of 100\$ was set.

## **DISCUSSION AND CONCLUSION**

The optimization of the original design lead to a balance between prosthetic forefoot elasticity required for an optimized gait cycle, and the strength required complying with the standard. The second prototype passed the forefoot compression test, thanks to its overload protection feature. The targeted price was respected.

# REFERENCES

- [1] Laferrier JZ, J Nov Physiother 2018; 8(1):380.
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# **ACKNOWLEDGEMENTS**

The authors acknowledge the ICRC and the Innosuisse organizations for their financial support.



## 3.3.8.d

# Scoping and Exploratory Work to Underpin the Research and Design Parameters to Develop a 'Fit-for-Purpose' Body-Powered Upper Limb Prosthesis

Maggie Donovan-Hall<sup>1</sup>, Alixandra Chadwell<sup>2</sup>, Dafne Zuleima Morgado Ramirez<sup>3</sup>, Robert Ssekitoleko<sup>4</sup>, Mohammad Sobuh<sup>5</sup>, Laurence Kenney<sup>2</sup>

<sup>1</sup>School of Health Sciences, University of Southampton, Southampton, United Kingdom. <sup>2</sup>School of Health and Society, University of Salford, Salford, United Kingdom. <sup>3</sup>University College London, London, United Kingdom. <sup>4</sup>School of Engineering, Mackerere University, Kampala, Uganda. <sup>5</sup>University of Jordan, Amman, Jordan

#### **BACKGROUND**

A higher incidence of trauma has increased the number of people living with upper limb loss in LMICs where access to P&O services are limited. This can have a devastating impact on the engagement in activities of daily living that are impossible to perform without an appropriate prosthetics and living at a subsistence level.

#### $\Delta IM$

The aim of this study is to develop a high quality upper limb prosthetic. However, to optimise the use and acceptability of a new prosthetic device, it is essential to understand the social, cultural and historical context of the environment.

## **METHOD**

Scoping and exploratory work was carried out to underpin the research and design parameters of a 'fit-for-purpose' body-powered upper limb prosthesis suitable for two LMIC Counties, Uganda and Jordan. This involved three key aspects:

- The development of thorough 'scoping reports' through the observations and note taking across a range of public, NGO and charity services.
- Informal scoping interviews within a 'Public, Patient Involvement' (PPI) framework with clinicians, technical staff, and people with upper limb loss.
- Telephone and Skype PPI interviews with International Committee of the Red Cross (ICRC) Rehabilitation Managers.

#### **RESULTS**

The collated findings provide clear insight into the specific needs of the users and wider stakeholder. This is essential for the next stage of research in the following ways: a) an insight into key social and cultural issues, b) influencing the remit of the study in terms of adjustable socket designs, c) establishing system and manufacturing considerations to ensure the sustainability, and d) developing relationships and partnerships.

## **DISCUSSION AND CONCLUSION**

This initial scoping and exploratory work has provided an important foundation for the main developmental study. This has promoted a user-centred design and a co-working and co-research approach.



# 3.3.8.e

# Real Life Use of Upper Limb Prosthetics in Lower and Middle Income Countries

<u>Dafne Zuleima Morgado Ramirez</u><sup>1,2</sup>, Alix Chadwell<sup>3</sup>, Mohammad Sobuh<sup>4</sup>, Robert Ssekitoleko<sup>5</sup>, Maggie Donovan-

Hall<sup>6</sup>, Catherine Holloway<sup>1,2</sup>, Laurence Kenney<sup>3</sup>

Interaction Centre, Computer Science, University College London, London, United Kingdom. <sup>2</sup>Global Disability Innovation Hub, London, United Kingdom. <sup>3</sup>School of Health and Society, University of Salford, United Kingdom. <sup>4</sup>Department of Orthotics and Prosthetics, University of Jordan, Amman, Jordan. <sup>5</sup>Department of Physiology, Makerere University, Makerere, Uganda. <sup>6</sup>School of Health Sciences, University of Southampton, Southampton, United Kingdom

#### **BACKGROUND**

Scoping studies in Uganda and Jordan have shed light on the multidimensional challenges and needs of prosthesis users.[1,2] One common problem is the lack of data regarding the real life use of prostheses. Past research has demonstrated the usability of wrist worn activity trackers to quantify prosthesis wear time and other measures.[3] Such approaches offer insight to the context in which current prostheses are used or not used in real life, putting the user at the forefront.

#### AIM

To work with multiple stakeholders in two different LMIC contexts to develop a context appropriate protocol for capturing the lived experience of prosthetic users, which combines tracking of upper limb prosthesis use and user experience in real life settings.

#### **METHOD**

A protocol was designed harnessing the lessons of past activity tracking research and scoping studies,[1,2] and building on human-computer interaction research techniques that provide a more holistic overview of human experiences in daily life contexts. The protocol had to take into account the geographical spread, literacy (or lack of) and needs of prosthesis users, types of prosthesis available in each country, access to communication networks including internet, local climate and culture. In addition, a review of commercially available wrist worn activity trackers was performed to find the most suitable device for the Ugandan and Jordanian settings. This review was done online and complemented visiting a wearable technology expo.

# **RESULTS**

Axivity sensors AX3 were identified to be suitable due to their cost, battery life, robustness, size and weight. Regarding the research protocol, a mixed methods approach was chosen consisting of: interview 1, activity tracking plus diary and elicitation interview. Interview 1 is semi-structured and seeks to understand the prosthesis users' perception of their daily activities and of their own prosthesis. Activity tracking involves wearing one AX3 on each wrist (prosthetic and intact) for 4 weeks (pilot study) and then for 8 weeks (main study refined through the pilot study). The diary captures information in written or audio format and photographs, that capture the experiences of the prosthesis users (including emotions and intentions) and utilizes mobile phones or smartphones that the participants already own. The elicitation interview consists in exploring themes which will emerge after analysing interview 1 and diary data.

# **DISCUSSION AND CONCLUSION**

Our main contribution is the development of a research protocol that takes into account the needs and challenges of multiple stakeholders. Ethical approval has been achieved and initial interviews show that participants are interested in progressing to the mixed methods study. We believe that this protocol is transferable to other LMICs and also for developed countries. We invite researchers to perform scoping studies in their local countries and involve multiple stakeholders and co-design fit for purpose research protocols.

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# **ACKNOWLEDGEMENTS**

Work funded by: Engineering and Physical Sciences Research Council and National Institute for Health Research under the grant number EP/R013985/1.



# 3.3.8.f

# Digital Tools for a Connected Community of Upper Limb Prosthesis Users in Lower and Middle Income Countries

<u>Dafne Zuleima Morgado Ramirez</u><sup>1</sup>, Alix Chadwell<sup>2</sup>, Mohammad Sobuh<sup>3</sup>, Robert Ssekitoleko<sup>4</sup>, Maggie Donovan-Hall<sup>5</sup>, Catherine Holloway<sup>1,6</sup>, Laurence Kenney<sup>2</sup>

<sup>1</sup>Interaction Centre, Computer Science, University College London, London, United Kingdom. <sup>2</sup>School of Health and Society, University of Salford, Salford, United Kingdom. <sup>3</sup>Department of Orthotics and Prosthetics, University of Jordan, Amman, Jordan. <sup>4</sup>Department of Physiology, Makerere University, Makerere, Uganda. <sup>5</sup>School of Health Sciences, University of Southampton, Southampton, United Kingdom. <sup>6</sup>Global Disability Innovation Hub, London, United Kingdom

# **BACKGROUND**

Challenges faced by upper limb prosthesis users were identified in recent scoping studies in Uganda and Jordan.[1,2] One common problem is the absence of a network through which prosthetic users can meet other prosthetic users and possibly cause a feeling of isolation. The current situation does not facilitate peer to peer support nor encourage communities to self-organize to influence public policy around prosthetics. Past research has identified that this problem is also reported in the UK.[3]

#### AIM

Co-create a protocol to explore the feasibility of enabling prosthesis users to develop a sense of community in Uganda and Jordan, using existing communication tools, while being context aware.

## **METHOD**

A protocol was designed utilizing digital technology relevant to LMICs. A human-computer interaction research technique was added to enable a more complete understanding and monitoring of the participant's experiences. The protocol took into account the geographical spread of participants, literacy level, communication needs (language, privacy and confidentiality), access to communication networks (including internet) and culture. In addition, a review of affordable UK mobile phones and smartphones was performed in order to find comparable options in Uganda and Jordan that could be utilized in this study, which required participants to record experiences using audio recordings and photographs.

#### **RESULTS**

The most suitable brand was identified to be Nokia, specifically, phones costing <£70, although similarly acceptable devices from Nokia, Samsung and Huawei were identified in Jordan. Comparable Ugandan options were more expensive. The research protocol design uses mixed methods: interview 1, communication and diary (12-24 weeks) and interview 2 or focus group. Semi-structured interview 1 seeks information about how participants solve their challenges in relation to the use of their prosthesis outside the hospital and identifying current communication technology used. The communication step consists of giving participants a list of known prosthesis users that have an anonymous identity and have given consent to receive a calls or texts. The diary consists of written or audio messages of the participants' experiences. Interview 2 or focus group will provide participants an opportunity to discuss their experiences and the outcome of their communication.

# **DISCUSSION AND CONCLUSION**

Our main contribution the design of a research protocol that takes into account communication needs and cultural context. By enabling an anonymous and a gender segregated participation and employing mobile phones and smartphones already owned by participants, we have overcome challenges in way that is acceptable to all stakeholders. Ethical approval has been achieved and initial interviews show that participants are interested in participating in this protocol. We believe that this protocol will be transferable to other countries.

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# **ACKNOWLEDGEMENTS**

Work funded by: Engineering and Physical Sciences Research Council and National Institute for Health Research under the grant number EP/R013985/1.



# 3.3.8.g

# Research in Prosthetics and Orthotics Bachelor Level: The Case of Designing Research Program in PO School, Thailand

Manunchaya Samala, Pitchaya Rayothee, Juthamas Siriwatsopon Sirindhorn School of Prosthetics & Orthotics (SSPO), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

#### **BACKGROUND**

To date, a growing need for research is becoming visible for the P&O professional.[1] Sirindhorn School of Prosthetics and Orthotics (SSPO) students should be able to have the ability to work on research for health development of disable person. It was necessary to obtain guideline of developing an appropriate in order to create a management framework in producing graduates of the SSPO with academic standard leading to social development in the country efficiently further.

#### AIM

This paper aimed to investigate the current, problems and expectations for research management andto examine opinions and suggestions from experts and stakeholders to develop potentially appropriate research management guideline in the SSPO.

## **METHOD**

The first stage of policy research and Mixed Research Methodology were used.[1] The first stage was the development of management concept and idea by institutional survey method which is consisted of investigating the current, problems and expectations for research management. The population consisted of consist of the SSPO's staffs and students. Data analysis was descriptive qualitative analysis.

# **RESULTS**

The results from institutional survey research by using documentary analysis such as SSPO Strategic Map as shown in Figure 1 and SWOT analysis questionnaire summarised that currently the SSPO of provides research-based education at bachelor level in

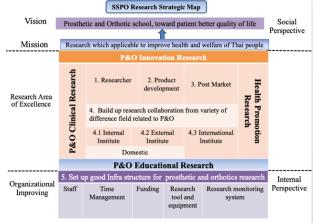


Figure 1: SSPO Research Strategic Map.[3]

all curricula. As mention previously,the SSPO' students should be able to have the ability to work on research. So, the research program can help in improving the competences of students.

The creation of a successful infrastructure for prosthetic and orthotic research and scholarship would require the collaboration and cooperation of faculty from a variety of different departments and academic units. However, there are the limitations to achieving the success of researching as listed: time management, a facility for testing or tools, and motivation.

# **DISCUSSION AND CONCLUSION**

The study by F. Holtkampand L. Peeraer [2] mentioned that the research in PO bachelor level education is needed. Therefore, SSPO circular integrated students into research by making them part of the research program. Tthis study provided concept in research curricular management, which were appropriate and feasible to use for achieving the SSPO vision and mission. Further study on the analysis of appropriateness and the possibility of program concept and idea by an expert in-depth interview, and stakeholder group operational seminar will be needed.

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#### **ACKNOWLEDGEMENTS**

The author would like to acknowledge staffs and students in SSPO for helping to give information to process this research.



# Symposium Outcome Measurements

# 3.4.1

# Scientific Approaches to Outcome Measurement for Basic to Advanced Upper Limb Prostheses

<u>Jacqueline Hebert</u><sup>1</sup>, <u>Jon Sensinger</u><sup>2</sup>
<sup>1</sup>University of Alberta, Edmonton, Canada. <sup>2</sup>University of New Brunswick, Fredericton, Canada

#### **Abstract**

Outcome measures are essential for understanding the impact of treatment interventions, however clinicians face difficulties in choosing the most relevant metrics to administer. Furthermore, existing metrics are limited in the ability to detect important changes in upper limb prosthesis performance related to advancements in myoelectric control, multi-function grasp patterns, and novel mechanisms of sensory feedback. As part of the DARPA HAPTIX Program, our team created scientifically-founded novel metrics that were targeted towards advanced sensory-motor-integrated prostheses yet are applicable to current standard-of-care prostheses. The metrics are flexible to account for numerous systems approaches, sensitive to system performance, and reflective of requirements for quantifying different control and feedback strategies.

# This symposium will:

- 1) review available upper limb metrics in use in the field, including strengths and limitations;
- 2) introduce novel scientifically based metrics designed for the assessment of advanced upper limb sensorymotor function that have been validated and tested in prosthesis user populations;
- 3) discuss the potential advantages and disadvantages of the mechanistic scientifically-based approaches to upper limb functional measurement in comparison to existing metrics. The material presented will stimulate interdisciplinary discussion on evaluation strategies that can best inform design, implementation, and clinical translation of prosthesis technology. By the end of the symposium, the attendees will have an appreciation of how a fundamental mechanistic approach to outcome evaluation can span the range from basic to advanced prosthesis options, and offer clarity and insight to increasingly complex prosthetic systems.

## Statement of the objective / learning objectives

The goal of this workshop is to share new methodologies for assessing upper limb prosthesis function that accommodate recent advances, and reflect on where these metrics fit with exiting options for upper limb prosthesis evaluation.



# Advanced IC Orthotics: Lower Limb Neurological

# 3.4.2

# **Optimization of Treatment Outcome in Ankle-Foot Orthotics**

Merel Brehm, Frans Nollet
Amsterdam UMC, Academic Medical Center, Amsterdam, Netherlands

#### **Abstract**

People with neuromuscular disorders often experience mobility limitations due to impaired calf muscle strength. To reduce mobility problems, ankle-foot orthoses (AFOs) are commonly provided. However, there is large variety in types of AFOs that are applied and their mechanical properties, such as ankle stiffness are often insufficiently matched to the complex health needs of patients exhibiting calf muscle weakness. This calls for precision orthotics, i.e. individually optimizing the stiffness mode-of-action of ankle foot orthoses to the patients' health needs.

An opportunity of this approach is that it may lead to improvement of treatment outcome, i.e. substantially benefitting physical mobility for the individual patient. In this instructional course, we will provide a knowledge base of informed AFO prescription in neuro-rehabilitation, we will demonstrate the promising value of precision orthotics using a modular AFO and gait analysis to objectively optimize AFO stiffness, and we will highlight current state-of-the-art in simulation-based stiffness optimization of AFOs as future direction for implementation in clinical practice.

# Statement of the objective / learning objectives

To provide a knowledge base of ankle-foot orthosis prescription in neuro-rehabilitation and show how optimization of ankle-foot orthosis stiffness can support healthcare professionals in applying treatment more effectively.



# Symposium Developing Countries

## 3.4.3

# From Rehabilitation to Societal Integration

Marc Zlot<sup>1</sup>, Chapal Khasnabis<sup>2</sup>, Jess Markt<sup>1</sup>, David Constantine<sup>3</sup>

International Committee of the Red Cross, Geneva, Switzerland. <sup>2</sup>World Health Organization, Geneva, Switzerland. <sup>3</sup>Motivation, Bristol, United Kingdom.

#### **Abstract**

There is a growing body of empirical data demonstrating the link between disability and poverty, including a World Bank study of fifteen developing countries, which found that people with disabilities were significantly worse off, were more likely to experience multiple deprivations, and had lower educational attainment and employment rates than non-disabled people). As a result, many are forced into poverty and excluded from day-to-day activities as health-care services, education, employment, transportation, information and technology often remain out of reach. Disability also impacts the individual's community, as the community must provide socio-economic support to individuals with physical disabilities who do not have the means at their disposal to support themselves.

It is worth underlining again that provision of physical rehabilitation services should not be perceived as an objective in itself but as an essential part in contributing to the full rehabilitation and integration into society of people with disabilities. Enabling a person with a mobility impairment to walk or to move again is, by itself, an important achievement, but only a first step in enabling the person to participate in his or her community, to work and/or access education and to, eventually, reach his or her full potential.

ICRC physical rehabilitation program celebrates in 2019 its 40 anniversary. We would like to celebrate this by showing a short movie as introduction followed by a panel discussion on societal integration.

# Statement of the objective / learning objectives

Technology is important but rehabilitation should not stop there, a multidisciplinary cross sector approach is needed to enable social inclusion of PwD, this will also help to boost local economies instead of affecting them negative



# Free Paper Session Footwear

# 3.4.4.a

# Quantitative Analysis of Effect of Footwear Modification in Osteoarthritis Knee on Radiological and Gait Parameters

Soumaya Saxena<sup>1</sup>, <u>Shiv Lal Yadav</u><sup>2</sup>
<sup>1</sup>PGIMER, Chandigarh, India. <sup>2</sup>AIIMS, New Delhi, India

#### **BACKGROUND**

Excessive knee joint loads play a role in the pathogenesis of knee osteoarthritis and may contribute to symptoms of knee pain. The foot is an integral component of the lower limb closed kinetic chain and its position and motion influence knee load. Because of this, shoes modification can increase or decrease knee load depending on their design features and thus potentially help in pain reduction.

#### AIM

To assess the effect of lateral wedging in footwear on radiological parameters (tibial and femoral angles and joint space) and foot pressure parameters.

## **METHOD**

We included 40 patients of either sex, of age between 35 to 75 years suffering from primary medial compartment osteoarthritis knee according to ACR criteria and having grade 2 or 3 on Kellgren-Lawrence scale who gave informed consent. Ethical clearance was obtained before starting the study.

Footwear modification: Lateral wedge. Exercise regime: Quadriceps and Hamstrings strengthening protocol. Tab. Aceclofenac 100mg BD for 5 days. Main Outcome Measure(s): Change in Hip-Knee-Ankle, Tibial, Femoral and Condylar-Plateau angles and foot pressure parameters. Change in pain on VAS.

# **RESULTS**

Significant decrease in the magnitude of Condylar-Plateau angle (indicator of joint space) and HKA angle after wearing modified shoes and improvement in pain score on VAS. This signifies that the lateral wedging in shoes of the magnitude of 1/4 inch does produce changes in the weight line at the knee joint. Peak plantar pressures shifted towards lateral zone.

# **DISCUSSION AND CONCLUSION**

Lateral wedging in footwear produces significant measurable changes and is an effective treatment for medial compartment OA knee.



## 3.4.4.b

# Introduction of the Orthopedic Shoe Education for Prosthetics and Orthotics (P&O) and Orthopedic Shoe Technology Students

#### Kenta Tonai

Kobe College of Medical Welfare, Sanda city, Japan

#### **BACKGROUND**

The Kobe College of Medical Welfare (KCMW) has developed four programs over the past two decades to keep up with industrial needs. As our college met these needs over time, two paths emerged: a technical path and a clinical path. There are now four distinct programs that place emphasis on the different skills needed depending on the expected position after the students graduate from our college. There is overlap between each program but each serve different goals in the industry.

#### AIM

To meet industry needs and fill a skill gap in the Japanese labor force in the P&O field, specifically with orthopedic shoes.

## **METHOD**

To grow and evolve the PO programs at KCMW in a dynamic way to best match industry needs. To do this, we maintained a close relationship and surveyed the needs of industry leaders by meeting with representatives twice a year.

#### **RESULTS**

Over the course of 21 years, the programs offered by our school has expanded into four distinct programs, each focusing on either the technical or clinical side of the P&O discipline.

Two of there programs are outline bellows, the first is technical and the second is clinical.

- 1. Orthopedic Shoe Technology Program
  The KCMW's Orthopedic Shoe Technology Program has been the only program focusing on orthopedic shoe technology in Japan. This program was initially designed with a shoe Meister training program in Germany as a role model.
- 4 year Prosthetics and Orthotics Program
   Nearly 12 years has passed since the establishment of KCMW's 4 year P&O Program in addition to its
   3 year P&O program. The 4 year P&O program has focused on orthopedic shoe technology, assistive
   technology, research method, and international education.

# **DISCUSSION AND CONCLUSION**

The goal of KCMW is to tightly match the demands of the Japanese market so that patients can get high quality service and P&O devices in order to improve their quality of life. Our school has done this by working closely with the industry and adapting our programs to meet their needs. So far, we have been highly successful in this endeavor with close to 100% of our students going in to industry or hospital positions.

#### **REFERENCES**

[1] Uhida, Mituhiko. Journal of the Japanese Society for Medical Study of Footwear 2009; 23(2) 48-50.



# 3.4.4.c Longitudinal Bending Stiffness Effects of Shoes with Forefoot Rocker Profiles

<u>Laurens van Kouwenhove</u><sup>1</sup>, Rienk Dekker<sup>1</sup>, Klaas Postema<sup>1</sup>, Bart Verkerke<sup>1,2</sup>, Juha Hijmans<sup>1</sup>

University of Groningen, University Medical Center Groningen, Department of Rehabilitation Medicine, Groningen, Netherlands. <sup>2</sup>University of Twente, Department of Biomechanical Engineering, Enschede, Netherlands

# **BACKGROUND**

Shoes with forefoot rocker profiles are commonly used in load management in patients with Achilles tendinopathy. Proximally placed rockers can reduce the internal plantarflexion moment and with that the load on the Achilles tendon and ankle range of motion during gait. Rocker profiles are usually stiffened. However, the relation between rocker stiffness and ankle kinematics and kinetics is not well known.

#### AIM

To examine the differences in ankle kinematics and kinetics between stiffened and flexible rocker profiles with different apex positions (rolling point) at a self-selected walking speed.

#### **METHOD**

Twelve healthy female adults walked on a control shoe and on the same shoe with modifications to the stiffness and the apex position. The apex positions of the rocker shoes were placed at 50% and 60% (proximal to metatarsal region) of the shoe length. Shoes were stiffened with carbon fiber inlays. Subjects walked at self-selected walking speed over a ±10m walkway where kinematic and kinetic data were recorded. Primarily, peak ankle dorsiflexion moment and peak ankle dorsiflexion angle for the dominant leg were analyzed.

#### **RESULTS**

The subjects had a mean( $\pm$ SD) age of 21.3( $\pm$ 1.5) years, body weight of 62.9( $\pm$ 6.7) kg, and body height of 1.72( $\pm$ 0.05) m. The average walking speed was 1.37( $\pm$ 0.19) m/s. Below the ankle angles and angle moments for each condition are plotted. Peak dorsiflexion angle and peak dorsal flexion moment are reduced (stiff > flexible) and 50% > 60% (Figure 1).

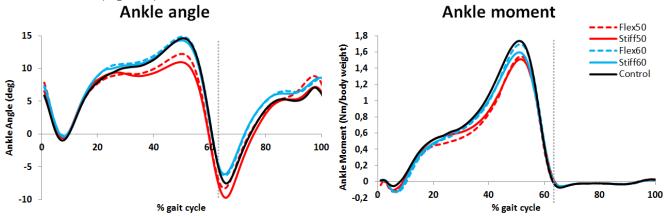


Figure 1. Ankle angle and ankle moment during the gait cycle for the different conditions: apex position of 50% (red), 60% (blue) flexible (dashed) and stiff (solid). The vertical grey line represents toe-off. The region of interest lays between 45 and 55% of the gait cycle.

#### **DISCUSSION AND CONCLUSION**

Preliminary results show that the stiffest and most proximal apex condition is the most optimal configuration, whereas stiffness does not have an effect on more distal apex positions. Flexible profiles seem less optimal, but have still, when the apex position <60%, beneficial effects. Therefore, when toe dorsiflexion is not permitted, flexibility can be used in the design of rocker shoes in the conservative load management of patients with Achilles tendinopathy.

# **ACKNOWLEDGEMENTS**

The authors would like to thank Roy Reints for his contribution to the collection of the data.



## 3.4.4.d

# The Effect of Orthopedic Shoes on the Gait Adaptability in HMSN Patients

<u>Lysanne de Jong</u><sup>1,2</sup>, Yvette Kerkum<sup>3</sup>, Noel Keijsers<sup>1,2</sup>

<sup>1</sup>Sint Maartenskliniek, Nijmegen, Netherlands. <sup>2</sup>Radboud University Medical Centre, Nijmegen, Netherlands. <sup>3</sup>OIM Orthopedie, Assen, Netherlands

## **BACKGROUND**

Orthopedic shoes are an intervention to improve stability during standing and walking, resulting in a normalized walking pattern (e.g. higher walking speed and step length, normalization of kinematics [1]). Disadvantage of these gait pattern measures is the inability to reflect the gait capacity related to dynamic balance and the ability to adjust the gait pattern to changing environmental demands. This so called gait adaptability, is seldom studied, yet much more important for independent living and social participation.

#### AIM

Evaluate the effect of orthopedic shoes on the gait adaptability in HMSN patients.

#### METHOD

HMSN patients with orthopedic shoes participated in this study. They performed a 2 minute walking test in the self-paced mode and a precision stepping task on the GRAIL (Gait Real-time Analysis Interactive Lab). The tasks were performed in two conditions: with orthopedic shoes and with regular shoes. Primary outcome measure was the performance of the precision stepping task expressed as the distance between the middle of the target and the middle of the foot. Secondary outcome measures were walking speed and spatiotemporal gait parameters.

#### **RESULTS**

Preliminary results of two patients are presented in Table 1. A decreased and similar target-foot distance for the orthopedic shoes compared to the regular shoes was found for patient 1 and 2, respectively. Both patients showed an increase in walking speed and step length, and a decrease in step width for the orthopedic shoes compared with the regular shoes.

Table 1. Distance target-foot, walking speed, step length and step width for both patients and both conditions. Values displayed as mean ± SD.

	Patient 1	Patient 2		
Orthopedic shoes	Regular shoes	Orthopedic shoes	Regular shoes	
Target-foot distance (mm)	36.6 ± 22.6	66.3 ± 35.9	33.7 ± 21.5	35.3 ± 22.4
Walking speed (m/s)	1.08	0.90	0.88	0.78
Step length (mm)	595.3 ± 54.9	510.4 ± 68.00	498.6 ± 40.0	422.0 ± 53.4
Step width (mm)	149.7 ± 31.3	161.2 ± 45.3	137.6 ± 20.2	162.0 ± 19.6

# **DISCUSSION AND CONCLUSION**

The smaller target-foot distance suggest an increase in gait adaptability when wearing orthopedic shoes. This finding and the increase in walking speed and decrease in step width suggests that orthopedic shoes have a positive influence on gait capacity. In the next months, additional patients will be tested.

### **REFERENCES**

[1] Guzian MC. Prosthet Orthot Int 2006.



## 3.4.4.e

# Cost-Effectiveness of Offloading-Improved Custom-Made Footwear to Prevent Plantar Foot Ulcer Recurrence in High-Risk Patients with Diabetes

<u>Sicco Bus</u>, Nora Mejaiti, Marcel Dijkgraaf Amsterdam UMC, Amsterdam, Netherlands

#### **BACKGROUND**

Randomized controlled trials show that custom-made footwear of which the offloading properties are improved by using plantar pressure analysis in the design and/or evaluation of the footwear, can reduce risk of plantar foot ulcer recurrence in patients with diabetes, under the condition that the footwear is worn.[1] Whether the effectiveness of the approach in preventing foot ulcers and treatment costs thereof offsets the investment cost involved remains to be investigated.

#### AIM

The purpose was to assess the cost-effectiveness of using in-shoe plantar pressure guided optimization of custom-made footwear offloading properties on risk reduction of plantar foot ulcer recurrence in high-risk patients with diabetes.

#### **METHOD**

171 neuropathic diabetic patients with a recently healed plantar foot ulcer were randomly assigned to 1) custom-made footwear which was evaluated, optimized and monitored at 3-monthly visits based on in-shoe plantar pressure analysis or 2) usual care custom-made footwear. Primary clinical outcome was plantar foot ulcer recurrence in 18 months. Healthcare costs included intervention costs input) and ulcer treatment costs (output). Intervention costs included the time investment of the footwear technician to modify the footwear and measure pressure, footwear materials costs, and write-off costs for equipment. The average total for direct treatment costs for diabetic foot ulceration were derived from existing Dutch reference data.[2]

#### **RESULTS**

33 of 85 patients in the intervention group and 38 of 86 patients in the usual care group had a recurrent ulcer (relative risk -11%, P=0.48). A total of 1183 footwear modifications were made in the intervention group and 33 in the usual care group. The total expenditures were €38.507 for the intervention and €206 for the usual care group. Average costs for treatment of a foot ulcer are €9.472 Offloading-improved custom-made footwear led to lower costs since its effectiveness offsets the added costs of the intervention and was cost-saving by €9.059. In secondary analysis, for those 79 patients who were adherent to wearing their custom-made footwear, the intervention was cost-saving by €98.014, based on 9 of 35 patients in the intervention group and 21 of 44 patients in the usual care group that had a foot ulcer recurrence.

# **DISCUSSION AND CONCLUSION**

Based on exact data for the intervention costs and reference data for ulcer treatment costs, offloading-improved custom-made footwear seems cost-effective compared with custom-made footwear that does not undergo such improvement.

#### **REFERENCES**

[1] Bus et al. Diabetes Care, 36(12), 4109-16.

[2] Rinkel et al. Diabetes Res Clin Pract 2017; 132:68-78.



## 3.4.4.f

# Custom-Made Footwear for Indoor Use Increases Adherence in People at High-Risk for Diabetic Foot Ulceration

Renske Keukenkamp, Jaap van Netten, Tessa Busch-Westbroek, <u>Sicco Bus</u> Amsterdam UMC, Amsterdam, Netherlands

#### **BACKGROUND**

Adherence to wearing prescribed custom-made footwear is a problem in people with diabetes at high-risk of ulceration.[1] Adherence is lowest indoors, while patients are most active inside their house.

#### AIM

The aim of this study was to investigate changes in adherence following provision of custom-made shoes that are specifically designed for use indoors.

#### **METHOD**

In patients with a history of foot ulcer who had custom-made orthopaedic footwear, baseline adherence was measured with the @monitor adherence sensor work in the shoe, and a Stepwatch activity monitor. Percentage steps while adherent to wearing the footwear was calculated. Patients were classified as non-adherent when <80% of their steps were made in their prescribed footwear. All patients were then provided with a pair of custom-made indoor footwear. Plantar pressure was measured with Pedar-X (Novel, Germany) in both the regular and the indoor custom-made footwear. Adherence was again measured with the @monitor and a Stepwatch after provision of the indoor footwear.

#### **RESULTS**

35 patients participated (mean age 70 (SD:10) years; n=15 female; n=26 type 2 diabetes). Of the 32 patients who completed the first adherence measurements, 23 were classified as non-adherent and 9 as adherent. Complete follow-up was available for 19 non-adherent patients. Peak plantar pressure in the forefoot regions was similar between regular and indoor custom-made orthopaedic footwear (hallux: 121 vs. 115 kPa respectively, p=0.319; first metatarsal head: 153 vs. 139 kPa respectively, p=0.636; all other regions also p>0.05). Total adherence increased significantly after provision of the indoor footwear: before 59%, after 71%; p=0.003. This was the result of a significant increase of indoor adherence (before: 42%; after: 64%; p<0.001), while outdoor adherence increased non-significantly (before: 87%; after: 91%; p=0.213).

# **DISCUSSION AND CONCLUSION**

Custom-made indoor footwear that is provided in addition to existing custom-made footwear significantly increases adherence in patients at high-risk of diabetic foot ulceration who are non-adherent to wearing their footwear. The indoor footwear has similar offloading quality (peak plantar pressure reduction) compared to the regular footwear, and is therefore safe to use. The combination of both forms of custom-made footwear might prevent foot ulceration.

#### **REFERENCES**

[1] Waaijman et al. Diabetes Care. 2013; 36(6):1613-8.



# Free Paper Session Orthotics: Spinal

# 3.4.5.a

# Follow-up of Brace Treated Scoliosis in Children with Cerebral Palsy and Spina Bifida

Annika Blomkvist, <u>Meta Nyström-Eek</u> Regional Rehabilitation Centre, Queen Silvia Children's Hospital, Gothenburg, Sweden

#### **BACKGROUND**

Scoliosis is common in children with cerebral palsy and spina bifida. It is often associated with an asymmetric sitting position affecting daily activities. Treatment options for scoliosis are conservative or surgery, but reports on the effect by brace treatment are scarce. At our centre, braces are adjusted to be well fitted to the patient at an in-patient period, and with instructions to families on how to handle the brace.

#### AIM

The aim of the study was to describe brace use and progression of scoliosis in children with CP and spina bifida treated with a corrective scoliosis brace.

#### **METHOD**

A retrospective review of medical records of all children with CP and spina bifida fitted with scoliosis braces of a Boston type at an in-patient period at the rehabilitation centre during 2003-2013.

Data was retrieved on diagnosis and motor function. Measurement of scoliosis (Cobb angle) was made from x-rays in sitting with and without the brace at start of treatment and at follow-up. Compliance to brace treatment was noted as well as complications with the brace use.

#### **RESULTS**

A total of 65 patients were included, 44 with CP and 21 with spina bifida. The mean age at start was 10.0 years (1.9–17.5). There were 30 boys and 35 girls. Mean Cobb angle was 49.9 degrees (23-126), and with a statistically significant correction in the brace to a mean of 29.3 degrees (0-76) (p<0.001).

At follow up of 59 patients, 4-5 years after start of brace treatment, there was a progression of the scoliosis to 60.5 degrees (30-100), with a mean yearly increase of 3.8 degrees.

The brace was well tolerated by most patients, also children with severe scoliosis. Adverse events were reported in 19 patients, most of the complications were transient and handled through adjustments of the brace.

# **DISCUSSION AND CONCLUSION**

There was a progression of the scoliosis in spite of brace treatment, but the progression was delayed compared to the natural development in these groups as described in earlier studies. Braces were well tolerated, even in children with severe scoliosis. This may be due to the thorough adjustment of the braces and instructions to families at the start of treatment. In addition to scoliosis treatment, braces can have a positive impact on sitting, making everyday life easier.

# **ACKNOWLEDGEMENTS**

The study was supported by the Petter Silfverskiöld memory Foundation.



## 3.4.5.b

# Impact of a Flexion Orthosis on Clinical Parameters in Patients with Neurogenic Claudication. A Prospective Randomized Trial

Andreas Hahn<sup>1</sup>, Sylvia Schreyer<sup>2</sup>, Catherine Disselhorst-Klug<sup>3</sup>, Klaus John Schnake<sup>2</sup>
<sup>1</sup>Otto Bock Healthcare Products GmbH, Vienna, Austria. <sup>2</sup>Schön-Klinik Nürnberg Fürth, Center for Spine and Scoliosis Surgery, Nürnberg, Germany. <sup>3</sup>RWTH Aachen University, Dept. of Rehabilitation and Prevention Engineering, Aachen, Germany

#### **BACKGROUND**

Conservative treatment of neurogenic claudication includes physical therapy and epidural steroid injections.[1] The Dyneva® dynamic lumbar flexion brace (Otto Bock Healthcare GmbH, Duderstadt, Germany) utilizes a 3-point-pressure principle with an innovative spring mechanism that connects the upper and lower parts of the dorsal frame to actively promote straightening and unloading of the dorsal aspects of the lumbar spine.

#### AIM

The purpose of this study was to examine the clinical effects of an innovative lumbar flexion orthosis in patients with neurogenic claudication due to spinal Stenosis.

#### METHOD

A prospective randomized trial included patients suffering neurogenic claudication due to lumbar spinal stenosis. Clinical tests with 6 standardized elements of relevance in everyday life (standing upright, standing bent forward, trunk rotation, stairs up and down, chair rising and 6 minutes walking test) were performed at baseline and at the end of the follow-up period. Outcomes included the EQ-5D\_5L, Zurich Claudication Questionnaire (ZCQ), Oswestry Low-Back Pain Disability Index (ODI), pain measured by visual analogue scales (VAS) and analogsics use.

#### **RESULTS**

Twenty patients (mean age 62.7 years, 12 male) used the orthosis over a period of 21-28 days. 10 patients (mean age 71.7 years, 3 male) served as controls. Follow-up rate was 100%. There was a significant and clinical relevant improvement in the 6-minute walk test with a mean increased walking distance of 13.3%. The chairrising and stairs-up-and-down tests also showed a clear positive effect with a mean improvement of 27.6% and 18.8%, respectively. All 5 self-reported assessments showed an improvement in the orthosis group, especially in the ZCQ, ODI and pain VAS, whereas the control group showed a tendency towards deterioration. Thus, the new dynamic lumbar flexion orthosis contributes to improvements in performance in important activities of daily living, such as walking, sitting down and getting up, and climbing stairs.

# **DISCUSSION AND CONCLUSION**

The tested orthosis showed a significant and clinical relevant effect on the walking distance in patients with neurogenic claudication due to lumbar stenosis. Positive effects were seen in all used assessments. The dynamic lumbar flexion brace may be considered a non-surgical treatment option in patients with neurogenic claudication.

# **REFERENCES**

[1] Kalff et al. Dtsch Arztebl Int 2013; 110:613-624.

## **ACKNOWLEDGEMENTS**

The trial was sponsored by Otto Bock Healthcare. A. Hahn is a full time employee of Otto Bock.



## 3.4.5.c

# Brace Indication in Scoliosis Influenced by Diagnostic Investment

#### Franz Landauer

University Clinic of Orthopaedics and Traumatology, Salzburg, Austria

#### **BACKGROUND**

Non-idiopathic (symptomatic) scoliosis seems underestimated in its frequency and influence to brace treatment in adolescent scoliosis.

#### AIM

A differentated medical history and MRI in a high quality should be available to indicate bracing in children with non rightconvex thoracic curve of the spine.

#### **METHOD**

In a retrospective study, 1148 patients with scoliosis were examined after exclusion of obvious neurological conditions. After x-ray of the spine, especially in cases with lumbar curves an MRI was offered to the patients. Scoliosis-related diagnoses (spinal malformations, intraspinal changes, neonatal thoracic surgery, leg length discrepancy > 1.5 cm, growth hormone treatments, connective tissue pathologies, etc.) were summarized in the group of non-idiopathic scoliosis. These data are compared to a former study without free availability of MRI scans (n-285).

# **RESULTS**

In the current study, 24.2% (n-278) of patients were diagnosed as non-idiopathic scoliosis, in contrast to a previous study of 19.3%.

In the current study the most common cause of non-idiopathic scoliosis is malformation 47% (n-131). The lumbosacral transition disorder accounts for a significant proportion of 28.9% (n-38) (2/3 of the cases could only be confirmed by MRI). Also in 18% (n-24) vertebral body malformations could be diagnosed. In 19.9% (n-26) of patients a syndrome could be dedected. In 6.8% (n-9) of patients with pain spondylolysis / spondylolisthesis could be found. Hormonal imbalance as a propable cause of scoliosis was diagnosed in 6.8% (n-9). Surgery in infancy was recorded in 6,8% (n-9). Syringomyelia could be diagnosed in 2 patients. Cases of various diagnoses could be found in 16% (n-14).

# **DISCUSSION AND CONCLUSION**

An extended medical history and availability of MRI examination is crucial in the diagnostic of scoliosis. The availability of MRI in a high quality (>3,5 Tesla and pictures in all three planes) increases the number of non-idiopathic (symptomatic) scoliosis. In consequence it is important for the indication and treatment goal of braceing.

In all adult non rightconvex thoracic scoliosis a differentiated medical history and MRI examination becomes crucial.

# **REFERENCES**

[1] Berven SH, Lowe T. Neurosurg Clin N Am 2007; 18(2):207-13.



## 3.4.5.d

# Relations Between Curve Magnitude and Trunk Muscle Endurance in Individuals with Primary Thoracic Scoliosis

Zilan Bazancir, Elif Kirdi, Gozde Yagci, Nilgun Bek Hacettepe University, Faculty of Physical Therapy and Rehabilitation, Ankara, Turkey

#### **BACKGROUND**

Spinal deformities affect the overall alignment of the spine and thereby alter line of pull and angle of pull of the trunk muscles. This situation causes the muscle's moment-arm length to change. Due to change of muscle's angle of pull and unbalanced spinal segments, alignment change may affect the trunk muscle endurance of individual. This is particularly important in idiopathic scoliosis patients who may suffer from malalignment, stiffness and pain.

#### AIM

To investigate the relations between curve magnitude and trunk muscle endurance in individuals with primary thoracic scoliosis.

## **METHOD**

A total of 67 (50 females, 17 males) idiopathic scoliosis patients with primary thoracic scoliosis between 7-18 years of age were included in the study. Cobb angle were obtained to determine the curve magnitude from radiological evaluations of individuals, and the type of curve was determined. McGill's core endurance tests (trunk extensor, trunk flexor, right and left side bridge) were used to evaluate the trunk muscle endurance. "Spearman's Rank-Order Correlation" was used to evaluate the relationship between the variables because of non-parametric test.

#### **RESULTS**

The mean age of the patients in the study was 14.6±2.5 years, Cobb angle was 23.3±7.4 degree, Body Mass Index was 19.2±2.9 kg/m², endurance of trunk extensor 28.2±15 sec, endurance of trunk flexion 35.7±16.4 sec, right lateral bridge 14.8±9.8 sec, left lateral bridge 15.4±8.7 sec. When the study results were examined, no correlation was found between curve magnitude and trunk muscle endurance in individuals with primary thoracic scoliosis (p>0.05).

#### **DISCUSSION AND CONCLUSION**

The results of the study indicate that, in individuals with primary thoracic scoliosis, there is no relations between curve magnitude and trunk muscle endurance. This is a platform for future studies assessing other scoliosis type, biomechanics feature and to determine the effects of altered trunk muscle endurance in this context and its implication in patient management and outcomes.



# 3.4.5.e

# One Case Study of Hip Orthosis Combined with Lumbar Sacral Orthosis Prescribed for Patients with Obesity after Lumbar Fusion Surgery

<u>Yusuke Takeuchi</u> Kawamura Gishi Co., Ltd., Daito, Japan

#### **BACKGROUND**

Lumbar sacral orthosis are commonly prescribed in order to restrict the movement of the spine after lumbar fusion surgery. However, fixation using LSO is less effective for people with obesity because of increased frequency of dislocations. Moreover, the risk of non-unions is high among the elderly population due to low recovery rates. Necessitating the design of an LSO to prevent dislocation for elderly with obesity after surgery.

#### AIN

The aim of this case study is to investigate the effectiveness of a new post surgical LSO for elder person with obesity to achieve bone union.

## **METHOD**

Hip orthosis combined with lumbosacral orthosis consists of a trunk support, a thigh support and a hip joint. As the hip joint is extended, the tension of the iliac femoral ligament and the hip flexor muscle increases, and the

pelvis tilts forward. As a result, the anteversion of the pelvis augments the lordosis of the lumbar [1]. Extension angle of the hip joint is restricted to 0 degree to prevent anteversion of the pelvis and extension of the spine due to extension of the hip joint . Flexion angle of the hip joint was set at 90 degrees to prevent excessive flexure.

## **RESULTS**

The individual started wearing the brace on the first day after surgery to start rising training. She became to be able to walk with a cane on seven days after surgery, and could don the brace by herself after ten days, walk in hospital, up and down stairs and on irregular ground. After surgery, pain from the left buttocks to lower limbs and numbness of the left leg ameliorated. The outcome of the treatment was good after the discharge. The patient was discharged from the hospital and was able to perform activities of daily living (see figure 1).

## **DISCUSSION AND CONCLUSION**

It is reported that lumbosacral orthosis reduced the mean angular movements at each level to 40% of normal, a thoracolumbosacral orthosis (TLSO) with thigh piece reduced the mean angular movements at each level to 90% of normal in the segmental sagittal mobility of the lumbosacral spine [2]. The outcome of this case study suggests that this hip orthosis combined with lumbosacral orthosis may be as effective as those orthoses for fixation of the lumbar spine.



Figure 1. Hip orthosis combined with lumbosacral orthosis.

# **REFERENCES**

- [1] Takuya Ibara, Japanese Journal of Physical Fitness and Sports Medicine 2010.
- [2] Fidler MW & Plasmans CMT, The effect of four types of support on the segmental mobility of the lumbosacral spine. J Bone Joint Surg 1983.



# 3.4.5.f Successfully Enabling HAND FUNCTION for SCI on C4-C6 with ROBOTICS

<u>Sofie Woge</u>, Robin G, Sarawut Nielsen, Pontus Renmarker Tendo AB, Lund, Sweden

#### **BACKGROUND**

In Sweden alone, 5000 people are living with a spinal cord injury (SCI) and the incidence rate is 150 new cases yearly. About 60% of the patients were under the age of 30 at the time of the injury and the impact on Activities of Daily Living (ADL), is often severe. The loss of movement and sensation often leads to limitations which requires continued assistance and it, consequently, leads to a significant loss of independence and quality of life (QOL).

#### AIM

To enable hand function and increase QOL for people with a C4-C6 SCI, such that they can perform ADL with a lessened need of assistance from caretakers, without the need for invasive procedures and complex surgeries.

#### METHOD

The technique has been developed with a user-centric design methodology, where the subjects are incorporated into every step of the development process, from initial ideation to usability testing through workshops and interviews, such that the technology is made to specifically address their needs. By collaborating with hospitals that specialize in SCI, a comprehensive understanding of patients suffering from SCI has been developed. The evaluations conducted with subjects have been based on basic ADL, such as drinking and eating, with and without the technology, to determine overall improvement of the subject's hand function in regards to an enhanced tenodesis grip.

#### **RESULTS**

To achieve the result, an active bioelectrical hand orthosis was developed. It improved subjects' hand function by assisting the grip-and-release motion as well as adding strength. The grip was controlled entirely by the subject's own intended motion.

An evaluation was conducted with a tetraplegic subject with paralysis in the majority of the body, but with some mobility in one arm - and with minimal to none grip function. With this technology, the subject could, for the first time in 23 years, take part in many ADL once again. He could, e.g. during a dinner party with friends, easily shift grip between e.g. a fork and a wine glass by himself without another person's assistance. It was clear that this ability led to a tremendously increased feeling of independence and QOL - a joy that was shared by everyone around the table.

# **DISCUSSION AND CONCLUSION**

Further research is needed to compare different cases. The process could benefit from an improved methodology and more standardized set-up. Results was limited to short-time-evaluations (<8 h) and might be affected by long time usage. Also, a limitation regarding "time since injury" should be considered. As a conclusion; the subject's level of independence and the number of ADL-activities achieved was increased significantly with support from the technology and it showed great potential in a challenging patient group.



# Free Paper Session Psychosocial Issues / Quality of Life - General

#### 3.4.6.a

# Effect of Postoperative Ambulation on the Quality of Life in a Trans-tibial Amputee

#### Amit Saraf

Teerthanker Mahavir Medical College, Moradabad, India

#### **BACKGROUND**

Quality of life of a trans-tibial (TT) amputee is not only determined by his functional rehabilitation but also social, economical and psychological rehabilitation. A number of studies have analyzed the influence of lower limb amputation on these factors. This study analysed the effect of functional recovery on other parameters of quality of life in a TT amputee.

#### AIM

To assess the influence of level of ambulation postoperatively on the socioeconomic and psychological aspects in a transtibial amputee.

#### **METHOD**

This was a 10 years retrospective and 2 years prospective study. A total of 160 patients of trans-tibial amputation were followed. Their postoperative ambulatory status was calculated using Pinzur's ambulatory level. Their quality of life was determined on the basis of answers to a five point questionnaire which included their social, economic and psychological aspects. These parameters were correlated to assess the influence of functional recovery on the quality of life.

# **RESULTS**

All the amputees with Pinzur's 0-1 level of ambulation suffered loss of income consequent to loss of job. All of them felt increased level of depression and anxiety after amputation. 50% of the patients with postoperative 0-1 level of ambulation felt socially neglected. Comparatively much less percentage of amputees with 5-6 level of ambulation suffered economic, social and psychological crisis.

# **DISCUSSION AND CONCLUSION**

Quality of life of a TT amputee is determined not only by his functional rehabilitation but also social, economical and psychological factors. From this study we concluded that post operative functional outcome significantly affects the quality of life of an amputee. An amputee with better ambulation level fares better economically, psychologically and socially in comparison to an amputee with poor ambulatory outcome.

Table 1: Pinzur et al (1993) ambulatory scale

Level	Walking capacity		
6	Independent community ambulator		
5	Limited community ambulator		
4	Unlimited household ambulator		
3	Limited household ambulator		
2	Supervised household ambulator		
1/0	Transfer- bedridden		

Table 2: Five point questionnaire for quality of life

Question	Answer	
Have you changed your occupation/ lost job after amputation?	Yes	No
Is there an income decline after amputation?	Yes	No
Do you feel socially neglected?	Yes	No
Do you feel more depression after amputation?	Yes	No
Has your anxiety increased after amputation?	Yes	No

Table 3: Correlation of ambulatory scale and quality of life

Questionnaire	Answer	Ambulation level			
		0-1 (n=8)	2-4 (n=56)	5-6 (n=96)	Total (N=160)
Occupation change/lost job	Yes	100% (8)	75% (42)	34.4% (33)	51.9% (83)
	No	0% (0)	25% (14)	65.6% (63)	48.1% (77)
Income decline	Yes	100% (8)	83.9% (47)	41.7% (40)	59.4% (95)
	No	0% (0)	16.1% (9)	58.3% (56)	40.6% (65)
Loss of social support	Yes	50% (4)	57.1% (32)	12.5% (12)	30% (48)
	No	50% (4)	42.9% (24)	87.5% (84)	70% (112)
Increase in depression	Yes	100% (8)	92.9% (52)	51% (49)	68.1% (109)
	No	0% (0)	7.1% (4)	49% (47)	31.9% (51)
Increase in anxiety	Yes	100% (8)	82.1% (46)	31.3% (30)	52.5% (84)
	No	0% (0)	17.9% (10)	68.7% (66)	47.55 (76)

# **REFERENCES**

[1] Pinzur et al. Clin Orthop Relat Res 1993; 286:247-249.



## 3.4.6.b

# Musculoskeletal Pain of the Non-affected Arm, Neck and Back in Patients with Brachial Plexus Injury

<u>Corry K. van der Sluis</u>, Sietke G. Postema, Jeroen M. van Bodegom, Klaas Postema, Pieter U. Dijkstra University Medical Center Groningen, Groningen, Netherlands

#### **BACKGROUND**

A brachial plexus injury (BPI) has a restricting effect on the function of the affected arm. As a result, the non-affected arm performs more daily tasks or perform tasks unilaterally which normally are executed bilaterally. This could lead to musculoskeletal complaints (MSC) of the non-affected arm, neck or upper back.

#### AIM

To assess the prevalence of MSC of the non-affected arm, the neck and/or upper back in persons with BPI compared to a control group. Secondary objectives were to investigate factors predicting pain and disability

#### **METHOD**

Individuals with BPI were recruited from three outpatient rehabilitation centres/departments. Inclusion citeria were: unilateral brachial plexus injury, aged 18 years or above, date of injury more than 1 year ago, understanding the Dutch language. Healthy people were recruited to serve as controls. MSC was defined as pain in the muscles, tendons and/or bones not caused by an accident, sports injury, infection or joint disease. A postal survey was executed, comprising of questions regarding personal characteristics, MSC, health care consumption and severity of BPI. Furthermore, RAND-36 (pain, health perception, mental health), PDI (Pain Disability Index) and DASH (Disability of Arm Shoulder Hand) were filled in.

## **RESULTS**

Seventy-nine patients (mean age: 51yr; 65% men) and 114 controls (mean age: 50yr; 63% men) participated. The prevalence of musculoskeletal pain in BPI patients (52%) was higher compared to controls (37%, p=0.008). Within the BPI-group, patients with pain scored lower on the RAND health and mental questions (p=0.043 and p=0.045, respectively), time since BPI was longer (p=0.000), their arm function was worse (p=0.000) and disability (DASH) was higher (p=0.000). Presence of pain (p=0.021) and worse arm function (p=0.000) were related to more disabilities on the DASH.

#### **DISCUSSION AND CONCLUSION**

Patients with BPI have higher prevalence of pain than healthy controls. Pain is related to lower general and mental health. Time after injury and severity of functional loss are predictors for pain. Pain and worse arm function are predictors for disabilities.

Clinical Message: Clinicians should pay attention to the unaffected arm, neck and back in the acute and chronic phase after BPI and make individuals with MSC aware of possible risks for MSC.



## 3.4.6.c

# A Cross Sectional Study of Effect of Post Amputation Pain on Quality of Life in Lower Extremity Amputees Attending Outpatients

Nidhi Gupta<sup>1</sup>, Corinna Leung<sup>2</sup>
<sup>1</sup>Westmead hospital, Sydney, Australia. <sup>2</sup>Westmead hospital, Sydney, Australia

#### **BACKGROUND**

Post amputation pain is common and could be an important determinant of quality of life (QOL) in this cohort. There is conflicting literature on this issue with equivocal results. Furthermore there is minimal literature on relationship of QOL to the use of pain medications and how these correlate to each other.

# **AIM**

- 1. Compare QOL in lower limb amputees with moderate to severe pain to those with nil to mild pain.
- 2. Compare QOL in amputees on multiple medications and/or high opioid doses for pain to those on minimal / nil medications.

## **METHOD**

Participant completed paper based questionnaires were used to collect data from 100 consenting lower limb amputees attending outpatient clinics. All were adult(>18 years age), acquired amputations, 6 months post amputation.

Standardized scales - brief pain inventory interference scale (BPI), Euro quality of life scale (EQ-5D-5L), and pain self-efficacy scale (PSEQ) were used. A questionnaire collecting amputee specific demographics along with specific pain questions was also used. Pain data was dichotomized and patients on 3 and more pain medications and/or ≥40 mg morphine equivalent were grouped into multiple pain medication group.

A quantitate analysis was done using SPSS version 24 for windows after institutional ethics approval.

#### **RESULTS**

The mean age of patients was 59.  $9\pm14.1$  years, 68% unilateral transtibial amputees. Diabetes  $\pm$  Peripheral vascular disease (42%), trauma (34%) were common causes. Post amputation pain was high (69%) but only 13% were on multiple medications.

Patients with moderate/severe pain interference had poorer QOL (median 0.528, IQR 0.263-0.660) in comparison to mild group (median 0.767, IQR 0.565-1; p<0.05). Similarly those with lower PSEQ also had poorer QOL (median 0.516, IQR 0.211-0.654) in comparison (median 0.767, IQR 0.528-1; p<0.001) on general linear analysis.

Patients on higher medications (n=13) had higher pain interference (n=9) and lower self-efficacy (n=7). However patients with pain could still be on minimal medications (n=31; n=20 respectively). There was negligible rank correlation between the variables (p>0.05). Patients on higher medications were found to have worse QOL but it did not reach clinical significance (p>0.05).

# **DISCUSSION AND CONCLUSION**

Post amputation pain continues to be a major determinant of QOL in lower limb amputees. The results show that only pain interference or self- efficacy are independent predictors of QOL and not age, gender or cause of amputation. The use of pain medications does not necessarily improve QOL which appears to be more a matter of personal choice rather than a necessity.



## 3.4.6.d

# Health-Related Problems Persist at Two Years in Persons Following Traumatic Lower Limb Amputation

<u>Jemma Keeves</u>, Adrian Sexton, Thomas Hale Epworth Healthcare, Hawthorn, Australia

#### **BACKGROUND**

There is a paucity of research of functional outcomes in younger persons with traumatic amputations compared to those with amputations due to diabetes or vascular disease. Thus, longitudinal research in this area is necessary to optimise health-related outcomes in this patient population and to inform healthcare service delivery.

#### AIM

To examine the health-related outcomes for people following non-vascular, traumatic lower limb amputation over a two-year period.

## **METHOD**

Forty-one subjects were recruited from the amputee rehabilitation unit at Epworth Hospital between 2014-2019. Self-reported questionnaires assessing physical functioning, mental heatlh, post-traumatic stress disorder, prosthetic satisfaction, ambulation, pain and self-efficacy were administered at 4 months, 8 months, 1 year and 2 years following amputation.

#### **RESULTS**

86% of subjects were male, with a mean age of 48.7 years at time of amputation. The mean Injury Severity Score (ISS) was 17.4 indicating major injury. 36% had a concurrent traumatic brain injury. At one-year, 50% of patients had anxiety in the abnormal range (median = 7/21) and 25% patients had abnormal depressive symptoms (median 4/21) on Hospial Anxiety and Depression Scale. At one-year following amputation, 8.3% had returned to their previous vocational roles in a full time capacity and 25% deemed themselves 'non-vocational'. Pain intensity remained moderate at one and two-years post amputation (VAS: 1 year median = 4.1/10; 2 year median = 5.1/10). Pain descriptors included at two-years: tender, aching, burning, sharp, stabbing, shooting on the McGill Pain Questionnaire. Mobility (PEQ-MS) continued to improve over time with 50% subjects having PEQ-MS score greater than 64/100 at two-years.

# **DISCUSSION AND CONCLUSION**

At two-years following traumatic amputation, health-related problems persist to limit normal life roles and physical functioning. Despite abnormal anxiety and limited mobility at one-year following amputation, there was continued improvement in these domains when assessed at two years post amputation. Pain remained at a moderate level at two-years. Earlier interventions for psychological and pain management may be beneficial to improve long-term outcomes following traumatic amputation. Further research with a larger cohort and longer follow-up is warranted to provide stronger evidence.

# **ACKNOWLEDGEMENTS**

This project was patially supported by an Epworth Research Institute seeding grant.



## 3.4.6.e

# Perception of Patients on the Experience of Lower Limb Amputation: A Qualitative Study

<u>Denise Matos</u><sup>1,2</sup>, Tereza Araujo<sup>2</sup>

Sarah Network Rehabilitaion Hospitals, Brasilia, Brazil. <sup>2</sup>Brasilia University, Brasilia, Brazil

#### **BACKGROUND**

The loss of a part of the body can cause physical, psychological and social disturbances. Frustration with goals resulting from functional disabilities may lead individuals to adopt meaning-building strategies, such as reorienting their priorities and understanding functional disability, trying to find benefits in their limb loss. There is a redefinition of meanings and expectations as a way of confronting the situation and the years to come.

#### AIM

To describe and understand the perception of people with lower limb amputation on the experience of amputation and the changes that occurred after it.

## **METHOD**

A semi-structured interview was carried out with 10 patients with lower limb amputations, with time since surgery of more than six months and using prostheses, which are accompanied longitudinally, in a rehabilitation hospital. The researcher conducted the interviews. The audio recordings were transcribed in full and the results obtained from the analysis of the speeches of the participants of the interviews through the Iramuteq software. Data regarding sociodemographic characterization and amputation were obtained in electronic medical records. The data were collected in an orthopedic workshop of a rehabilitation hospital, Brazil.

#### **RESULTS**

The sample consisted of 10 participants, mean age 42.5 years, singles 50% and above the knee 90%. Trauma corresponds to 50%, with mean time of amputation in 21 years and the average time of use of the prosthesis 13.4 hours / day. The perception of people with lower limb amputation was categorized into five themes: becoming an amputee, a sense of pain, prejudice and barriers, resumption and overcoming and sense in the use of the prosthesis. While becoming an amputee was more related to the need to accept oneself and the relations with relatives, in the theme of prejudice and barriers, the participants punctuated the society's gaze, this theme being the most expressive. Resumption and overcoming are associated with the beginning of use of the prosthesis. The aesthetic or functional value was pointed in the direction of use of the prosthesis.

# **DISCUSSION AND CONCLUSION**

Participants described feelings in the physical, psychological and social domains. They reinvented their lives, reporting to two distinct moments of existence, before and after the amputation, from the look of themselves and the society in which they are inserted. Initiating the use of prosthetics represented an important aspect of identity recovery, such as returning to work, engaging in routine activities and recovering that coherent identity and objectively valued having his life back.



## 3.4.6.f

# Use of the Theory of Planned Behaviour to Predict Adherence to Use of AFOs in People with Stroke

Christine McMonagle <sup>1</sup>, Susan Rasmussen<sup>2</sup>, Mark Elliott<sup>2</sup>, Robbie Rooney <sup>3</sup> <sup>1</sup>NCPO, Department of Biomedical Engineering, University of Strathcylde, Glasgow, United Kingdom. <sup>2</sup>School of Psychological Sciences and Health, University of Strathcylde, Glasgow, United Kingdom. <sup>3</sup>NHS Lanarkshire, Wishaw, United Kingdom

#### **BACKGROUND**

Ankle-foot Orthoses (AFOs) can be used to effectively manage impairments to gait, following a stroke. However, non-adherence to orthoses is an inefficient use of resources, and poor adherence is also associated with poorer outcomes in physical and mental health. Use of a theoretical model of behaviour to understand adherence to AFOs is important because interventions based on theory are more likely to be successful in changing behaviour. One such model, is the Theory of Planned Behaviour (TPB).[1]

## **AIM**

This investigation aimed to examine the utility of the TPB as a model for predicting intention and adherence to AFO use in people with stroke.

## **METHOD**

A prospective design was employed. Forty-nine participants who had been prescribed an AFO following stroke in NHS Lanarkshire, Scotland, completed a TPB postal questionnaire. The TPB constructs of attitude, subjective norm, perceived control, and intention were measured at time 1 and behaviour was measured, one month later. Regression analyses were conducted to identify predictors of intention to use an AFO as recommended and actual use of the AFO. Correlations between the underlying beliefs, their global constructs, intention and behaviour were analysed to identify the most appropriate beliefs which might be targeted in a future intervention to increase adherence to use of AFOs in people with stroke.

## **RESULTS**

Adherence to use of AFOs as recommended was 63%. The TPB was able to account for 57% variance in intentions and 42% variance in use of AFOs as recommended. Attitude was the only significant predictor of intention, and intention was the only significant predictor of behaviour. The attitudinal beliefs positively associated with intention to use an AFO were: using my AFO will; increase my mobility (r=.50, p<.001); and help me to improve during rehabilitation (r=.32, p=.04). The attitudinal beliefs negatively associated with intention were: using my AFO as recommended; will be heavy (r=-.55, p<0.01); cause me pain or discomfort (r=-.33, p=.03); and requires a lot of effort (r=-.30, p=.049). Attitudinal beliefs positively associated with AFO use were: the AFO will: increase my mobility (r=.52, p=0.01); and prevent falls/ aid balance (r=.33, p=.045).

# **DISCUSSION AND CONCLUSION**

The significant amount of variance accounted for suggests the TPB is a useful model for understanding adherence to AFOs in this patient group. This study provides a valuable preliminary strategy for the development of an intervention designed to increase adherence to use of AFOs in people with stroke. A future intervention could promote positive attitudes and intentions towards AFO use, for stroke survivors.

### REFERENCES

[1] Ajzen I, Organizational Behavior and Human Decision Processes, 1991; 50(2):179-211.

#### **ACKNOWLEDGEMENTS**

Chest, Heart and Stroke Scotland, NRS Stroke Research Network and Orthotics Education and Training Trust (OETT) supported this work.



# 3.4.6.g

# Disaster Relief to Recovery: Community Based Assistance for Older Adults in Puerto Rico post Hurricane Maria

<u>Sarah Schuyler</u>, Danielle Butin The Afya Foundation, Yonkers, USA

#### **BACKGROUND**

In response to Hurricane Maria in Puerto Rico, Afya coordinated and mobilized a coalition of local and international partners to meet urgent healthcare requests for older adults, in real-time. Afya's disaster relief model rests in supporting the development of a comprehensive, sustainable and replicable medicinal system. This is achieved by incorporating the existing infrastructure while responding to frontline heathcare workers' expressed needs during the transition of disaster relief through recovery.

#### AIM

Develop a reliable disaster relief chain and pilot a disaster recovery program to impact, in a quantifiable way, health care delivery for older adults.

## **METHOD**

During the disaster relief phase following Hurricane Maria, a local team reviewed conditions at older adult homes following an assessment training with Afya senior staff. They assembled accurate and holistic needs-lists ensuring each shipment was specifically adjusted to the conditions of recipients. Air cargo schedule, detailed packing lists, weights and financial evaluation was prepared for each shipment with last-mile distribution reported daily. As Puerto Rico transitioned to disaster recovery, Older Adult Providers requested training and psychosocial support which was developed and executed in training sessions including individual case review. Additionally, focus shifted to rural/hard-to-reach supply deliveries to increase the scope of older adults who can be treated.

#### **RESULTS**

In 30 shipments, Afya delivered 200,000 lb valued at \$6.2 million, impacting 20,000 individuals throughout the course of both disaster relief and recovery. The relief initiative reached more than half of all Puerto Rico older adult homes, including 400+ sites visited and a total of 7,000 elders benefitting from supplies delivered. At approximately 8 months, there was a distinct transition to recovery. The monetary value of supplies was significantly less during recovery versus relief. One hundred older adult providers and community leaders throughout the island completed a Psychosocial Support Training Program. An additional 1,000 older adults received supplies in rural and hard-to reach areas, incorporating 25 more municipalities to the overall impact.

## **DISCUSSION AND CONCLUSION**

The need for geriatric home care assessments, supply support and training, is pervasive. During disaster relief, private-public partnerships, was paramount. By focusing supply delivery to areas where care is limited during recovery, the social safety net is extended providing much needed relief to a recovering and resource-poor community. Utilizing supply chain expertise and a holistic approach, Afya ensures the provision of medical supplies to older adults. This program has enormous potential for replication and impact throughout the world.

#### **ACKNOWLEDGEMENTS**

Greater New York Hospital Association, UJA-Federations of New York, US Department of Justice, Accion Social, Russel Berrie Foundation



# **Basic IC**

#### 3.4.7

# **Establishing Standardized Processes for Professional Ethics and Disciplinary Programs**

#### Stephen Fletcher

American Board for Certification in Orthotics, Prosthetics and Pedorthics, Alexandria, USA

#### **Abstract**

O&P organizations should have legally defensible disciplinary rules and procedures when determining the validity of claims of unethical conduct by their credential holders/members. The procedures must provide for due process and transparent communications between parties. Common mistakes include failure to follow an organization's own rules and procedures, poor communication with certificants/members, failure to conduct comprehensive and timely investigations, failure to follow past precedent, breaches of confidentiality and a lack of oversight of the ethics committee. Establishing a clear, fair and legally defensible ethical disciplinary structure is critical to the integrity of the O&P profession. Patients and referral sources expect accountability and a predictable process when there is a question of unethical behavior. This course will discuss best practices and give examples of the US professional discipline program.

# Statement of the objective / learning objectives

Participants will learn the importance to O&P governing entities of establishing a consistent, fair and defensible ethical disciplinary process. Due process and transparency are critical for the profession and these concepts will be described.



# Free Paper Session Orthotics & Prosthetics - Modeling and Fabrication

# 3.4.8.a

# Digital Mapping of Clinician Behavior during AFO Fabrication

Zhanzi Wang<sup>1,2</sup>, Harold Matthews<sup>3</sup>, Jonathon Lillia<sup>1</sup>, Daniel Balassone<sup>1</sup>, Lei Bi<sup>2</sup>, Jinman Kim<sup>2</sup>, Joshua Burns<sup>2,1</sup>, <u>Tegan Cheng</u><sup>1,2</sup>

<sup>1</sup>Children's Hospital at Westmead, Sydney, Australia. <sup>2</sup>University of Sydney, Sydney, Australia. <sup>3</sup>Murdoch Children's Research Institute, Melbourne, Australia

#### **BACKGROUND**

Traditional fabrication methods for ankle-foot orthoses (AFOs) involve the use of plaster to create and modify lower limb positive casts. These plaster modifications are added by the orthotist to improve comfort and control the fit of the final AFO. However, there have been no studies that describe or quantify (map) these modifications.

#### AIM

This study aims to characterize and digitize the actions of the orthotist during modification steps, including the location and magnitude of plaster additions, to aid in our understanding of an ideal AFO modification.

#### **METHOD**

Plaster casts of children's lower limbs (n = 50) were obtained from the Orthotics Department (Children's Hospital at Westmead, Sydney, Australia) under an approved human ethics protocol (LNR/17/SCHN/242). Any child prescribed AFOs at the Hospital was eligible for inclusion. Pre- and post-modified casts from one orthotist were 3D scanned using a light-based scanner (Eva, Artec Luxembourg). 3D scans were registered using 3-matic (Materialise, Belgium) and compared using CloudCompare and analyzed in Matlab (Mathworks, MA, USA). The test-retest and intra-rater reliability of mesh registration was assessed using intraclass correlation coefficient (ICC). Mean modification distance (MMD) is the normal difference in position between the pre- and post-modification casts.

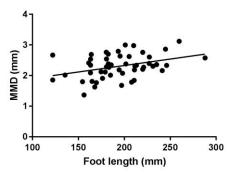


Figure 1. Mean modification of plaster casts during AFO fabrication plotted against patient foot length

# **RESULTS**

Participants included in this study ranged from ages 1 to 18 years (mean 8.6, SD 3.5) with 62% male. The most common condition was cerebral palsy (52%) followed by congenital talipes equinovarus (14%) and spina bifida (6%), who were prescribed fixed (60%) or hinged (32%) AFOs. Mesh registration was assessed for test-retest and intra-rater reliability was found to be excellent (ICC = 0.99). The MMD for all casts was 2.3 mm +/- 0.4mm. The areas of largest plaster modification were the plantar surface of the foot and the lateral and medial sides of the ankle. There was a weak trend between MMD and foot length (Fig 1,  $r^2 = 0.136$ ), and no relationship with patient age or AFO type.

# **DISCUSSION AND CONCLUSION**

This study has found cast modifications occurred regularly at key locations with similar amounts of plaster added and/or subtracted regardless of foot size or age of the pediatric patient. Future studies will expand patient cast numbers and include more orthotists. Thus, this study has quantified and visualized the behavior of an orthotist during the manual modification of plaster casts during AFO fabrication.

# **ACKNOWLEDGEMENTS**

Dr. Tegan Cheng was supported by the Thrasher Research Fund Early Career Award Program.



## 3.4.8.b

# **Novel Strain-Stiffening Structures for Applications in Orthotic Devices**

<u>Michael Timmermann</u>, Sören Kaps, Rainer Adelung, Dr. Christine Selhuber-Unkel University of Kiel - Institute for Materials Science, Kiel, Germany

#### **BACKGROUND**

Strain-stiffening materials increase their stiffness in response to deformation. Examples for this special material behavior can be commonly found in nature. One example is skin. Consequently, it would be favorable for materials used in orthoses and prostheses to mimic this behavior and provide a skin-like wearing comfort. Additionally, if included in novel bandages, strain-stiffening materials are soft and comfortable as long as they are moved in the correct direction; if wrong movements are made they become stiff and block motion.

#### AIM

We aimed at developing a strain-stiffening structure that shows a reversible and rate independent stiffening and high flexibility in the choice of underlying materials. Today's commercially available materials lack either one or more of these properties.

## **METHOD**

We have developed an approach that is based on pure structuring of a material and can be applied to any elastic material. The resulting structure shows full reversibility of the stiffening effect and the effect occurs independent of the rate of deformation. The structure contains blocks of parallel arranged slats that touch upon a pre-defined deformation. Touching of the slats introduces an increase of the structure's stiffness. With the help of computer simulations we were able to detect all geometrical parameters that have an influence on the stiffening behavior of the structure and the results were experimentally verified.

#### **RESULTS**

Computer simulations (finite element method) as well as mechanical testing of the structure, verifying the simulated results, showed that we are able to tune the initial stiffness of the structure, the degree of deformation before the switching between soft and stiff as well as the final stiffness of the structure. This is achieved by choosing an applicable underlying material and optimizing certain geometrical factors of the structure towards the desired strain-stiffening behavior.

We have also set up the method to predict the mechanics of the material without the need of computer simulations. This will allow to quickly adapt the structure and its mechanical properties to application dependent load cases. Finally, to present the possibilities of the material we have set up several demonstrators.

## **DISCUSSION AND CONCLUSION**

As the developed structure can be applied to all elastically behaving materials, it does not only show fully reversible and rate independent strain-stiffening behavior, but can also be produced with materials that are already certified to be used in orthotic devices. We suggest that the strain-stiffening structures could be part of novel and comfortable orthotic devices that could replace stiff splints for the cure of orthopedic traumata of the lower limbs, like ligament ruptures.

# **ACKNOWLEDGEMENTS**

We would like to thank the European Research Council for funding this project with the Proof of Concept Grant No.812943.



# 3.4.8.c

# Recycled Plastics: An Alternative Material for Prosthetic Check Socket Fabrication

<u>Feliz Nicole Arcilla</u>, Anna Katrina Garcia, Andre Dominic Rubiano, Marc Andre Sarthou, Anna Margarita Lugue UERMMMCI, Quezon City, Philippines

#### **BACKGROUND**

Plastic wastes comprise 17% of the total waste in the Philippines. Check Sockets are transparent version of prosthetic sockets that allow accurate inspection of the limb during fitting procedures. Polyethylene Terephthalate Glycol (PETG) is a thermoplastic often used for fabricating check sockets. Properties that enable PETG to fulfill check socket requirements are (1) vicat softening point, (2) tensile strength, and (3) impact resistance.

#### AIM

To develop an alternative material to virgin plastics in fabricating prosthetic check sockets. Specifically, to determine its material properties and to compare it against the standard check socket, PETG.

#### METHOD

Alternative materials were made from recycled plastic bottles, sando bags and a plasticizer. A two-roll mill and compression molder was used to fabricate the alternative materials for the test. All samples were prepared and tested according to the American Standard for Testing Materials (ASTM) for each property test. Kruskal-wallis test with Post-hoc analysis of Mann-Whitney-U test (p-value: 0.05) was used for Impact Resistance test results while Descriptive Analysis was used for Vicat Softening Point and Tensile Strength test results.

#### **RESULTS**

Sando bags performed best against recycled Bottles for all tests, and exhibited acceptable vicat softening point and impact resistance compared to the standard, PETG. On the other hand, Bottles performed poorly in all 3 tests.

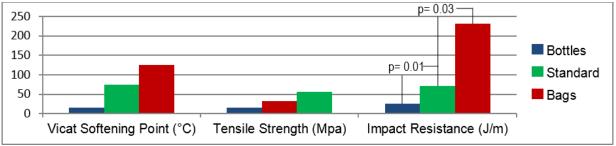


Figure 1. Mean material properties of PETG, Plastic Bottles, and Sando bags

## **DISCUSSION AND CONCLUSION**

Although Sando bags exhibited good potential as an alternative material to the standard, further improvements to tensile strength should be undertaken. A possible cause for general failure of both Bottles and Sando bags can be due to fabrication method, reinforcement used, and recycling generation of raw materials. Sando bags were shown to have acceptable properties as an alternative to the standard material. However, further testing must be implemented to pass tensile strength.

# **REFERENCES**

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## 3.4.8.d

# Finite Element Simulations in the Virtual Safety and Performance Assessment of Individualized Prosthetics & Orthotics

<u>Benjamin Gröschel</u>, Franziska Glas, Bence Rochlitz Mecuris, Munich, Germany

## **BACKGROUND**

In the United States, virtual certification of 3D-printed medical devices based on FE simulations is already recognized. For the first time, a digital process chain will be established in Germany, which enables the virtual quality assurance of individualized prostheses and orthoses. Thereby the focus is developing and validating a set of virtual test benches and models for design optimization as well as quality prognosis.

#### AIM

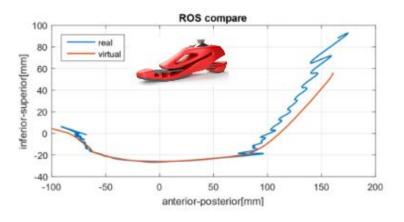
To assure the quality of 3D printed individual prosthetics and orthotics a digital process chain is developed using FE simulations to virtually evaluate parameters of performance and safety individually for each patient.

#### METHOD

For the digital process chain virtual test benches are built and validated against physical test benches according to ISO norms. We compare not only outcome parameters like Roll Over curves, but also strain values to verify whether the computation of the real and virtual strain yields the same result. All virtual test bench results are based on finite element analysis in computer simulations. Crucial parameters in the validation of a virtual test bench is the modeling of loading conditions as well as material behaviors. Hence, we perform research in material theory in order to not only prognose a static loading behavior but predict fatigue behaviour of 3D-printed material.

#### **RESULTS**

First results have shown promising similarities of real and virtually tested strains in our simulation-based test benches. Next to the safety testing of ISO 10328, we focus on adapting prosthetic and orthotic devices by performance parameter like the roll over shape of ISO 22675 / ISO 16955. This enables the creation of virtually optimized and individualized, orthopaedic devices. The Roll Over Shape of our virtual test bench shows a great overlap with the curves of the physical setup. Beyond the normative standards, we evaluate movements and contributed forces of



children's O&P products. As there are no standards describing the performance and safety criteria for children, we can use our easily adaptable virtual test benches to improve products specifically for the challenging field of pediatric care.

# **DISCUSSION AND CONCLUSION**

By combining a multitude of 3D technologies in one intuitive Solution Platform, we want to enable orthopaedic technology to step into the digital age. We exploit the broad portfolio of virtual design, testing and manufacturing in our digital process chain. The quality inspection and optimization by FE simulations is integrated into this process chain. Our goal is to ensure quality in safety and performance of each individualized product for the needs of each wearer.



## 3.4.8.e

# A Finite-Element Model of a Passive Dynamic Ankle-Foot Orthosis to Characterise its Offloading Capacity

<u>Kirstie Edwards</u>, Grigoris Grigoriadis, Diagarajen Carpanen, Arul Ramasamy, Spyros Masouros Imperial College London, London, United Kingdom

#### **BACKGROUND**

The prescription of a custom made passive-dynamic ankle-foot orthosis (PD-AFO) has been shown to greatly improve functional outcomes for limb salvage patients following traumatic injury.[1] The PD-AFO consists of a carbon fibre cuff and base with two posterior struts. Although the PD-AFO has improved functional outcomes, the amount it offloads the hind foot has not been quantified before.

#### AIM

To develop a finite element (FE) model of the PD-AFO to allow characterisation of its offloading capacity.

## **METHOD**

The PD-AFO was compressed to a maximum of 10mm at a rate of 0.05mm/s in a materials testing machine (INSTRON 5866). Two different locations on the PD-AFO were loaded (Fig.1). A resin base was produced to ensure the posterior struts were parallel to the direction of loading. Axial compression of the struts was carried out to quantify their material properties.

A CT scan of the PD-AFO was segmented and an FE model developed. Boundary conditions were chosen to mimic the experiments. The resin and cross head were assumed rigid. Results from anterior loading were used in an inverse FE algorithm to determine the material characteristics of the base and cuff.

#### **RESULTS**

The material properties of the components of the PD-AFO were determined. The struts were found to be linearly elastic with a Young's Modulus of 12.8±0.7GPa. From the inverse FE algorithm, the Young's Modulus of the base and cuff was found to be 7.17GPa. Using these properties, the stiffness of the PD-AFO ascertained experimentally in posterior loading, was 10% stiffer computationally.

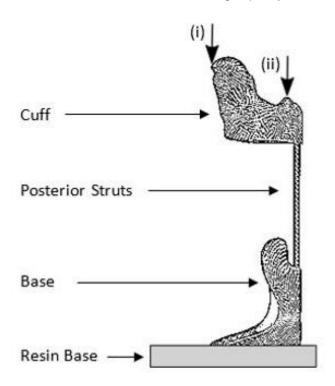


Figure 1: (i) Anterior loading configuration (ii) Posterior loading configuration

## **DISCUSSION AND CONCLUSION**

Preliminary validation of the FE model was completed in this study. Anisotropic material properties need to be considered to further improve the accuracy of the model. The model will be used in conjunction with an FE model of the leg to characterise the offloading capabilities of the PD-AFO.

#### **REFERENCES**

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#### **ACKNOWLEDGEMENTS**

We thank Blatchford for provision of the PD-AFO and the Royal British Legion for funding the study.



## 3.4.8.f

# Modeling the Biomechanical Requirements of Reciprocal Gait with Orthoses for Persons with Lower Limb Paralysis.

#### W Brett Johnson

Massachusetts Institute of Technology, Cambridge, USA

#### **BACKGROUND**

This presentation is about understanding the biomechanical requirements of reciprocal gait with orthoses for people with Lower Limb Paralysis (LLP). Upright ambulation has been thought to have physiological benefits.[1] However, upright ambulation with a reciprocal gait requires a great deal of energy, limiting its utility in daily life.[2] Reciprocal gait places large loads on the upper extremities of persons with LLP through their walking aides, which may contribute to the large energy requirements.[3]

#### AIM

This project uses a computer simulation to identify the shoulder joint forces and moments required for people with LLP to ambulate with a reciprocal gait over a range of kinematic patterns.

## **METHOD**

The stance leg, trunk, arms, and crutches in the sagittal plane were modeled as rigid linked segments. The hips, shoulders, and points of contact with the ground were modeled as hinge joints, while a slide joint between the arms and crutches simulated the action of the upper extremities pushing against the ground. The orientation of

the trunk, stance leg, and arms served as inputs for the model and were varied to explore the effects of trunk posture, step length, and crutch placement on the forces and moments acting at the shoulder joint during leg swing, assuming a passive hip joint.

# **RESULTS**

These varying inputs created different possible paths for the body center of mass during leg swing. Varying the acceleration of the body center of mass along those paths varied the distribution of forces acting on the feet and crutches as well as the shoulder moments (Fig. 1). Certain path accelerations minimized the axial loading of the crutches (grey line), but maximized shoulder

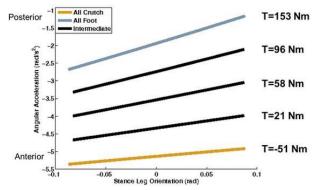


Figure 1: Shoulder joint moments for different accelerations along the same path.

moments (T). Increasing forward (anterior) acceleration down the path transferred more force to the crutch while decreasing shoulder moments (black lines) until reaching the maximum crutch load (gold line). The simulation also showed that reducing step length and increasing trunk flexion with respect to the vertical encouraged anterior acceleration of the body center of mass.

## **DISCUSSION AND CONCLUSION**

The muscle action needed to generate the moments and forces at the shoulder requires energy. Since shoulder forces correlate negatively with shoulder moments, there may exist an acceleration for a given path that minimizes the energy required for that path. Finding this minimum can help people with LLP ambulate more efficiently with passive or powered orthoses. Future work will focus on finding this minimum, and expanding the simulation to include frontal plane motion and the entire gait cycle.

#### **REFERENCES**

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# **ACKNOWLEDGEMENTS**

This research was funded in part by the Ministry of Science and Technology (MOST) in Taiwan (NSC-102-2218-E-002-010; MOST-103-2218-E-002-004; MOST-104-2218-E-002-001).



# **Tuesday, 8 October**

# **Keynote Lecture 4.0**

# Osseo-Neuromuscular Integration of Prosthetic Limbs and Neurorehabilitation from Phantom Limb Pain

Max Ortiz Catalán1

<sup>1</sup>Chalmers University of Technology, Department of Electrical Engineering, Gothenburg, Sweden

### **Abstract**

Technology has the potential to allow patients to reintegrate into society after traumatic events leading to amputations. In addition to the functional challenges associated with amputation, chronic neuropathic pain can further hinder these patients' quality of life. Similarly, children born with congenital limb malformation face functional challenges to overcome what are otherwise lifelong handicaps.

Dr. Ortiz Catalán will present clinically viable neuroprosthetic technologies to restore patients' quality of life. He led the development of the first bionic arm integrated directly into a patient's bone, nerves, and muscles. The first patient implanted with this osseo-neuromuscular interface has used it without interruption in everyday life for over 5 years. Patients implanted with this system are also provided with intuitive sensory feedback via direct nerve stimulation. Direct skeletal attachment via osseointegration, along with control and sensory feedback via implanted neuromuscular electrodes, can now be provided in a self-contained prosthesis for use in daily life without supervision in controlled environments. Originally developed for above-elbow amputations, this technology is now being implemented for below-elbow and lower limb amputations.

Dr. Ortiz Catalán will also discuss novel hypotheses about the origin and treatment of Phantom Limb Pain, and how motor prediction technology in combination with Augmented Reality can be used to treat it.



# **Symposium Rehabilitation Medicine & Surgery**

### 4.1.1

# Enhancing Patient Specific Outcomes by Improving Amputation Level Decision Making in Patients with Peripheral Artery Disease and/or Diabetes

Joseph Czerniecki<sup>1,2</sup>, Michael Dillon<sup>3</sup>, Dan Norvell<sup>4</sup>

<sup>1</sup>University of Washington, Seattle, USA. <sup>2</sup>Seattle VA Medical Center, Seattle, USA. <sup>3</sup>La Trobe University, Melbourne, Australia. <sup>4</sup>CLiMB research center at the Seattle Veterans Administration, Seattle, USA

### **Abstract**

Current health care practices emphasize the importance of providing "patient-centric" health care. That is, patients should be informed about the risks and benefits of different treatment options so that their decisions will best align with their outcome values and preferences. Patients with peripheral artery disease (PAD)/diabetes who require an amputation have been shown to want more information and to want to participate in amputation level decisions. High quality evidence communicated effectively to patients and their providers is critical to optimizing the decision-making process.

One of the most challenging decisions to be made in this population is whether to have a limb sparing distal amputation or a transtibial amputation. Unfortunately, this decision is often informed by overly simplified or inaccurate information. Many believe that distal amputation is critical to the preservation of mobility, and that the primary benefit of transtibial amputation is to reduce the risk of wound failure and secondary amputation. The relative importance of these and other key outcomes to the decision is uncertain. An additional challenge is how to best communicate these risks in the context of this populations poor overall long-term survival.

This symposium will present current research identifying the outcome priorities of patients who are facing dysvascular amputation, the value of patient decision aids in informing outcomes and personal outcome priorities, as well as, the role of decision support tools in informing surgeons about probable patient specific outcomes. Together they support shared decision making and improved outcomes for patients undergoing this life altering surgical procedure.

# Statement of the objective / learning objectives

Understand the outcomes that are important to dysvascular amputees.

The use of patient decision aids to inform amputation level selection.

The use of decision support tools to predict specific amputation level outcomes.



# Advanced IC Orthotics: Lower Limb Neurological

## 4.1.2

# The Role of Microprocessor Controlled KAFOs: Patient Benefit and Results 6 Years After Introduction and Future Perspectives

Thomas Schmalz<sup>1</sup>, Shenan Hoppe-Ludwig<sup>2</sup>, Michael Schaefer<sup>3</sup>, Andreas Hahn<sup>4</sup>

Ottobock SE & Co. KGaA/Clinical Research & Services, Goettingen, Germany. Shirley Ryan Ability Lab, Chicago, USA. POHLIG GmbH, Traunstein, Germany. Ottobock SE & Co. KGaA/Clinical Research & Services, Wien, Austria

### **Abstract**

In 2012, the microprocessor controlled KAFO "C-Brace" was introduced to provide greater mobility and safety to patients with severe deficits in leg control. This system enables controlled knee flexion during weight bearing and variable speed during swing, providing features not available in conventional KAFO or SCO designs. Together with a state-of the art safety algorithm, patients with complex lower limb muscle paralyses are able to execute a wide range of ADLs in a safer and biomechanically more effective way.

Following an overview of known KAFO principles, the symposium highlights to date's evidence showing the benefits experienced by patients. The symposium summarizes results from the biomechanical comparisons between C-Brace and conventional KAFOs, measured in different ADLs. Both clinical and biomechanical parameters document that the primary patient benefit of fittings with C-Brace is an increased level of safety. Results from a first landmark randomized controlled trial confirm such findings. Early investigations on the latest C-Brace generation demonstrate further improvements with respect to safety and usefulness in daily life. Examples of practical patient fittings show that the use of the C-Brace principle enables patient performances and quality of life that are not achievable with KAFOs based on conventional orthotic knee joint principles.

# Statement of the objective / learning objectives

Based on scientific data and clinical fittings examples, the symposium demonstrates benefits that patients with severe deficits in leg control can expect from use of a microprocessor controlled KAFO "C-Brace".



# Symposium Developing Countries

## 4.1.3

# Digital Technologies for the Benefits of the Users for Equitable Access to Rehabilitation Services in Challenging Contexts

<u>Jerome Canicave</u><sup>1</sup>, <u>Pierre Moreau</u><sup>2</sup>, <u>Isabelle Urseau</u><sup>3</sup>

<sup>1</sup>Independant, Antananarivo, Madagascar. <sup>2</sup>Medecins Sans Frontieres Foundation, Paris, France. <sup>3</sup>Humanity and Inclusion, Lyon, France

### **Abstract**

**Humanity and Inclusion** implemented a pilot project in 2016 about the use of digital technologies (*CAD*, 3D printing) for the supply of trans tibial prostheses in Togo, Madagascar and Syria, In order to confirm and scale up the first results *Humanity & Inclusion* (HI) proposes different projects. Through scientific studies and evidence-based results, the new projects aim to demonstrate that the use of innovative solutions allows better access to services while meeting quality requirements. Thus clinical and technological trials are conducted in various contexts through partnerships with local professionals, universities and companies specialized in new technologies:

- In West Africa (Togo, Mali, Niger) a university research allows the comparison of the effects of conventional orthotic equipment with a 3D orthosis printed for 100 people.
- In Syria, the equipment of 50 people waiting for a trans tibial prosthesis is performed remotely by rehabilitation's professionals, specialists in digital technologies and 3D printing.
- In Madagascar, technological research aims to provide 3D printed tibial prostheses at much lower costs than those proposed during the 2016 pilot project.

**Doctors without Borders** (MSF Foundation) in 2017, initated the "3D Project" at the MSF Amman Reconstructive Surgery Hospital with the aim of evaluating the feasibility of locally designing, manufacturing and fitting customized 3D printed upper limb prostheses and 3D assisted burn facial orthosis for pressure therapy, while providing comprehensive clinical care. The multi---disciplinary team included local staff and expats from several specialties including P&O, physiotherapy, occupational therapy and biomedical engineering.

## Statement of the objective / learning objectives

Projects above offer a unique opportunity to develop innovative technologies in African and Middle East contexts and will provide comprehensive responses for the benefits of populations who currently do not have access to rehabilitation services



# Advanced IC Prosthetics: Lower Limb Transfemoral

## 4.1.4

# The Experience of Providing Low Activity Trans-Femoral Prosthetic users with Microprocessor Knees (MPK): Who Benefits?

<u>Fiona Davie-Smith</u>, <u>Bruce Carse</u> NHS GG&C, Glasgow, United Kingdom

### **Abstract**

Transfemoral prosthetic users are faced with many challenges; increased metabolic effort to walk, reduced walking speed and increased risk of falling. Many of the less active prosthetic users' ambulatory status is so poor that average activity levels fall below the sedentary level. Lack of exercise and the risk of falls often affect their ability to continue with prosthetic use which impacts upon their quality of life.

Funded by compensation claims, MPKs have been prescribed in the UK private sector for many years and NHS Scotland has been providing MPKs to K2-K4 activity users since 2014. As a large number of the lower activity users are generally older they present with their own unique set of complications such as reduced cognition, contralateral limb issues and co-morbidities. In addition, their goals are often more task specific to overcoming low level environmental barriers i.e. stairs in and out of the home and working in their garden or kitchen without a walking aid.

This course will give an overview of this cohort and outline who have and have not benefited from MPK prescription and why. We will evidence this with demographic descriptors, objective functional and gait lab outcome measures and qualitative user feedback. Through the use of case studies, we will also highlight the physiotherapy implications for the rehabilitation of these users and prescription considerations. This course is intended for prosthetists, physiotherapists and rehabilitation consultants who wish to gain an insight into the experience of provision of MPKs in the lower activity level patient.

### Statement of the objective / learning objectives

This will assist the audience to accurately identify which lower activity users are most likely to benefit from MPK provision, whilst developing an understanding of the unique challenges faced by this specific cohort of users.



# **Free Paper Session**

# **Prosthetics: Lower Limb Transfemoral - Gait**

### 4.1.5.a

# Stance Phase Duration Estimation from Inertial Sensors in a Population of People with **Transfemoral Amputation: Comparison of Five Algorithms**

Emeline Simonetti<sup>1,2,3</sup>, PhD Coralie Villa<sup>1,2</sup>, PhD Joseph Bascou<sup>1,2</sup>, MD Isabelle Loiret<sup>4</sup>, PhD Elena Bergamini<sup>3</sup>,

PhD Giuseppe Vannozzi<sup>3</sup>, PhD Hélène Pillet<sup>2</sup>

<sup>1</sup>INI/CERAH, Créteil, France. <sup>2</sup>Arts et Métiers ParisTech / Institut de Biomécanique Humaine Georges Charpak, Paris, France. <sup>3</sup>University of Rome "Foro Italico"/ Laboratory of Bioengineering and Neuromechanics of Movement, Roma, Italy. <sup>4</sup>Institut Régional de Réadptation, Ugecam Nord-Est, Nancy, France

Stance phase duration (SPD) is a key descriptor of gait function and quality in people with transfemoral amputation (TF). Its quantification may assist therapists in decision-making during rehabilitation and in prosthetics prescription.[1] Heel strikes (HS) and toe offs (TO) detection is crucial for SPD estimation.[1-7] Although many algorithms have been proposed to identify these events from inertial measurements units (IMU). only two were specifically designed for TF and they were not compared to other published algorithms. [2,3]

### AIM

The aim of this study was to quantify the accuracy of 5 algorithms in estimating SPD in TF. The results were compared to reference values derived from insoles data.

### **METHOD**

Six TF were instrumented with 3 IMUs (100Hz) over their shanks and sacrum, synchronized with pressure insoles (100 Hz), used as reference for HS and TO detection. Participants walked at 3 self-selected speeds (slow, comfortable, fast) along an 8-meter pathway. Five algorithms were implemented and used to identify gait events from the shanks (M-S. M-T. M-L, M-M) [2-5] or the sacrum IMU (M-MC).[6] The performance of the algorithms was compared in terms of events detection rate (expressed as a percentage of the total number of events to detect) and accuracy of SPD estimates (quantified as the average and standard deviations of the error relative to the reference).

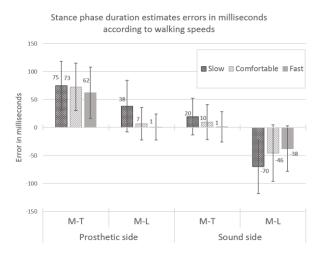


Figure 1: Stance phase duration error estimates in ms using M-T and M-L algorithms compared to pressure insoles.

### **RESULTS**

Only M-T and M-L resulted in a negligible rate of extra events (less than 0.5%). Thus, only SPD estimated with these two methods was evaluated in the present abstract. Figure 1 shows the error compared to the reference for the three walking speeds.

# **DISCUSSION AND CONCLUSION**

Our results confirm the performance of M-T and M-L algorithms for SPD estimation. SPD estimates were more accurate with M-L for the prosthetic side and with M-T for the sound side. This suggests that combining both algorithms should allow reaching a reasonable accuracy for SPD clinical interpretation.[7] Although these results should be interpreted in the light of the context-specific minimum clinically important difference, they open important perspectives for patients' progression monitoring and long-term follow-up directly in-the-field.

## **REFERENCES**

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- [3] Ledoux, IEEE Trans Biomed Eng 2018.
- [5] Trojaniello, J Neuroeng Rehabil 2014.
- [7] Trojaniello, Gait Posture 2014.

- [2] Magbool, IEEE Trans Neural Syst Rehabil Eng 2017.
- [4] Selles, IEEE Trans Neural Syst Rehabil Eng 2005.
- [6] McCamley, Gait Posture 2012.

### **ACKNOWLEDGEMENTS**

This study is supported by the Fondation des Amputés de Guerre de France and the Université Franco-Italienne.



### 4.1.5.b

# Spatio-Temporal Variables of Trans-Femoral Amputees' Walking

Tahmineh Rezaeian<sup>1</sup>, Pouyan Mehryar<sup>2</sup>, <u>Mahboobeh Mehdikhani</u><sup>3</sup>, AminReza Khandan<sup>4</sup>, Neil Messenger<sup>1</sup>, Daniella Strauss<sup>1</sup>

<sup>1</sup>School of Biomedical Sciences, University of Leeds, Leeds, United Kingdom. <sup>2</sup>Institute of Design, Robotic, and Optimisation, University of Leeds, Leeds, United Kingdom. <sup>3</sup>Institute for Health and Sports, Victoria University, Melbourne, Australia. <sup>4</sup>Faculty of Mechanical Engineering, Sharif University of Technology, Tehran, Islamic Republic of Iran

### **BACKGROUND**

The mobility of lower limb prosthesis users might be different from non-amputees. In addition, limb loss affects their balance during daily activities which might lead to falling. More than half of lower limb amputees (LLAs) have at least one falling experience each year.[1] While research show evidences about the positive effects of insoles use on balance [2] which might be beneficial for LLAs. In this paper, spatio-temporal variables of transfemoral amputees and non-amputees during walking with/without insoles are presented.

### ΔIM

To assess the differences between non-amputee and trans-femoral amputees' walking in terms of spatio-temporal variables and probable effects of a commercial insoles use (for intact side of LLAs and both feet of non-amputees) on these variables.

### **METHOD**

Ten male unilateral trans-femoral amputees (5 fallers -55±5.34 yrs, BMI=26.74±4.41 kg/m², 5 non-fallers -55.2±12.19 yrs, BMI=26.27±4.66 kg/m²) and 14 non-amputees (aged 27.36±5.82 yrs, BMI=24.58±4.8 kg/m²) participated in the study. All participants were in good health and able to walk without assistive devices. Biomechanical data were recorded by utilizing a motion capture system (based on reflective marker tracking) and two force platforms. A pair of commercial insoles (Dr.Scholl's® P.R.O.) was provided for each participant. Participants walked in their comfortable speed and 3 successful trials (contact of each foot with one force platform) were recorded. One stride of each leg was analysed to extract the variables.

### **RESULTS**

Spatio-temporal variables of two groups have been shown in Table 1. As it is seen non-amputees had a more efficient walking with higher speed, longer step and stride lengths and symmetry between right and left variables. Amputees had spent longer time on their IL and had longer double support time particularly during PL step. In the comparison of faller and non-faller amputees also fallers had lower velocity (0.65 m/s vs 0.88 m/s for non-fallers) and less symmetry between IL/PL. The stride time of IL was shorter for fallers (1.16s vs 1.3s) while their PL stride time was longer (1.6s vs 1.3s) which might be due to their more trust on prosthetic side. Insoles had no

significant effect on the variables of amputee and non-amputee participant

		(m/s)	IL step (m)		PL step (m)		R Stride Le		L Stride Le		R	R	R step	L	L	L step
	7		W	Le	W	Le	Le	T(s)	Le	T(s)	Stance Swin	Swing	DS	Stance	Swing	DS
Amputees	Total	0.76	0.16	0.53	0.17	0.56	1.10	1.47	1.10	1.45	70.8%	29.2%	15.8%	62.3%	37.7%	17.1%
	(SD)	(0.18)	(0.04)	(0.04)	(0.03)	(0.06)	(0.10)	(0.24)	(0.08)	(0.22)	(3.4%)	(3.4%)	(1.2%)	(2.6%)	(2.6%)	(2.1%)
	F	0.65	0.15	0.52	0.17	0.55	1.06	1.62	1.06	1.59	71.6%	28.4%	15.2%	63.1%	36.9%	17.6%
	NF	0.88	0.16	0.55	0.16	0.58	1.14	1.31	1.13	1.30	69.9%	30.1%	16.4%	61.6%	38.4%	16.6%
NonAmputees (SD)		1.10	0.09	0.68	0.10	0.65	1.32	1.21	1.35	1.23	63.7%	36.3%	13.9%	63.3%	36.7%	13.7%
		(0.14)	(0.04)	(0.05)	(0.05)	(0.04)	(0.07)	(0.10)	(0.09)	(0.09)	(2.1%)	(2.1%)	(1.9%)	(2.1%)	(2.1%)	(2.1%)
Note: F	with a	t least	one fallir	ng expe	rience d	uring las	st 12 mg	onths, N	F: witho	ut falling	experier	nce. V: w	alking ve	locity, R:	right (IL f	or

### **DISCUSSION AND CONCLUSION**

LLAs have lower efficient walking which was observed in the form of lower speed of walking, smaller step and stride lengths in addition to asymmetrical locomotion and extensive reliance on intact limb (longer stance phase). The observed lower walking velocity and asymmetry in step length, stride time of faller in comparison to nonfaller amputees- which was not affected by insoles use as an orthotic intervention- might be considered as key points in walking training/retraining and rehabilitation exercises.

### **REFERENCES**

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### **ACKNOWLEDGEMENTS**

The authors would like to thank the cooperation of amputee and non-amputee participants in this study.



### 4.1.5.c

# Straight Walking in Unilateral Transfemoral Amputees: Symmetric Mediolateral Force Impulse Through Asymmetric Gait Strategy

Genki Hisano<sup>1,2</sup>, Satoru Hashizume<sup>2</sup>, Motomu Nakashima<sup>1</sup>, Hiroaki Hobara<sup>2</sup>
<sup>1</sup>Department of Systems and Control Engineering, Tokyo Institute of Technology, Tokyo, Japan. <sup>2</sup>Artificial Intelligence Research Center, National Institute of Advanced Industrial Science and Technology (AIST), Tokyo, Japan

### **BACKGROUND**

Straight path walking is the most fundamental and essential functions for gait rehabilitation after lower limb amputation. To maintain the straight path, the net mediolateral ground reaction force (GRF) impulses should be counterbalanced between affected and unaffected limb. GRF impulses can be accounted for by the stance time and the mean mediolateral GRFs. However, little is known about how affected limb of unilateral transfemoral amputees produce net mediolateral GRF impulses to the same extent as unaffected limb.

### AIM

To investigate the mediolateral GRF variables between affected and unaffected limb during straight walking in unilateral transfemoral amputees.

### **METHOD**

Fourteen unilateral transfemoral amputees (10 males and 4 females) were asked to walk in a straight 10-m walkway at their self-selected speeds using their habitual prosthetic components. We recorded the GRF using seven force platforms. From the mediolateral GRFs, we analyzed the net GRF impulse, the stance time, the

mean force and absolute mean medial/lateral force for five successful trials in both affected and unaffected limb. Kolmogorov-Smirnov test was used to check the assumption of normality of data. Further, Wilcoxon signed-rank tests and paired *t*-tests were used to compare dependent variables between affected and unaffected limb.

### **RESULTS**

Fig. 1 showed a representative mediolateral GRF profiles during the stance phase of walking for both limbs. There was no significant difference in net mediolateral GRF impulse between affected and unaffected limb, indicating that participants in the present study could maintain a straight path at each step. However, the stance time of affected limb was significantly shorter than that of unaffected limb (p < 0.01). Further, mean mediolateral GRF of affected limb was significantly greater than unaffected limb (p = 0.02). No significant difference was observed in absolute medial mean force between limbs. However, the absolute lateral mean force of affected limb was smaller than unaffected limb (p = 0.04).

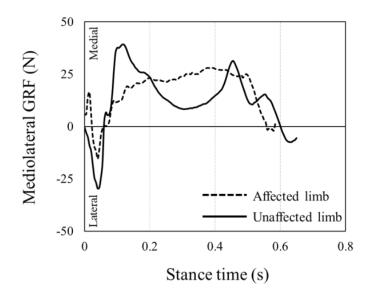


Figure 1. Representative mediolateral GRF during the stance phase of walking (recorded from one participant). Dashed and solid lines indicate affected and unaffected limb, respectively.

### **DISCUSSION AND CONCLUSION**

A previous study indicated that thigh muscle groups mainly contribute to the lateral GRF production.[1] These muscles are lost after transfemoral amputation. Indeed, participants in our study showed a smaller absolute mean lateral force in affected limb than unaffected limb. Consequently, the net mean mediolateral GRF of affected limb was greater than that of unaffected limb. These results suggest that unilateral transfemoral amputees achieved the symmetric mediolateral GRF impulses through asymmetric GRF production strategy for affected and unaffected limb.

## **REFERENCES**

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### 4.1.5.d

# Why don't we see Step Length Asymmetry in Individuals with Unilateral Transfemoral Amputation?

Erik Prinsen<sup>1,2</sup>, Marc Nederhand<sup>1,3</sup>, Han Houdijk<sup>4,5</sup>, Maarten Prins<sup>6,4,7</sup>, Bart Koopman<sup>2</sup>, Jaap Buurke<sup>1,8</sup>, Hans Rietman<sup>1,3,2</sup>

<sup>1</sup>Roessingh Research and Development, Enschede, Netherlands. <sup>2</sup>Department of Biomechanical Engineering, Faculty of Engineering Technology, Technical Medical Centre, University of Twente, Enschede, Netherlands. <sup>3</sup>Roessingh, Centre for Rehabilitation, Enschede, Netherlands. <sup>4</sup>Department of Human Movement Sciences, Faculty of Behavioral and Movement Sciences, Vrije Universiteit Amsterdam, Amsterdam, Netherlands. <sup>5</sup>Department of Research and Development, Heliomare Rehabilitation, Wijk aan Zee, Netherlands. <sup>6</sup>Research and Development, Military Rehabilitation Centre 'Aardenburg', Doorn, Netherlands. <sup>7</sup>Institute for Human Movement Studies, HU University of Applied Sciences Utrecht, Utrecht, Netherlands. <sup>8</sup>Biomedical Signals and Systems, Faculty of EEMCS University of Twente, Enschede, Netherlands

### **BACKGROUND**

A previous study found that step length asymmetry in individuals with unilateral transtibial (TT) amputation might be related to reduced prosthetic push-off.[1] The reduced push-off slows down the forward center-of-mass (CoM) velocity during the double support phase (DSP) in which the intact leg is leading.[1] Reducing intact step length would facilitate CoM progression and enhance backward margins of stability. To our surprise we found no such asymmetric step length in individuals with a unilateral transfemoral (TF) amputation.[2]

### AIM

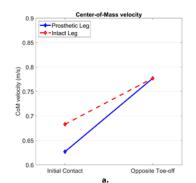
The aim of this study was to investigate why individuals with a unilateral transfemoral amputation do not show step length asymmetry in light of the mechanism described for individuals with a transtibial amputation, despite also showing reduced prosthetic push-off.

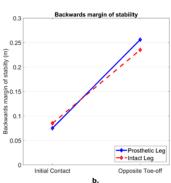
### **METHOD**

Nine individuals with a transfemoral amputation were included, all walking with the Rheo Knee II. Participants walked at preferred walking speed on a treadmill while their gait was recorded with a 12-camera Vicon system. 35 markers were placed according to the Vicon full-body plug-in-gait model. We calculated CoM velocity, by taking the first derivative of the CoM position, and the extrapolated center of mass (XcoM) according to Hof *et al.*[3] We analyzed the CoM velocity, foot forward placement (FFP; distance between the ankle marker and the CoM at initial contact), and the backwards margin of stability (BMoS; distance between the XcoM and ankle marker) during the DSPs.

### **RESULTS**

All data are presented as median scores. As previously reported, the prosthetic and intact step lengths were not significantly different (resp. 43.18 vs 43.35 cm; p=0.678).[2] FFP was not significantly different between legs. In addition, we found that CoM velocity at initial contact was significantly lower for the prosthetic step when compared to the intact step (resp. 0.63 vs 0.68 m/s;p=0.008), while no difference was seen at toe-off of the opposite leg (Figure 1a). Logically, the increase in CoM velocity





during the DSP was also larger for the prosthetic step when compared to the intact step (resp. 0.13 vs 0.06 m/s; p=0.013). BMoS at initial contact was significantly smaller for the prosthetic step when compared to the intact step (resp. 0.074 and 0.085 m; p=0.008) while no difference was seen at toe-ff of the opposite leg (Figure 1b).

# **DISCUSSION AND CONCLUSION**

In people with TF the lack of step length asymmetry is accompanied by a lack of difference in CoM velocity at toe-off between steps which results in a similar BMoS. This is in contrast with a previously studied TT group. Potential explanations might be reduced energy absorption of the intact leg after initial contact preventing CoM velocity to drop, or the substantially lower walking speed in this TF group compared to previously investigated TT groups. These mechanisms need further investigation.

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### **ACKNOWLEDGEMENTS**

We would like to thank Jeroen Olsman, CPO, for performing all prosthetic adjustments.



### 4.1.5.e

# Comparison of Three Methods to Compute the Velocity of the Center of Mass of People with Transfemoral Amputation

Noah Marvisi<sup>1,2</sup>, Céline Lansade<sup>1,2</sup>, Dr Julia Facione<sup>3,2</sup>, Xavier Bonnet<sup>2</sup>, Coralie Villa<sup>4,2</sup>, <u>Helene Pillet</u><sup>2</sup>

<sup>1</sup>Institut Robert Merle D'Aubigné, Valenton, France. <sup>2</sup>Institut de Biomécanique Humaine Georges Charpak / LBM / Arts et Métiers ParisTech, Paris, France. <sup>3</sup>HIA Percy, Clarmart, France. <sup>4</sup>INI/CERAH, Créteil, France

### **BACKGROUND**

The monitoring of the velocity of the body center of mass (vCOM) has applications for both the prosthetic control and the definition of rehabilitation quantitative target. In the literature, three methods have been proposed to compute the kinematics of body center of mass during walking: i/ full body motion capture combined with anthropometric modelling of body segments (SEG) [1] ii/ approximation by a pelvic marker (MARK) [2] iii/ integration of force plates data (FP).[3]

### AIM

The aim of this study was to compare the three above-mentioned methods for the computation of vCOM of people with transfemoral amputation during level walking.

### **METHOD**

Following the approval by the relevant ethics committee, a prospective study was carried out including 8 volunteers with transfemoral amputation. Motion tracking at 100 Hz was performed using a Vicon system synchronized with three force plates used to acquire ground reaction forces at 1000 Hz on a total of 3 meters. vCOM was obtained by the three methods for at least three trials of gait at self-selected walking velocity. The segmentation described in [1] was used for the SEG method. The midpoint of the two posterior pelvic iliac spines markers was chosen for the MARK method. Finally, for the FP method, integration constants were chosen as proposed in [3].

RMS (m/s)	FP vs SEG	MARK vs SEG
Medio-lateral vCOM	0.06 (0.04)	0.13 (0.10)
ero-posterior vCOM	0.04 (0.00)	0.09 (0.01)
Vertical vCOM	0.08 (0.02)	0.06 (0.01)

Table 1. Root Mean Square error of vCOM obtained from MARK and FP methods compared to SEG method – average (SD) for the 8 patients.

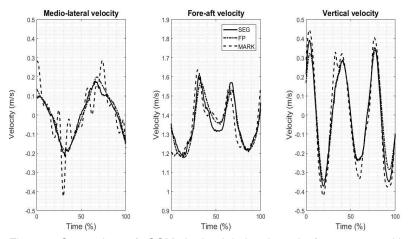


Figure 1. Comparison of vCOM obtained during the gait of one person with transferoral amputation using the three methods.

# **RESULTS**

Figure 1 shows for one person and one trial the evolution of vCOM as a function of time. Root Mean Square Error between both MARK and FP methods regarding SEG method considered as the reference are reported in Table 1.

# **DISCUSSION AND CONCLUSION**

Previous attempts to compare the different methods have focused on displacement or/and excursion in non-amputee population.[4, 5] To the author knowledge, there is no study reporting the velocity of the COM of people with transferoral amputation. Our results highlight the possibility to obtain vCOM in this population from a marker less method, which opens the way to extensive analysis and/or use during the clinical follow-up.

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### 4.1.5.f

# Does Prosthetic Componentry Affect Toe Clearance, Gait Stability and Inverted Pendulum Model Adherence in Unilateral Transfemoral Prosthesis Users?

<u>Cleveland Barnett</u><sup>1</sup>, Amy Sullivan<sup>1</sup>, Liam Hughes<sup>1</sup>, Gerda Strutzenberger<sup>2</sup>, Maria Bisele<sup>1</sup>, Alan De Asha<sup>1,3</sup>
<sup>1</sup>Nottingham Trent University, Nottingham, United Kingdom. <sup>2</sup>University of Salzburg, Salzburg, Austria. <sup>3</sup>C-Motion, Germantown, USA

### **BACKGROUND**

Safety, stability and economy are important factors during walking for unilateral transfemoral (UTF) prosthesis users. Improved toe clearance is safer, reflecting reduced trip risk.[1] Co-ordinated centre of mass (COM) movement and increased margins of stability (MoS), result in economical and stable walking.[2,3] Clinical walking tests are used to infer gait performance. Microprocessor controlled knee (MPK) and hydraulic ankle (HYD) components improve prosthesis users' gait. However, the benefits of their combined use in UTFs is not clear.

### **AIM**

To investigate the effects of MPK and HYD ankle use on gait performance. Specifically, their effects on toe clearance, margins of stability and inverted pendulum model adherence in UTFs during level walking.

### **METHOD**

Individuals with UTF (age 48.8±19.4years, height 1.9±0.02m and mass 90.5±14.7kg) completed two, two-minute walk tests (2MWT) along a 13m walkway at self-selected speeds in four conditions. The conditions were; using an MPK (Orion3, Chas A Blatchford and Sons, Basingstoke, UK) with hydraulically articulating (HYD) and non-articulating (NART) ankle-foot components (Echelon and Esprit, Chas A Blatchford and Sons, Basingstoke, UK). This was followed by a non-MPK controlled knee device (NMPK) with both ankle-foot devices. Conditions were counterbalanced across participants. Reflective markers were placed on the feet and pelvis, with a 13-camera motion capture system (Qualisys AB, Gothenburg, SE) capturing kinematics at 100Hz.

### **RESULTS**

Preliminary analysis (n=3) showed that using MPK and HYD ankle-foot devices improved 2MWD i.e. self-selected walking speed. Analysis of minimum toe clearance, backwards MoS and inverted pendulum model adherence is currently underway.

Table 1. Mean±SD Two-minute walk distance (m).

Variable	MPK+HYD	MPK+NART	NMPK+HYD	NMPK+NART
2MWD (m)	135.1±16.7	128.3±11.4	123.3±15.2	117.8±20.3

### **DISCUSSION AND CONCLUSION**

In terms of gait performance, the preliminary analysis suggested that both MPK and HYD ankle devices benefited UTFs independently. The highest 2MWD was observed when participants used the MPK+HYD in combination. This suggested this combination may reflect an optimal configuration for self-selected speed walking on level ground. Further analysis of toe clearance, backwards MoS and inverted pendulum model adherence is required to elucidate specific gait adaptations related to safety, stability and economy, important factors separate from gait performance.

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### 4.1.5.g

# Gait Outcomes for Children in a Conventional versus Early Prosthetic Knee Prescription Protocol

Mark Geil, Zahra Safaeepour Kennesaw State University, Kennesaw, USA

### **BACKGROUND**

Conventional treatment for young children with limb loss above the knee prescribes a prosthesis without a working knee joint to provide a stable base for development. Alternatively, an "Early Knee" protocol prescribes a working knee in the first prosthesis, during the development of crawling. Previous research has documented aspects of walking of children using the two protocols,[1] but to date no study has compared spatial and temporal gait parameters of independent samples of children using both protocols.

### AIM

The purpose of this study was to examine differences between protocols in gait parameters in young children, along with an age-matched control population of typically developing children.

### **METHOD**

Fourteen children 5 years old and younger in three groups participated in the study, including five children with limb loss at a site where the Traditionally locked (TR) protocol is standard, four children with limb loss at a site where the Early Knee (EK) protocol is standard, and five age-match typically developing children in a Control group (C). Gait analyses were conducted using similar Vicon motion analysis systems at each site. Each child in the TR and EK groups used their own definitive prosthesis. Subjects walked at self-selected speed while kinematics were measured at 100 Hz. Data from both sites were processed by a single researcher at Georgia State.

### **RESULTS**

Bilateral asymmetries were present in both groups. However, children in EK group walked with more symmetrical steps in all categories except step time. The EK group showed longer steps but lower cadence than the TR group. Children in the EK group utilized the passively articulating prosthetic knee for swing phase knee flexion, with an average of 66.7 degrees flexion. Including both limbs and the prosthetic side alone, EK was not significantly different from C in the Gait Deviation Index, while TR was significantly different (p=0.003 overall, p=0.048 prosthetic). Clearance adaptations were present in some children in each group.

### **DISCUSSION AND CONCLUSION**

Children use a knee if provided during the development of walking gait, and subjects in our study revealed no stability concerns using a passively articulating prosthetic knee. There was no definitive improvement in symmetry for EK, apart from swing phase knee motion. EK produces a gait more similar to age-matched typically developing children, although deviations were present in all groups. Because there is no cost associated with early knee prescription, it should be considered as a new standard of care.

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### **ACKNOWLEDGEMENTS**

This research was supported by a grant from the Gerber Foundation (1828-3236).



# Free Paper Session Prosthetics: Upper Limb - Design

### 4.1.6.a

# Design of a Cosmetic Prosthetic Finger with Positionable, Locking, and Uni-lateral Use Features

Jacob Segil<sup>1</sup>, Stephen Huddle<sup>2</sup>, <u>Levin Sliker</u><sup>3</sup>, Richard Weir<sup>2</sup>

<sup>1</sup>University of Colorado at Boulder, Boulder, USA. <sup>2</sup>University of Colorado, Denver | Anschutz Medical Campus, USA. <sup>3</sup>Point Designs LLC, Louisville, USA

### **BACKGROUND**

Amputation can cause physical, psychosocial, and economic damage to an individual and can lead to depression, anxiety, low self-esteem, and social isolation.[1, 2] Upper limb amputees with partial hand amputation out number all other upper limb amputation populations by a factor of 10, however the available technology for partial hand amputees is lacking. Most partial hand amputees are fitted with a cosmetic restoration of the missing digits which is not able to be positioned for functional tasks.

### AIM

The design of a positionable and locking cosmetic prosthetic finger would address many of the needs of those

with partial hand amputation and is not currently available.

### **METHOD**

This work presents the design and fabrication of a cosmetic prosthetic finger with positionable, locking, and uni-lateral use features. Based upon the success of the *Point Digit*, a design process was undertaken to simplify the features, reduce the size of the digit, and enable the use of a cosmetic covering of the digit. Focus groups



Figure 1. A partial hand amputee displaying the intact hand (left), ratcheting cosmetic prosthetic finger (center), and cosmetic covering (right).

were conducted with prosthetists and patients to ensure all user needs were well defined. Then, an iterative design process took place using 3D modeling tools and rapid manufacturing techniques to produce numerous prototypes.

# **RESULTS**

Successful prototypes were produced at the end of the design process (Figure 1). The cosmetic digit design includes a curved knuckle track for anatomical fittings as well as a single-handed use operation. The reduction in number of joints and narrowing of the lateral width of the digit enables the use of a cosmetic covering. Furthermore, the fabrication of the components using metal laser sintering 3D printing ensures that all digit lengths between 55mm and 115mm can be accomplished and thereby fit 5<sup>th</sup> percentile women as well as 95% percentile men.

# **DISCUSSION AND CONCLUSION**

Prior cosmetic restorations for partial hand amputees used wire to maintain the position of the prosthetic digit. Here, we have shown a positionable and locking cosmetic finger which can be operated in a single-handed manner. Previously, this combination of features was not available in a cosmetic prosthetic finger. Future work will focus on the clinical outcome measures when using this technology.

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### 4.1.6.b

# Prosthetic Hand with Hook-Plugin for Holding a Rice Bowl

Modar Hassan<sup>1</sup>, Yukiyo Shimizu<sup>2</sup>, Reiko Watanabe<sup>2</sup>, Luis Ccorimanya<sup>1</sup>, Yasushi Hada<sup>2</sup>, Kenji Suzuki<sup>1</sup> University of Tsukuba, Tsukuba, Japan. <sup>2</sup>University of Tsukuba Hospital, Tsukuba, Japan

### **BACKGROUND**

In Japanese culture, it is customary to hold a rice bowl with one hand and eat the rice using chopsticks with the other hand. There is no research about grasping such dinnerware with a prosthetic hand. Upon the request of one of our visitors, we address this issue with a novel design of a prosthetic hand with a passive hook-plugin to hold bowl-shaped dinnerware. Here we describe the design of the hand, and a preliminary test with the the pilot.

### **AIM**

The aim is to enable users to hold a rice bowl during a meal with a passive plugin to their prosthesis, that is easily attached to the hand, and imposes no restraints on the regular use of the prosthesis.

### **METHOD**

The designed hand consists of three Mechanical Linkage (ML) fingers driven by a single DC motor. This design was selected because it enables controlling 3 fingers to achieve a variety of grasping tasks using only one actuator.[1] The hook is a passive curved beam designed with a 3D printer, that can be attached to the palm of a prosthesis in the radial-distal direction; between the thumb and pointer fingers (Figure 1). Its mechanical function is to provide a third support point for the held rice bowl and to alleviate the weight of the bowl from the fingers and transfer the weight to the palm of the prosthesis.

### **RESULTS**

The pilot was an 11-year-old boy with congenital hand deficiency of the right arm. He can perform basic activities of daily life without a prosthesis. His hope is to eat rice while holding the bowl with his right hand. His right hand ends almost at the wrist joint with rudimentary five fingers. He can pronate and supinate his forearm. He was able to control the prosthesis seamlessly and hold several objects of different shapes (Figure 1). With the hook, he was able to hold an empty rice bowl with minimal effort. We tested the hand with 5 non-amputee persons using Blocks & Box Test.[2] The participants could move  $11.8 \pm 1.3$  blocks in one minute with the prosthesis, and  $46.8 \pm 4.4$  with their own hands.

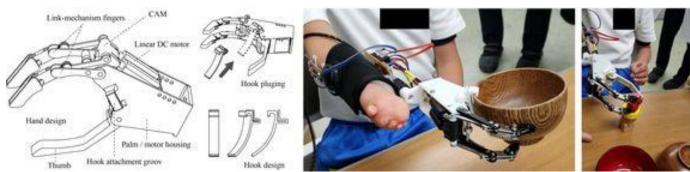


Figure 1. Design of the prosthetic hand, and screenshots from the pilot test.

# **DISCUSSION AND CONCLUSION**

The child amputee gave positive feedback on the prosthesis, but only complained about the weight of the device. The Pro Cuff socket simulator was also uncomfortable for the child. We will consider weight saving techniques in the design of future iterations of the prosthetic hand, better fitting relative to the arm, and proper socket mounting to the forearm. This experience shows that 3D-printed custom attachments could augment the regular function of a prosthetic hand to address specific user needs.

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### 4.1.6.c

# 3D Printed Hand Prosthesis Featuring Articulated Bio-Inspired Fingers

<u>Juan Cuellar</u>, Gerwin Smit, Dick Plettenburg, Amir Zadpoor, Paul Breedveld Delft University of Technology, Delft, Netherlands

### **BACKGROUND**

The role of prostheses (replacements of human body parts) is becoming important with a continuous increase of amputations reported around the globe. 3D printing is an emerging technology that facilitates the manufacturing of parts with complex shapes. This characteristic has opened ways for new design approaches. Several hand prostheses have been designed for 3D printing, however many of the advantages of this manufacturing technique could be used to fabricate prosthetic parts that are based on their biological counterpart.

### ΔIM

The aim of this study is to use a bio-inspired design approach to fabricate articulated fingers for a new hand prosthesis that satisfies basic user requirements.

### METHOD

The design approach of the prosthetic hand is based on the study of the biological construction of the human finger, more specifically the bones and their connecting structures; and continues with the study of the components for movement control in order to design the transmission and actuation system. Some working principles are stablished and different simplifications are considered in order to fabricate the prosthetic hand using a Multi material and filament extrusion-based 3D printer. A mechanical evaluation is then performed in order to measure pinch force and energy usage for the operation of the prosthetic design.

### **RESULTS**

The prosthetic hand can be seen in the Figure and it is 3D printed in PLA, TPU and Nylon. Its total weight is 92 g and its total material price is 12 US dollars. The energy used to operate the hand is 0.380 Nm and the maximum pinch force is ~16 N for an activation force of 100 N. The design proposed in this work shows various features based on biological components of the human hand and was successfully manufactured using 3D printing. The hand is able to perform different grasping patterns thanks to the adaptive grasping delivered by the articulated fingers.



## **DISCUSSION AND CONCLUSION**

The pinch force achieved (~16 N) is higher than another fully 3D printed BP hand prostheses (~6 N) but still not matching other BP hand prosthetic designs (20-60 N). To the extent of the authors' knowledge this is the first bio-inspired prosthetic hand that is 3D printed, body-powered, and has the following characteristics: adaptive grasping, articulating fingers and minimized assembly. In addition, its low cost and low weight makes this prosthetic design a worthy alternative particularly in developing countries.

### **ACKNOWLEDGEMENTS**

The authors aknowledge the Delft Global Initiative for their financial support



## 4.1.6.d

# Paediatric Soft Robotic Prosthetic Hand for Children with Upper Limb Loss

Alireza Mohammadi<sup>1</sup>, Jim Lavranos<sup>2</sup>, Peter Choong<sup>3</sup>, Denny Oetomo<sup>1</sup>

The University of Melbourne, Melbourne, Australia. <sup>2</sup>Caulfield hospital, Melbourne, Australia. <sup>3</sup>St Vincent's Hospital, Mlebourne, Australia

### **BACKGROUND**

The loss of an upper limb severely affects the ability to execute daily tasks and it occurs to people of any age, including those in the prime of their lives and some even from birth. Replacement of an upper limb with a functional prosthetic hand has the potential to return some of the limb functionality. Design of prosthetic hand for children is challenging due to small size and constant growth of their hand.[1]

### AIM

We have designed an anthropomorphic light-weight soft robotic prosthetic hand for adults using 3D printing of compliant materials.[2] The objective of this study is to develop this design to accommodate the children with upper limb loss.

### **METHOD**

The design has conducted with focus on a low complexity interface, to allow intuitive, robust, and reliable control in addition to light weight. This is done by firstly focusing on providing only the most common grasps for the activities in daily living and secondly using 3D printing techniques to manufacture the overall hand with low infill in the structure to reduce the weight. We have realised the two most commonly used grasps: pinch grasp and power grasp. Combined, these grasps will cover more than 70% of the daily activities as reported in [3]. For fabrication of the whole hand, we used a commercially available 3D printer to print TPU90.

### **RESULTS**

Figure 1 shows the kid-size soft robotic prosthetic hand. The proposed design has one motor which pulls five cables, each corresponding to one of the hand fingers. Using different size of the spools for pulling tendon cables of each finger, the hand is able to provide pinch and power grasp. The overall weight of the hand including the controller and actuator is less than 200 gr. Due to the parametrised CAD design of the hand, the dimensions of the hand can be readily customised for different hand sizes. The hand is controlled using two EMG electrodes for opening and closing of the hand. Compliance of the hand enables users to grasp a wide range of object in one specific hand preshape eliminating the need for multiple switching between different grasps.



## **DISCUSSION AND CONCLUSION**

The designed hand is ultra-light, durable, cheap and easy to manufacture. It is readily customisable for different hand size due to parameterised CAD design and using 3D printing techniques. The proposed design addressed the challenges in design of prosthetic hand for children due to their small size and constant growth.

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# **ACKNOWLEDGEMENTS**

This work is supported significantly by the Valma Angliss Trust.



### 4.1.6.e

### Silicone Functional Prostheses for Children with Hand Defects

### Anton Kruglov

LLC Prosthetic and Orthopedic Center Scoliologic.ru, Saint-Petersburg, Russian Federation

### **BACKGROUND**

The individual approach to prosthetics of children with partial hand defects is relevant. The article reveals the possibilities of individual prosthetics, taking into account the needs of children and the wishes of their parents, the resource of the residual function of the hand to manage the prosthesis.

The article reveals examples of the individual construction of a prosthesis for practicing various sports that are interesting for a child.

### **AIM**

Develop and test prostheses for children with partial hand defects for practicing tennis, basketball, swimming, bike, and other activities

### **METHOD**

The group of experimental prosthetics included 32 children. Patients in the study group had various variants of congenital redaction anomalies of the hand, requiring prosthetics. The minimum age is 7 months, the maximum is 13 years. Each child is made functional or functional-cosmetic prosthesis of individual design. The socket of all hand prosthesis for children is made of vulcanized silicone for medical purposes high temperature vulcanization - HTV silicone. The basic principle that is being developed is to simplify the design against the Background of the realization of the child's indicated need.

### **RESULTS**

In the appointment of functional hand prosthesis used an individual approach. Be sure to take into account the request of the parents or the child to perform a specific manipulation, as well as the possibility of using the residual function of the hand when managing the prosthesis or using its passive capabilities.

Studies on the bench showed that a group of children with congenital hand defects, corresponding to the stumps of the hand proximal to the metacarpophalangeal joints, after hand prosthesis functionality increased, and the indicators on the questionnaire "DASN" were down (for conscious patients). This indicated the effectiveness of the supply of functional prosthesis.

# **DISCUSSION AND CONCLUSION**

The introduction of silicone technology allows not only to increase the comfort of wearing a prosthesis in a child, but also to build individual terminal devices. The creation of a close team of an orthopedist, a prosthetic technician and a sculptor artist contributes to the manufacture of convenient individual functional prostheses that solve the tasks of a specific user.



# 4.1.6.f

# Development and Evaluation of a Myoelectric Prosthetic Hand adaptable to Individuality for Children

<u>Yoshiko Yabuki</u><sup>1</sup>, Yuta Murai<sup>1</sup>, Yusuke Yamanoi<sup>1</sup>, Xiaobei Jing<sup>1</sup>, Xu Yong<sup>1</sup>, Yuankang Shi<sup>1</sup>, Shunta Togo<sup>1</sup>, Yinlai Jiang<sup>1</sup>, Takehiko Takagi<sup>2</sup>, Hiroshi Yokoi<sup>1</sup>

<sup>1</sup>The University of Electro-Communications, Tokyo, Japan. <sup>2</sup>National Center for Child Health and Development, Tokyo, Japan

### **BACKGROUND**

Early use of myoelectric prosthetic hands in childhood is effective to prevent muscle degeneration, promote both hands movement, and improve body balance. However, the rate of spread of myoelectric prosthetic hand in Japan is as low as 2 %. Proficiency is the conditional to the provision of myoelectric prosthesis. However, there is few facilities provide proficiency training. The necessity to change socket for children during their growth is another problem.

### AIM

Development of myoelectric prosthetic hands for children that can be mastered without long training, and be used for a long time unaffected by growth.

### **METHOD**

We developed an architecture that control the prosthetic hand according to both the user's situation and the external operation from an assistant. The architecture allows an external assistant to adjust the parameters of the prosthesis controller. In this system, the myoelectric potentials of the upper limb are shown in real time. The assistant can adjust the parameters of the prosthetic hand control device. With this function, children that have difficulty verbally communicating can obtain properly adjusted prosthetic hands.

Furthermore, we proposed a rolled-cloth socket with good air permeability and an opaque glove with high extensibility, which are adaptable to growth.

### **RESULTS**

Using the proposed architecture, the user successfully adapted threshold control to individuality by adjusting the two thresholds in real time. Parents successfully adjusted the parameters for the children who could not adjust by themselves. Elder children could adjust and use by themselves. Furthermore, the highly adaptable rolled-cloth socket was able to be adjusted with hook and loop fastener without considering the thickness of the resection stump. The opaque and highly stretchable glove covered the robot hand that matched the size of a healthy hand.



Figure 1. prosthetic hand for child made with rolled-cloth socket

### **DISCUSSION AND CONCLUSION**

With the architecture that enables external assistance, parents could non-verbally teach the children how to use a prosthetic hand, and the children's awareness of manipulating the prosthetic hand by themselves was improved. The proposed architecture improved the children's motivation to use a prosthetic. In addition, the rolled-cloth socket was excellent in appearance and comfort, and the children could wear it by themselves without any tool.

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### **ACKNOWLEDGEMENTS**

This research is partially supported by JSPS KAKENHI (grant number 16K12951).



# 4.1.6.g

# Breathable Non-Slip Body-Powered Upper Limb Prosthetic Harness with One-handed Hardware, Designed to Eliminate Axillary Pressure and Distribute Loads

<u>Jonathan Kuniholm</u><sup>1,2</sup>, Zachary Meyer<sup>1</sup>, <u>Pooja Mukul</u><sup>3</sup>
<sup>1</sup>StumpworX LLC, Portland, OR, USA. <sup>2</sup>Open Prosthetics, Durham, NC, USA. <sup>3</sup>Jaipur Foot Rehabilitation Center, Jaipur, India

### **BACKGROUND**

Traditional upper limb body-powered harnesses are uncomfortable, can cause permanent nerve damage through the axillary pressure that they cause, and are often cited as a reason for rejecting a prosthesis. Usually permanently attached to the arm, the harness is difficult to keep clean, and to don and doff when worn under clothing. The cosmetic appearance of the harness is utilitarian at best, and, at worst, looks like a restraint.

### **AIM**

Body powered harnesses currently provided are identical to those in use more than 50 years ago, and are sorely in need of updating. This research sought to address all of the deficiencies of the traditional harness, improving acceptance and compliance.

### **METHOD**

Inspired by modern athletic and technical apparel, a new harness was designed using digital patternmaking and a combination of sewn and no-sew techniques, replacing Dacron webbing and metal hardware. By internally stiffening the harness and adding texture, slippage and axillary pressure are eliminated. Breathability and comfort are maintained by using stretch-woven polyester fabric, by perforating the internal stiffener, and through the use of perforated and stretch glues. Magnetic one-handed fasteners are used for the attaching the control cable, as well as the y-strap ends to the backplate, which remains attached to the arm. The harness and control cable can be removed and reattached without removing clothing.

### **RESULTS**

This harness was designed to be used in a variety of environments, including developed, developing, and transitional economies, and in different social contexts. The harness was tested on five patients in India. The patients preferred the harness to a traditional one, both in comfort and function, as well as in cosmetic appearance. All of the patients declared that they were more likely to wear their prosthetic arm with the new harness. No quantitative data on compliance was collected. Despite the larger surface area of the harnesses, less sweat was observed induced under the composite construction than under comparatively smaller areas covered by webbing. Suspension and control cable loads were reported to be more comfortably borne by the design. Plans are underway to produce the harness at the Jaipur Foot Clinic, as well as to introduce it to other markets.



### **DISCUSSION AND CONCLUSION**

Cost pressures may make this design impractical to deliver anywhere in the world, because of similar cost constraints and the way that health care is delivered. In the US, it remains to be seen if an approximately \$150 reimbursement can support this new design in product form. It is our belief that patient preference would support it, and the design is being shared as open source as a way to encourage further innovation.

### **ACKNOWLEDGEMENTS**

Much thanks to Mr. D.R Mehta and Dr. Pooja Mukul, Jaipur Foot, The Fetzer Institute, Open Prosthetics and StumpworX LLC.



# Advanced IC Seating & Wheelchair

## 4.1.7

# CUSTOMISING the FUTURE - more ACCURACY, more CHOICE - a new MODEL for WHEELCHAIRS and ASSISTIVE TECHNOLOGY.

<u>Jake Honeywill, Dominic Noble</u> Motivation Charitable Trust, Bristol, United Kingdom

### **Abstract**

No two people are the same; we are all different shapes and sizes, we partake in different tasks and activities and we do them in vastly varied environments. As such, mass-produced wheelchairs cannot provide the optimum product for all individuals regardless of the skills of the service provider. There are many challenges with the current sector model which limits product choice, and also has questionable long term sustainability.

In this presentation we will demonstrate a new provision model for wheelchair services which aims to resolve some of the fundamental challenges within current methods. We will explain new innovations in digital measurement and Computer Aided Design systems which will give clinicians new tools to automatically and accurately generate made-to-measure wheelchairs specifically suited to the user and their environment.

These new innovations enable an interactive assessment process and give choice for the client and clinician to select product features that will best serve their daily living requirements. Whilst maintaining the clinician at the very heart of this process, the prescription of the optimum combination of seating posture and chassis performance may be achieved.

We will explain how the application of additive manufacture can empower this system, and how it may work on a larger scale producing made-to-measure wheelchairs and custom seating units in a distributed production model that could enable wheelchair services across the world to reduce their dependence on the import of mass produced mobility products.



# Statement of the objective / learning objectives

To learn about the benefits of a mass customisation service model for assistive technology. We will demonstrate the stages of this model and explain the innovations which enable them.



# Advanced IC Prosthetics: Upper Limb

### 4.2.1

# Structured Training for Adult users of Hand Prosthesis – Introduction to SIRS-Adult for Patients with any Type of Prosthetic Hand

Liselotte Hermansson<sup>1,2</sup>, Cathrine Widehammar<sup>1,3</sup>

<sup>1</sup>University Health Care Research Centre, Faculty of Medicine and Health, Örebro University, Örebro, Sweden. <sup>2</sup>Dept of Prosthetics and Orthotics, Faculty of Medicine and Health, Örebro University, Örebro, Sweden. <sup>3</sup>Dept of Paediatrics, Faculty of Medicine and Health, Örebro University, Örebro, Sweden

### **Abstract**

New prosthetic hands with advanced technology making it possible to perform many different grasps and positions are now available on the market. This new advanced technology is also difficult for users to control, and studies have shown that the new hand functions are not used to the extent expected. Most training programs have their main focus on control training. The activity performance and regular occupational therapy training is less described.

In this instructional course we will present a new structured method for training adult patients with prosthetic hands of any type – from passive hands to new multifunctional hands. The method originates from the Skills Index Ranking Scale (SIRS), a method that was developed for children and has been in use for more than 30 years. Besides basic training the new version, SIRS-Adult, covers the new skills that patients need to master in order to use multifunctional hands to their full potential. The SIRS-Adult comprises integration of the artificial limb, structured control training, and activity performance in self chosen activities. By practicing use of the hand through performance of everyday activities, the patient achieves a natural use of the hand. The method can be applied upon prescription of any multifunctional prosthetic hand, and also for standard hands, body powered and passive prosthesis.

The instructional course will use practical demonstrations through videos and case examples. Active discussions will support the learning process. The attendees will have electronic access to written documentation that describes the SIRS-Adult in more detail.

### Statement of the objective / learning objectives

After completing this course the attendees should have learned hands on skills to perform SIRS–Adult to patients with any kind of hand prosthesis and gained deepened knowledge in how to learn patients use prosthesis.



# Free Paper Session Orthotics: Lower Limb Neurological - Clinical

### 4.2.2.a

# **Orthotic Management of Clonus**

### Paul Charlton

Peacocks Medical Group, Newcastle, United Kingdom

### **BACKGROUND**

Clonus is a clinical presentation of uninhibited rapid repeating muscle contractions seen in the presence of upper motor neuron disturbance. Clonus can be both disabling and distressing to patients. This presentation is of a hemiplegic patient presenting with clonus in the calf complex and describes how modifying orthotic intervention can control the clonus and improve function

### **AIM**

This presentation demonstrates how clonus can be managed by modifying orthotic intervention and is illustrated by a case study presenting outcomes of intervention

### **METHOD**

Clonus responds positively to stretching the affected muscle, both in inhibiting onset and stopping the presentation once initiated. An orthosis may be used to provide stretch however the resultant position may require modification for function. In the case presented, the patient has clonus in her calf despite wearing a well-tuned AFO. Stretch is increased by increasing dorsiflexion of the AFO however the pitch of the shoe then needs to be modified to optimize function. Video is presented with AFO tuned and modified along with impact on ten metre timed walk, Timed up and Go (mean values presented over three repetitions of tasks) and impact on Activity Specific Balance Confidence Scale.

## **RESULTS**

Video will be presented without AFO, with Tuned AFO and with modified AFO showing changes in quality of gait and alignment. The effect on 10 metre timed walk, Timed Up and Go and Activity Specific Balance Confidence Scale are shown in the table below

	Tuned AFO	Modified AFO
10MTW	17 steps 30.8 seconds	14 steps 21.3 seconds
TUG	29.6	23.1
Activity Specific Balance Confidence Scale	21.875	73.75

# **DISCUSSION AND CONCLUSION**

The results and video presented show the impact and positive effect orthotic intervention may have on patients presenting with uncontrollable clonus and how the intervention may need to be modified to optimise function

### **REFERENCES**

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### **ACKNOWLEDGEMENTS**

Peacocks Medical Group, UK; Orthotic Education and Training Trust (OETT).



# 4.2.2.b

# Ankle-Foot Orthoses: Examining Referral Trends of the Stroke Multidisciplinary Team

<u>Eileen Morrow</u><sup>1,2</sup>, Roy Bowers<sup>1</sup>

<sup>1</sup>University of Strathclyde, Glasgow, United Kingdom. <sup>2</sup>Oxford University Hospital Trust, Oxford, United Kingdom

### **BACKGROUND**

Stroke is a leading cause of long term disability, and commonly affects gait. Research of clinical practice has demonstrated AFO's can significantly improve the gait of post-stroke patients. Consequently stroke is a key area of practice for orthotists worldwide. The Best Practice Statement: Use of Ankle-Foot Orthoses Following Stroke [1] recommends 'any member of the multidisciplinary team (MDT) can refer...for orthotic assessment', and is supported by the ISPO Consensus Conference on the Orthotic Management of Stroke Patients.

### AIM

The objectives of this study:

- Assess referral patterns and trends to the Orthotic Service for post-stroke AFOs;
- · Identify barriers to referral;
- Assess awareness of the Best Practice Statement (BPS).[1]

### **METHOD**

A 2016 online survey of the stroke MDT (as per SIGN Guideline 118), working in Scotland, whose current role involves stroke patients. The survey was distributed via the Scottish Stroke AHP Forum, Scottish Stroke Nurses Forum, British Association of Stroke Physicians and Scottish Stroke Managed Clinical Networks.

### **RESULTS**

A statistically significant association was found among:

- Profession and whether clinicians have referred to orthotics for assessment for post-stroke AFOs;
- Physiotherapists (96%), GPs (88%), stroke physicians (82%), nurses (28%), other AHPs (20%).
- Profession and confidence in assessment criteria;
- All professions were considerably less confident in AFO referral criteria than physiotherapists.
- Profession and whether clinicians refer to departments other than orthotics;
- The most common department that clinicians referred to was Physiotherapy. Physiotherapists were least likely to refer to another department.
- Awareness of the BPS<sup>1</sup> and NHS Area.
- The West of Scotland (83%) had greater awareness of the BPS than in the East (53%).
- Clear referral patterns were identified: nurses, SLTs and OTs are unlikely to refer to Orthotics for assessment for post-stroke AFOs; most GPs and stroke physicians refer but are not confident in referral criteria whereas physiotherapists generally refer confidently.

## **DISCUSSION AND CONCLUSION**

The barriers to the Orthotic Service identified by most professions were lack of knowledge of referral pathways and limited ability to define mobility problems. This may be improved by dissemination of a guide such as the BPS, particularly as over a third of GPs requested further information or education of AFOs. 56% of referrals to departments of other than orthotics for assessment of post stroke AFOs are to physiotherapy, which may result in increased waiting times and delay in treatment.

## **REFERENCES**

[1] NHS Quality Improvement Scotland. Best Practice Statement: Use of Ankle-Foot Orthoses Following Stroke. Scotland: Healthcare Improvement Scotland, 2009.



### 4.2.2.c

# Prospective, Pilot Study to Evaluate Performance, Patient Benefits and Acceptance of a New C-Brace Microprocessor-Controlled Stance and Swing Control Orthosis

Andreas Hahn<sup>1</sup>, Milana Mileusnic<sup>1</sup>, Alexander Krebs<sup>2</sup>, Frank Braatz<sup>3</sup>, Thomas Schmalz<sup>4</sup>, Andreas Kranzl<sup>2</sup>
<sup>1</sup>Otto Bock Healthcare Products GmbH, Vienna, Austria. <sup>2</sup>Orthopädisches Spital Speising GmbH, Vienna, Austria. <sup>3</sup>PFH Göttingen, Göttingen, Germany. <sup>4</sup>Otto Bock Healthcare GmbH, Duderstadt, Germany

### **BACKGROUND**

KAFOs (Knee Ankle Foot Orthotics) are a common therapeutic option when treating patients suffering paralysis in the lower limb. Those systems may either be completely locked or only locked during stance phase. While KAFO systems enable basic ambulation, gait itself is highly asymmetric and of high metabolic demand. Recent developments (Ottobock C-Brace®) allow to maintain a significant knee resistance even if the orthosis is loaded in flexed conditions. Further, sensors allow to appropriately control stance and swing phase.

### ΔIM

We investigate the clinical and biomechanical effects of the latest C-Brace iteration as well as their acceptance by the test subjects.

### **METHOD**

Subjects were enrolled in this study at two clinical sites if they fulfilled the following criteria: unilateral or bilateral lower limb paresis or flaccid paralysis, sufficient muscle activity to allow swing through to ensure the safe use of the device and mental capacity to recognize and respond to audible signals. Contraindications included flexion contracture in knee and/or hip in excess of 10°, varus/valgus malposition in excess of 10° and moderate to severe spasticity. Performance was assessed at baseline and at 2 and 6 months. Outcomes included the Berg Balance Scale (BBS), 6 minute walk test (6MWT), perceived falls and stumbles, activities of daily living (ADLs) and preference.

### **RESULTS**

Eight subjects were enrolled (age 55 + 15, 4 female). Etiologies comprised poliomelytis, disc prolapse, incomplete spinal cord injury, neurofibratosis and nerve lesion. Three subjects had an earlier version of C-Brace as the original fitting, three subjects a swing control orthosis (SCO) and 2 subjects locked KAFOs. After 6 months of using the new C-Brace, 6MWT improved in the total group by 16+63m and by 30+84m for five subjects wearing the KAFO/SCO at the baseline. BBS did not change when considering the total group, but did improve by 5 points in the subgroup wearing initially the KAFO/SCO and by 8.5 points in the subgroup having increased risk of falling (baseline BBS < 45). Subjects reported of decrease in the number of stumbles and falls and improvements in the ADLs. 7 out of 8 subjects preferred it over their previous orthosis.

## **DISCUSSION AND CONCLUSION**

The results indicate a relevant increase in balance and associated functional safety. As a BBS score below or equal to 45 is associated with increased risk of falling, we hypothize that C-Brace shall significantly increase safety in such subjects. Such findings are in line with findings reported with an earlier version of C-Brace.

### **REFERENCES**

[1] Zacharias et al. J Prosthet Orthot 2012; 24(1):2-7.

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### **ACKNOWLEDGEMENTS**

The study was sponsored by Otto Bock.



### 4.2.2.d

# The Effect of Ankle-Foot Orthoses on Falls after Sub-acute Stroke: Results From a Randomized Controlled Trial

Corien Nikamp<sup>1,2</sup>, Johan Rietman<sup>1,2,3</sup>, Hermie Hermens<sup>1</sup>, Jaap Buurke<sup>1,2</sup>
<sup>1</sup>Roessingh Research and Development, Enschede, Netherlands. <sup>2</sup>University of Twente, Enschede, Netherlands. <sup>3</sup>Roessingh Centre for Rehabilitation, Enschede, Netherlands

### **BACKGROUND**

Falls are commonly reported post-stroke. Ankle-foot orthoses (AFOs) are often provided to improve safety and walking, but the effect of their use in reduction of falls after stroke is unknown. A randomized controlled trial on the effects of AFO-provision after stroke was performed.

### ΔIM

The aim of the current research was to study the effects of AFO-provision on the occurrence and circumstances of falls in sub-acute stroke.

### METHOD

Unilateral hemiparetic patients with indication for AFO-use, maximal 6 weeks post-stroke were included. Subjects were randomly assigned to AFO-provision early (at inclusion, study week 1) or delayed (eight weeks later, study week 9). Both groups were compared in the first eight weeks of the study, in which the early group was already provided with AFOs and used them throughout the day, whilst the delayed group was not yet provided with AFOs. Falls and their circumstances were registered using weekly diaries. Functional Ambulation Categories (FAC) and Berg Balance Scale (BBS) were assessed to determine walking independence and balance around the time of a fall.

### **RESULTS**

Thirty-three subjects were included (16 early, 17 delayed). Subjects in the early group, who were provided with AFOs, fell significantly more frequently compared with the delayed group, 11 versus 4 times, respectively (Incidence Rate Ratio=2.9; p=0.039). Despite AFO-provision, 7 of 11 falls in the early group (63.6%) occurred without AFOs, mainly during activities related to getting in/out bed and toileting/showering. Most of these falls occurred during transfers (36.4%) and standing (27.3%). Notably it were the subjects who did not have independent walking ability (indicating that physical help or verbal supervision was required for functional ambulation, 10 of 11 falls). In the delayed group 2 of 4 falls were related to independent walking ability. Low balance scores (BBS<45) were found in 7 of 11 falls in the early group, compared to 2 of 4 falls in the delayed group.

### **DISCUSSION AND CONCLUSION**

Early after stroke, falls occurred significantly more often in subjects who were provided with AFOs, compared to subjects not yet provided with AFOs. However, in subjects provided with AFOs, most falls occurred whilst without wearing AFOs and whilst subjects had no independent walking ability. This raises an interesting question of the importance of careful instructions to patients and their relatives, and the influence of potential cognitive impairments on the subjects' ability to take on these instructions.



### 4.2.2.e

# **Everyday Use of Lower Limb Orthotics and Satisfaction with the Device in Subjects with Neuromuscular Gait Disorders**

<u>Julia Block</u>, Stephanie Wendy, Thomas Kaib, Merkur Alimusaj, Sebastian I. Wolf, Martin Schwarze Heidelberg University Hospital, Dept. for Orthopaedics and Trauma Surgery, Heidelberg, Germany

### **BACKGROUND**

Orthoses for the lower extremities are prescribed to improve gait and prevent further deterioration. Little is known about the actual time worn and accompanying factors influencing how orthoses are used in everyday life. Examples for monitoring time worn can be found in studies addressed to scoliosis therapy.[1] It is known that this parameter is significantly over or underrated compared to reality when only reported by parents.[2]

### AIN

The study was designed to investigate the time worn of orthotics in everyday life and to identify areas of improvement to encourage wearing orthoses.

### METHOD

45 patients with neuromuscular gait disorders using lower limb orthotics and the ability to walk at least 30 m were included. At the first appointment (T1) users underwent a physical examination testing for range of motion, strength, deformities and spasticity. Temperature sensors (orthotimer®, rollerwerk medical engineering & consulting, Balingen, Germany) were implemented in all independently used parts of the orthotic concept. Values between 29-38.5 °C were rated as 'use-time'. After 90 days (T2) sensors were read and quality of life was determined via CP CHILD [3] and DISABKIDS.[4] Satisfaction with orthotics was rated via QUEST.[5]

### **RESULTS**

Occurring orthotic concepts in this study were dynamic-ankle-foot-orthoses (DAFO), shank high ankle-foot-orthoses (AFO), kneek-ankle-foot-orthoses (KAFO) and modular concepts consisting of a DAFO with a shank adaptation (mAFO). The time worn differs significantly between week-days and weekends in DAFOs and AFOs (week-day: 6.8 h/d; weekend: 4.5 h/d). KAFOs show a lower mean time worn (3.5 h/d), which is not influenced by the day of the week. Out of the 12 Quest items 'ease-of-use', 'comfort' and 'effectiveness', were rated as the most important aspects. Satisfaction with these is shown for the different levels of orthotic devices. (Table1).

aspects	DAFO n=5 in%	AFO n=21 in%	_	mAFO n=11 in%
ease-of-use	80	86	100	91
comfort	40	81	100	82
effectiveness	60	81	100	91

**Table1**. Satisfaction with the 3 most important QUEST aspects answered with "quite satisfied" or "very satisfied" in %.

# **DISCUSSION AND CONCLUSION**

From the user reports KAFOs are mainly used for therapy and training every day while the other types of orthoses follow the daily habits and demands. Weight, dimension as well as complexity, are accepted by the users as long as they experience the device as effective. Additional to biomechanical principles it is crucial to recognize the requirements given by the individual everyday life.

### **REFERENCES**

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- [2] Maas et al, Disabil Rehabil, 40:398-403, 2018.
- [3] Narayanan et al, Dev Med Child Neurol 2006; 48(10):804-12.
- [4] Ravens-Sieberer et al, Psychosoc Med 2007 12;4:Doc08. [5] Demers L, Assist Technol 1996; 8(1):3-13.

## **ACKNOWLEDGEMENTS**

We would like to thank all families for their participation.



# **Basic IC Rehabilitation Medicine & Surgery**

### 4.2.3

# Special Prosthetic Requirements for Rehabilitation of Amputees with Transcutaneous, Osseointegrated Prostheses (TOPS)

Horst - Heinrich Aschoff<sup>1</sup>, Oliver Breitenstein<sup>2</sup>, Siegmar Blumentritt<sup>3</sup>, Ruud Leijendekkers<sup>4</sup>

Sektion Endo-Exo-Prothetik, Hannover, Germany. Vitalcentrum Brandes u. Diesing, Hannover, Germany. Professor for Biomechanics, Göttingen, Germany. Physiotherapist Radboud University Medical Center Surgery 618, Nijmegen, Netherlands

### **Abstract**

Transcutaneous, osseointegrated prosthetic systems (TOPS) for rehabilitation following limb loss have proven their efficiency for patients with unconquerable difficulties wearing conventional socket prostheses over almost 30 years. During this time it became evident, that the surgical part only represents one module of the osseointegration procedure. The consecutive prosthetists work and add on physical rehabilitation cannot be seen as less important to the whole procedure. In the course of this adaption, adjustment and alignment of the exoprosthetic parts are representing new challenges to the skills of the prosthetist.

First the completely new prosthetic devices at the linkage between the skin perforating devices and the exoprosthesis must be understood. This prosthetic complex consists of a security component and different elements to ensure an anatomical correct adaption of the exoprosthesis to the osseointegrated implant. This accuracy is most important due to the direct transmission of load from prosthesis to bone. Further the joints proximal to the implant are supposed to react much more sensitive when they have to deal with an incorrect alignment of the exoprosthesis compared to a conventional socket prosthesis. We share our knowledge and clinical experience how prosthesis components should be biomechanically correct aligned.

Similar considerations are pertaining for the physical rehabilitation following transcuateneous osseointegration. In consultation with surgeon and prosthetist the physiotherapist has to induce weight bearing and training. The observation and correction of gait and joint function are his responsibility and only a critical feed back to the patient enables him to achieve the best result possible.

### Statement of the objective / learning objectives

With regard to their bone-guided function TOPS are demanding a different prosthetists understanding concerning adjustment and alignment of the exoprostheses. An included advanced pre- and postoperatively physiotherapy.leads to a measurable benefit for the patient



# Free Paper Session Prosthetics: Lower Limb Transtibial - Socket

### 4.2.4.a

# Reliability of Three Different Methods for Assessing Amputee Residuum Shape and Volume

<u>James Bilzon</u><sup>1,2</sup>, David Canepa Talamas<sup>3</sup>, Matthew Young<sup>2</sup>, Martin Twiste<sup>4,5</sup>, Vimal Dhokia<sup>3</sup>, Elena Seminati<sup>1,2</sup>
<sup>1</sup>Department for Health, University of Bath, Bath, United Kingdom. <sup>2</sup>CAMERA Research Centre, University of Bath, Bath, United Kingdom. <sup>3</sup>Department of Mechanical Engineering, University of Bath, Bath, United Kingdom. <sup>4</sup>School of Health and Society, University of Salford, Salford, United Kingdom. <sup>5</sup>United National Institute for Prosthetics & Orthotics Development (UNIPOD), University of Salford, Salford, United Kingdom

### **BACKGROUND**

Objective methods of assessing amputee residuum shape and volume are required to guide clinical care with regard to timing and design of prosthetic sockets. Computer Aided Design (CAD) methods (e.g. optical 3D scanners) can capture surface geometry and colour without the need for reference targets. Data collected on

residuum models suggest these novel methods may have greater validity and reliability than methods currently used in clinical practice.[1]

### **AIM**

The aim of this study was compare test-retest reliability and variance statistics when measuring residuum shape and volume using a new 3D laser-free scanner compared with two methods commonly adopted in clinical practice.

### **METHOD**

Three different operators measured residuum shape and volume of ten chronic lower limb amputees (5 transtibial, 5 transfemoral), on three separate occasions using: i) an

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Artec Eva 3D scanner (Artec, Luxembourg); ii) an Omega Tracer scanner (The Ohio Willow Wood Company, Mt. Sterling, Ohio, USA) and; iii) a geometrical formula based on anthropometric measures, using a Gulick measuring tape and crotch stick. Models were manually aligned using anatomical reference points. Intra and inter-rater reliability coefficients were calculated in accordance with Bland-Altman statistic, for measuring indices of residuum shape and volume for each method.[1] Variance components were calculated for all measurement conditions.

### **RESULTS**

Participants were established (>1 year) lower limb amputees with a mean±SD: body mass of 79±13 kg; height of 173±11.6 cm and; time post-amputation of 25.8±14.6 years. Residual limb volumes ranged from 1077 to 2406 ml. Intra-rater and inter-rater reliability coefficients for volume measurements are reported in Figure 1. The source of residuum volume error variance was attributed to: the measurement system (7.65%); the interaction between patient and measurement system (16.12%) and; the shape of the patient residuum (75.68%). This reflects the considerable between-patient variability in residdum shape and volume. Between-method variance in shape measurements will also be presented. Figure 1. Intra- and inter-operator reliability coefficients. Values correspond to percent variance of: 2.7 to 3.6% for the Artec scanner; 2.9 to 3.9 % for the Omega Tracer scanner and; >10% for the anthropometric measurements, respectively.

### **DISCUSSION AND CONCLUSION**

Prerequisites for a clinical method for assessing amputee residuum shape and volume are reliability, safety and portability. Optical 3D scanners, based on laser-free technology, are a promising method for assessing residuum limb volume changes in amputees. The Artec Eva 3D scanner revealed the lowest test-retest reliability coefficients and could be a useful method for quantifying acute and chronic changes in residuum shape and volume in lower limb amputees. Such measures may be indicative of recasting and/or refitting requirements.

# **REFERENCES**

[1] Seminati et al, PLoS ONE 2017; 12(9):e0184498.

### **ACKNOWLEDGEMENTS**

We would like to thank all of the participants that volunteered and gave their time to participate in this study.



# 4.2.4.b

# Clinical Usability and Reliability of Non-contact Scanners in Measuring Residual Limb Volume in Persons with a Trans-Tibial Amputee (TTA)

Rianne Kofman<sup>1</sup>, Raoul E. Winter<sup>1,2</sup>, Kees C.H. Emmelot<sup>2</sup>, Jan H.B. Geertzen<sup>3</sup>, Pieter U. Dijkstra<sup>3</sup> Department of Rehabilitation Medicine, Vogellanden - Rehabilitationcentre, Zwolle, Netherlands. <sup>2</sup>Department of Rehabilitation Medicine, Isala Hospital, Zwolle, Netherlands. <sup>3</sup>Department of Rehabilitation Medicine, University of Groningen, University Medical Center Groningen, Groningen, Netherlands

### **BACKGROUND**

In the past non-contact scanners have been tested for reliability to measure residual limb volume for research purposes in persons with a TTA. However new scanners are available on the market nowadays.

### $\Delta IM$

Aim of this study is to determine the clinical usability and reliability of these new non-contact scanners in measuring residual limb volume in persons with a TTA.

### METHOR

Thirty participants with a uni- or bilateral TTA older than 18 years, without any co-morbidity, potentially influencing residual limb volume, were included. Three non-contact scanners (Rodin4D, Omega Tracer, Biosculptor) were used to measure residual limb volume on two occasions by two observers. Time to take the measurement, patient satisfaction (0-10 scale) and Post-Study System Usability Questionnaire (PSSUQ) were determined for each measurement.

### **RESULTS**

The clinical usability of the Rodin 4D and Omega Tracer was significant better compared to the Biosculptor. Time to perform the measurements was significantly longer (78 sec) for the Omega Tracer compared to the other systems. Time to measure residual limb volume reduced on the second occasion (46 sec). Median satisfaction score for each system was 10.

The error variance was 8.4%. Participant and measurement system interaction explained most of the error variance (80.7%). Repeatability coefficients (smaller is better) of the systems were 16.5 cc (Omega Tracer), 26.4 cc (Rodin4D), 32.8 cc (Biosculptor).

## **DISCUSSION AND CONCLUSION**

The longer time to perform the measurements with the Omega Tracer is clinically irrelevant. The repeatability of the Omega Tracer was smallest. The Omega Tracer is clinically most usable and the most reliable non-contact scanner to measure the residual limb volume in persons with a TTA.



# 4.2.4.c

### Measurement of Shear Stresses on a Residual Limb in a Prosthetic Socket

<u>Takashi Nakamura</u>, Koji Nakamura, Hiroki Imai, Shigeru Toyama National Rehabilitation Center for Persons with Disabilities, Saitama, Japan

### **BACKGROUND**

Many researchers are interested in the quantitative evaluation of biomechanical interactions at the socket interface. The distribution of interface stresses in the socket has been considered as a direct indicator of socket fit and comfort. Interface pressures have been studied by many researchers using various transducers. However, measuring shear force has been considered difficult because of the lack of appropriate sensors. Recently we developed a new thin flexible shear force sensor.

### ΔIM

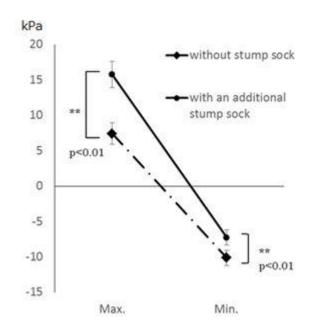
The aim of this research is to conduct a quantitative evaluation of socket fit with a new sensor, including biomechanical interaction at the socket interface.

### METHOD

As an attempt of performance evaluation of the new sensor, we quantified the piston movement of the stump in the socket with a liner. The sensor was attached on the tibial tuberosity of the subject with transtibial amputation. After donning the liner and socket, the subject stepped (10 times). The changes of the shear force were monitored during stepping. To investigate the relationship between the piston movement and the socket fit, two conditions were compared. One is the condition without a stump sock, and the other is the condition with an additional stump sock. It is easy to assume that an additional stump sock can change the socket fit.



The results are shown in Fig. The positive value means that the force works downward in which the liner comes off the stump. The negative value means that the force works upward, in which the stump pushes into the liner. Fig. 1 shows the average maximum and minimum values. The increase in minimum value means that the upward shear force was decreased. That is, the force to push the stump into the socket decreased owing to the addition of a stump sock. On the other hand, the increase in



maximum value means that the liner became easy to come off the stump. These results mean that the socket was getting too tight, and the additional stump sock worsened the socket fit.

### **DISCUSSION AND CONCLUSION**

The experimental result with the new sensor showed clear influence of the stump sock to the socket fit. This study reveals that the change in the socket fit can be described quantitatively with the measurement of shear force. We expect that this new sensor will be a powerful tool for quantitative evaluation of socket fit.

### **REFERENCES**

[1] Toyama et al, Sensor Lett 2013.

[2] Toyama et al, Sensors 2017.

### **ACKNOWLEDGEMENTS**

This work was supported by JSPS KAKENHI Grant Number JP18006936.



### 4.2.4.d

# Investigation into the Effect of Moisture and Prosthetic Liner Technology on Residuum Interface Mechanics

Michael McGrath, Ana Gallego, Joe McCarthy, Simon Jarvis, Piotr Laszczak, <u>Saeed Zahedi</u>, David Moser Blatchford, Basingstoke, United Kingdom

### **BACKGROUND**

Studies report up to 70% of amputees are affected by excessive sweating.[1] Silicone liners are commonly worn over the residual limb for cushioning, but this means that sweat cannot transport away from the skin surface,

affecting the interface mechanics. A perforated silicone liner has been produced for sweat management. Due to the complexity and variability of residual limbs, previous work [2] developed a technique to produce an artificial residuum for use as a residuum-socket interface simulator.

### AIM

Evaluate the efficacy for replicating the interface microclimate, under controlled laboratory settings, using a residuum-socket interface simulator. Examine the effectiveness of perforated liners designed for sweat management.

### **METHOD**

A model of a trans-tibial cast was made using of 3D scanning, additive manufacture and silicone moulding. Solid model bones were encased in silicone, which contained pores, allowing water flow. Firstly, the simulator was tested with 'dry' tests using different liners. It was compressed to 800N and then pulled into 100N tension, to represent the stance and swing phases of the gait cycle, respectively. Next, 'wet' tests were performed. Water was added to the central cavity and the loading forced it out of the 'pores', out to the residuum-liner interface. This test was performed for a regular liner and a perforated, sweat management liner (Silcare Breathe, Blatchford).

# **RESULTS**

The 'dry' tests showed that there were differences in the mean compression and tension displacements when the simulator was taken off and replaced on the machine (reproducibility).

Figure 1: The simulator on the test machine

However, the variation in these values (repeatability) across the 50 cycles was consistent across different tests. It was decided to use coefficient of variation (COV) as a comparison between test conditions. With the non-perforated liner, the addition of 'sweat' increased the COV of compressive displacement from 1.2% to 3.1%. The COV of hysteresis area increased from 8.2% to 9.4%. By comparison, when 'wet' the perforated, sweat management liner showed a compressive displacement COV of 1.2% and a hysteresis area COV of 7.2%, restoring variability to 'dry' test levels.

### **DISCUSSION AND CONCLUSION**

Under controlled laboratory conditions, the microclimate of the residuum-socket interface was simulated. The ability to replicate this environment in vitro will be useful for developing and further improving sweat management techniques. Consistent interface mechanics are desirable to aid prosthetic control and function. Current sweat management liners contribute to maintaining consistency.

### **REFERENCES**

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[2] McGrath et al. Proc Inst Mech Eng [H] 2017.



### 4.2.4.e

# Hydrocast socket interface pressures and wearer comfort over the gait cycle

Sheridan Laing<sup>1</sup>, Noel Lythgo<sup>2</sup>, Jim Lavranos<sup>3</sup>, Peter VS Lee<sup>1</sup>

<sup>1</sup>The University of Melbourne, Melbourne, Australia. <sup>2</sup>RMIT, Melbourne, Australia. <sup>3</sup>Caulfield Hospital, Caulfield, Australia

### **BACKGROUND**

Prosthesis users identify socket fit and comfort experienced among their most important concerns. However only limited studies have studied the relationships between transtibial socket pressures and wearer comfort.[1-2] Further, previous statistical tests have been limited to the maximum pressure value recorded or at discrete time points during the gait cycle.[1-2] In hydrocast sockets, high pressures have been observed at bony prominences,[1] however the relationships between these pressure magnitudes and wearer comfort remain unknown.

### AIM

To explore relationships between hydrocast socket interface pressures and wearer comfort over the whole gait cycle, considering both pressures over large regions and in anatomical areas of interest.

### METHOD

Sixteen participants with unilateral transtibial amputations were fit with hydrocast sockets, with cotton socks but no liners worn. Following 5-months usage, the socket interface pressures and Socket Comfort Score (SCS) were recorded. The pressures from the four most comfortable (SCS 9-10) and four least comfortable (SCS 6-7) participants were examined over the gait cycle and one-dimensional statistical parametric mapping (1DSPM) used to complete independent samples t-tests ( $\alpha$ =0.10).[3] The pressures of the SCS9-10 and SCS6-7 groups were compared for the mean region pressures (the proximal and distal halves of each aspect) and at anatomical points of interest (the patella tendon, distal tibia, popliteal depression, medial condyle and fibula head).

### **RESULTS**

There were no significant differences between the mean pressures over the proximal and distal halves of each aspect for the SCS9-10 and SCS6-7 groups. The SCS6-7 group experienced significantly higher pressures at the patella tendon region during late stance (p=0.027, Figure 1) and at the popliteal depression during mid-swing (p=0.007).

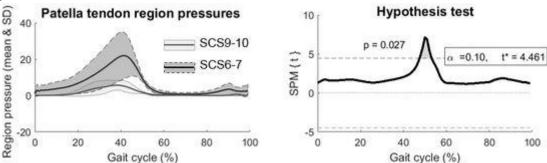


Figure 1. Pressures at the patella tendon region over the gait cycle (left) and the corresponding 1DSPM test results (right)

# **DISCUSSION AND CONCLUSION**

DSPM allows the calculation of statistical difference over continuous curves without reducing the data to summary statistics. Using this method, no differences were found when considering the mean pressure over large regions. However, less comfortable participants had higher pressures at the patella tendon and popliteal region. Pressures in these regions have previously been identified as uncomfortable in patella tendon bearing sockets.[2,4] This analysis has identified limb regions where higher pressures may be associated with wearer discomfort in hydrocast sockets.

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# **ACKNOWLEDGEMENTS**

This work was funded by the CASS Foundation, Rotary Club of Richmond, Promobilia Foundation, and Australian Government Research Training Program.



# 4.2.4.f

# Volume Adaptation of the Residuum of Lower Limb Amputees over Short and Long Term

Elena Seminati<sup>1,2</sup>, David Canepa Talamas<sup>3</sup>, Matthew Young<sup>2</sup>, Martin Twiste<sup>4,5</sup>, Vimal Dhokia<sup>3</sup>, James Bilzon<sup>1,2</sup>

<sup>1</sup>University of Bath, Department for Health, Bath, United Kingdom. <sup>2</sup>CAMERA centre, University of Bath, Bath, United Kingdom. <sup>3</sup>University of Bath, Department of Mechanical Engineering, Bath, United Kingdom. <sup>4</sup>School of Health and Society, University of Salford, Salford, United Kingdom. <sup>5</sup>United National Institute for Prosthetics & Orthotics Development (UNIPOD), University of Salford, Salford, United Kingdom

### **BACKGROUND**

Residuum volume in lower limb amputees reduces in the postoperative phase, leading to challenges in achieving comfort and restoring function when fitting prostheses. Variability in volume reduction rate within and between amputees is large, and there is currently no definitive method for establishing when the residuum volume has stabilised. A recently validated scanning technique [1] can help in the management of residuum volume with advantages for both amputees and prosthetists.

### **AIM**

The aim of this study was to analyse the longitudinal reductions of residuum volume among a cohort of lower limb amputees, using an Artec Eva laser-free optical 3D scanner (Artec, Luxembourg).

### **METHOD**

13 lower limb amputees were recruited, who had an amputation only 6-10 weeks ago ( $55.1 \pm 9.6$  years old, height  $1.7 \pm 0.1$  m, mass without prosthesis  $90 \pm 30$  kg). They had different levels and causes of amputation and they were involved in the study for a 9-month (i.e. 36-week) period during which their residuum was scanned every month. In the first month of monitoring participants were measured twice a day (morning and afternoon), with a minimum of 4 hours between measurements. Skin-mounted markers were placed consistently on three anatomical landmarks of the residuum to determine a transverse plane used as the proximal end of each scan.

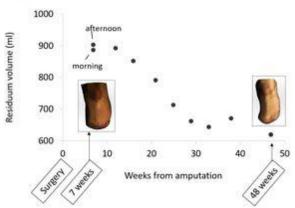


Figure 1. Residuum volume against time (in weeks after the amputation) for one amputee.

### **RESULTS**

Preliminary results show a rapid reduction in residuum volume and as much as 25% of the original volume in

the first 7 months. After that the residuum seemed to stabilise, or just slowly reduced in volume for the next 2 months (Figure 1). Within-day measurements of residuum volume show that there were small changes of 2% of the original volume, whereby these changes were not a reduction but an increase in volume between the first and second scan at the first 6-10 weeks after amputation.

## **DISCUSSION AND CONCLUSION**

The residuum volume reduced over time, which was drastic in the first 7 months, and after that the residuum seemed to stabilise. Also, there were within-day increases in volume that occurred within the first 6-10 weeks, which may have occurred because of the very early stage of the amputation when activity was limited. These data will help to identify, or predict, how long it might take for residuum to stabilise. This might therefore contribute in improving the long-term rehabilitation process.

## **REFERENCES**

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# **ACKNOWLEDGEMENTS**

We would like to thank the prosthtists at the BCE and all the amputees who took part in the study.



# 4.2.4.g

# Investigating the Physiological Effects on Dermal Tissues Following Simulated Prosthetic Loading in Intact and Trans-Tibial Residual Limbs

<u>Jennifer Bramley</u>, Peter Worsley, Luciana Bostan, Dan Bader, Alex Dickinson University of Southampton, Southampton, United Kingdom

## **BACKGROUND**

Post-amputation, reconstructed tissues are not conditioned to forces experienced during normal activity, potentially causing recurring damage.[1] Bioengineering tools enable physiological monitoring of loaded dermal tissues, including ischaemia and inflammation indicators.[2] However, a measurement array suitable for the distinct residuum-socket interface has not previously been reported, and understanding is limited regarding what constitutes safe loading protocols for early prosthetic rehabilitation. Ischaemia monitoring and inflammatory biomarker analysis have demonstrated potential to detect damage using a simulated skin-socket interface in intact limbs.[3]

### AIM

This study aims to establish an *in-vivo* protocol for assessing indicators of dermal tissue damage in residual and contralateral limbs representative prosthetic loading.

### **METHOD**

Pressure was applied to both lower limbs of participants with unilateral trans-tibial amputation using a pressure

cuff, inflated incrementally from 20-60 mmHg. These pressure magnitudes represent early prosthetic rehabilitation using the Pneumatic Post-Amputation Mobility (PPAM) Aid.[4] An array of measurements was applied at patellar tendon, lateral and posterior calf sites, including i) interface pressure (Oxford Pressure Monitor II, Talley, UK); ii) transcutaneous oxygen (TcPO<sub>2</sub>) and carbon dioxide (TcPCO<sub>2</sub>) tensions (Radiometer, Denmark) to characterise ischaemia;[5] and iii) sebum biomarkers, to assess inflammation.

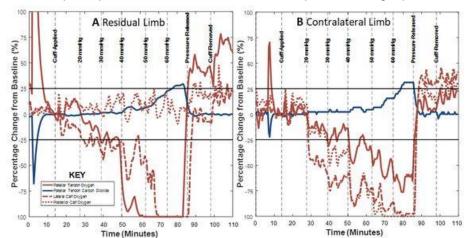


Figure 1 Transcutaneous Oxygen and Carbon Dioxide data for one participants' A; residual limb and B: contralateral limb calves under incremental cuff loading from 20-60 mmHg

### **RESULTS**

Preliminary data are presented for one female participant aged 46yrs. Applied cuff pressure of 60 mmHg corresponded to measured interface pressures of 47-72 mmHg, representative of static PPAM Aid usage during early rehabilitation. These applied loads were shown to affect vasculature with greater than 25% reduction in TcPO<sub>2</sub> at all locations and increase in TcPCO<sub>2</sub> at the patellar tendons, indicative of an ischaemic response (Fig1). The residual limb posterior calf was most tolerant to external loading. An ischaemic response was seen previously at 60 mmHg in 8/10 participants without amputation<sup>3</sup>, and was observed in both of this participant's limbs despite long-term patellar tendon bearing prosthesis use on the amputated side. At the time of writing inflammation markers were still under analysis.

## **DISCUSSION AND CONCLUSION**

This work highlights the importance of load duration and relief, particularly during early prosthetic rehabilitation. Investigation of these measurements in more participants with consideration of cyclic loading will help to inform strategies that could be used in everyday life to minimise the risk of tissue damage.

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## **ACKNOWLEDGEMENTS**

Ethics: ERGO41864. Funders: EPSRC (EPN5097471, EPN02723X1), IfLS and RAEng (RF130).



# Advanced IC Footwear

### 4.2.5

# Individualized Rocker Profile Shoes: Design, Biomechanics and Indications

<u>Juha Hijmans, Laurens van Kouwenhove</u>
Department of Rehabilitation Medicine, University Medical Center Groningen, Groningen, Netherlands

### **Abstract**

A rocker bottom shoe can be defined as: 'a shoe with an outsole rocker bar or a contoured outsole creating a curved anteroposterior profile'. In daily practice rocker profiles are used very often. However, the impression exists that the design is limited to the position of the apex, proximal, at, or distal of the MTP-region. In this course you will learn more about how all design parameters of rocker profiles influence biomechanics of gait and gain knowledge about indications for rocker profile shoes. The relation between the design parameters (e.g. apex position, apex angle, rocker angle / radius and flexibility) and biomechanics will be explained and research related to the working mechanisms will be presented. The design parameters will influence kinetics and kinematics of the lower limb and plantar pressure distribution. We will share research and biomechanical models on how rocker profiles can be used in targeted treatment of plantar fasciopathy and Achilles tendinopathy and redistribution of pressure in diabetic neuropathy. Focus on this course will be on the need for individualization. For targeted pressure reduction in diabetic neuropathy a specific position of peak plantar pressure requires a specific shape and flexibility. Also in plantar fasciopathy and Achilles tendinopathy different design parameters influence load of the plantar fascia and Achilles tendon in different ways. The attendants can expect to gain up to date knowledge of the current state of scientific research and clinical practice.

## Statement of the objective / learning objectives

Attendees will gain knowledge about the relation between design parameters of rocker profile shoes and biomechanics of gait. Emphasis will be on individualization of the rocker sole parameters in diabetes, Achilles tendinopathy and plantar fasciopathy.



# Symposium Outcome Measurements

# 4.2.6

# **Exploring Quality-of-Care Topics for Users of Custom Ankle-Foot Orthoses**

Allen Heinemann<sup>1,2</sup>, Stefania Fatone<sup>1</sup>

Northwestern University, Chicago, USA. <sup>2</sup>Shirley Ryan AbilityLab, Chicago, USA

### **Abstract**

As in all healthcare practice areas, there is a need to improve quality relevant to orthotic practice, but we lack information as to what aspects of healthcare quality are meaningful to measure. This symposium will report results from 3 phases of a project designed to identify the quality of care issues that are important to patients who use custom AFOs and the orthotists and physiotherapists who work with them. First, we will describe issues that are important to the quality-of-care for these stakeholders that emerged from focus groups. Participants discussed structural, process, and outcome domains of care quality relevant for people with custom AFOs. Next, we will report results from a scoping review that identified instruments that assess experience and outcomes with AFOs and the extent to which they are useful for evaluating care quality. We conducted 2 reviews: one focused on studies that evaluated experiences and outcomes of individuals who use AFOs; the second focused on psychometric properties of identified instruments. Finally, we will report results of a survey completed by orthotists and physical therapists regarding their priorities about quality measurement themes and the feasibility and utility of collecting data from persons using custom AFOs that could inform quality measure development. Results provide insight on the topics orthotists and physical therapists regard as priorities for defining healthcare quality for persons using custom ankle-foot orthoses and instruments for data collection.

# Statement of the objective / learning objectives

(1) Describe issues important to the quality-of-care for custom AFO users, (2) Discuss instruments that can measure these issues, and (3) Identify the measurement priorities of orthotists and physical therapists.



# Free Paper Session Developing Countries

### 4.2.7.a

# Risk of Caregivers in Manual Handling Involving in ADL and Transferring of Person with Disabilities in a Rehabilitation Centre, Bangladesh

Mahfuzur Rahman<sup>1</sup>, Shamim Miah<sup>2</sup>, Sharmin Sultana<sup>3</sup>
<sup>1</sup>International Committee of the Red Cross, Dhaka, Bangladesh. <sup>2</sup>Bangladesh Medical Research Council (BMRC), Dhaka, Bangladesh. <sup>3</sup>CRP Savar Dhaka, Dhaka, Bangladesh

#### **BACKGROUND**

Lacking of trained caregivers has a great impact on manual handing for person with disabilities and caregivers to stay alive entirely and raised a burning question at present. In Bangladesh, family members can play a vital role in caring whereas recover performance is demanding. It is a big challenge of caregivers to consider physical and mental effort for person with disabilities.

# AIM

The aim of the study is to find out the risk of carer in manual handling involving in activities of daily living and transfer of paralysis patients in a rehabilitation Centre in Bangaldesh

#### **METHOD**

The study was carried out in outdoor neurology unit, Department of Occupational Therapy of Centre for the Rehabilitation of Paralysed, Dhaka, Bangladesh. A purposive sampling technique and pre-tested structured questionnaire were used for data collection. Face-to-face interviews were taken with obtaining informed consent.

#### **RESULTS**

About 44.1% caregivers always faced awkward posture whereas 41.5% faced persistent repetitive hand movement during manual handling. Around one third (33.05%) felt back pain who caring 0.05 level.

Link for Tables & Figures:

https://drive.google.com/open?id=1K6Rk8LpQk085siGGb54Jb-FOIC3zrYWy

### **DISCUSSION AND CONCLUSION**

Awkward posture and persistent repetitive hand movements were the key problems of caregivers. Mental exhaustion was higher than physical exhaustion during the manual handling of person with disabilities.

## **ACKNOWLEDGEMENTS**

Authors are highly acknowledged to CRP for logistic, technical support, also grateful to all the caregivers for their active participation.



## 4.2.7.b

# Orthotic Management of Cerebral Palsy in Togo (West Africa)

Anarème Kpandressi ENAM Lomé, Lomé, Togo

#### **BACKGROUND**

As it is the case with many paediatric neurologic conditions, very little has been reported on Cerebral Palsy (CP) in the African context, talkless of Togo (West Africa), where CP orthotic management seems to be neglected compared to other conditions requiring an orthosis, despite the fact that P&O centres in Togo receive several children with CP and do offer them orthotic treatment. There is neither no questioning on the effectiveness of the management that is conducted.

#### AIM

This paper aims at painting a picture of orthotic management of CP in Togo compared to the international standards and highlight the opportunities and the weaknesses that need to be addressed.

#### METHOD

Our methodology consisted in (1) file review of all CP children that were treated with an orthosis from November 2015 to January 2018 at the National P&O Centre of Togo, (2) direct observation of scenarios of management of a CP child and (3) interviews with the Physiotherapists and Orthotists involved in the management. All the files were reviewed with a highlight on the seven following elements: (i) Number and gender of CP patients treated with orthosis, (ii) Age of CP patients treated with orthosis, (iii) Type of orthoses prescribed, (iv) Method of clinical assessment, (v) Assessment of the treatment, (vi) Management principles/protocol, and (vii) Training in CP management.

#### **RESULTS**

The results showed (i) a male patients' predominance over females, (ii) a predominant number of rigid AFO prescribed; no articulated orthosis was prescribed (iii) a positive multidisciplinary approach in the clinical assessment, (iv) a lack of gait consideration in the assessment, (v) more consideration for posture rather than gait in the management, (v) lack of assessment and follow-up of the treatment, (vi) absence of clear management principles and protocol, and (vii) a lack of training in CP management for the Orthotists involved.

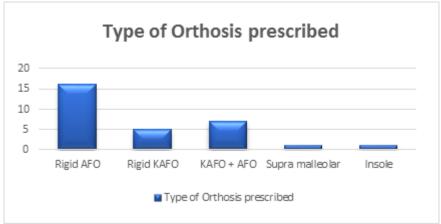


Figure 1. Type of orthoses prescribed

### **DISCUSSION AND CONCLUSION**

The study shows that boys are more affected than girls and also reveals positive points and weaknesses in the CP management system. All the weaknesses turn around two main aspects: the lack of training in CP management and the absence of clearly defined management protocol. Relevant actions to address these above-mentioned problems would definitely improve the whole orthotic management system of CP in Togo and ultimately lead to a better quality of life for the children with CP in Togo.



### 4.2.7.c

# Open Specification for Synchronisation of Electronic Healthcare Records Used by P&O Services in Lower- and Middle Income Countries

Stefanie Wiegand<sup>1</sup>, Alex Dickinson<sup>1</sup>, Gary Wills<sup>2</sup>

<sup>1</sup>Mechanical Engineering Dept., Faculty of Engineering & Physical Sciences, University of Southampton, Southampton, United Kingdom. <sup>2</sup>School of Electronics and Computer Science, Faculty of Engineering & Physical Sciences, University of Southampton, Southampton, United Kingdom

#### **BACKGROUND**

Conventional, paper-based and electronic healthcare record systems (EHCRs) for prosthetics and orthotics patients in lower- and middle income countries (LMICs), specifically Cambodia, have shortcomings related to data storage, aggregation and synchronisation.[1] We conducted a requirements analysis for synchronisation methods specific to users in this environment. We focused on connectivity issues in rural areas, secure data transfer and storage of sensitive data, and hard- and software limitations of legacy systems.

#### **AIM**

We aim to design an open specification to facilitate data synchronisation for EHCR systems. Other than conventional synchronisation, we optimise our methodology for the special use-cases in LMICs.

### **METHOD**

We set out to gather low-level requirements of an EHCR synchronisation system, directly from ground staff including IT administrators, receptionists and community visitors, to get a picture of how healthcare records, appointments and centre management systems are actually used, as opposed to how they are supposed to be used. This extended initial software requirements research,[1] based on higher-level views of senior individuals, which encompassed issues like consent for compliance with the General Data Protection Regulation (GDPR) and asynchronous, more granular data-transfer. We used shadowing and the example mapping technique from the test-driven development methodology to collect these requirements.

## **RESULTS**

One of the most important findings was that the use of ECHR systems is subject to interests of the Royal Government of Cambodia. While there are multiple different systems in use by various non-government organisations, the government aims to harmonise all patient data and eventually use just one system. However, it is yet undecided which system that will be. Furthermore, synchronisation can happen on a smaller scale than just between different clinic sites. Different mobile devices require data access to eliminate paper records and enable better communication of clinicians in case management and recording keeping. These devices would be used by different actors, e.g. receptionist, prosthetist or community worker, all of whom have different needs in accessing data for the enhancement of care and intervention of clients either through community- or clinic-based service.

### **DISCUSSION AND CONCLUSION**

As we do not know the direction in which the Cambodian Government may go, we had to adapt our architecture to operate independently of the political environment, database, schema or EHCR system, by developing an open specification for a database synchronisation layer that is potentially useful for a wide variety of applications. Our implementation serves as a proof-of-concept prototype and open-sourcing our work should encourage uptake by a wider audience.

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# **ACKNOWLEDGEMENTS**

Advisors: Exceed Worldwide. Funders EPSRC/NIHR (EP/R014213/1) and RAEng (RF/130). ERGO/FPSE/46271.



# 4.2.7.d

# Factors Affecting Availment of Expanded Z-MORPH Program in an Urban Community Based Rehabilitation Center in the Philippines: Mixed Methods Study

<u>Cybil Kwok</u>, Timothy Aromin, Ian Medina, Anna Bongalonta, Jerome Lovidad, Alyssa Gorgonio, John Balatucan, Jose Juangco
UERMMMCI, Quezon City, Philippines

#### **BACKGROUND**

Community-Based Rehabilitation, a strategy executed by the local government, aims to improve access by providing rehabilitation, ensuring social inclusion and equalizing rights among persons with disabilities in the community of developing countries. Believing in the same idea, the Philippine Health Insurance Corporation (PhilHealth), seeks to reintegrate persons with physical disabilities into the community by rendering affordable prosthetic and orthotic services and materialized the Expanded Z-MORPH Program. Unfortunately, the program only has few availers as of 2016.

#### AIM

The study aims to determine the factors that affect how the persons with disabilities avail of the Expanded Z – MORPH Program in an urban community-based rehabilitation center in the Philippines.

#### **METHOD**

The study uses a Quantitative – Qualitative mixed study design. A cross sectional study was conducted involving the Barangay Health Workers (BHW) and PWDs in Barangay 185 Malaria, Caloocan City, using a questionnaire on the possible factors affecting the utilization of Expanded Z-MORPH Program gathered using related literature. Factors include issues in transportation, family support, finances and etc. A Case Study of the community was done for the qualitative aspect using focus group discussions to further delve into the details of the factors identified in the quantitative results. Descriptive analysis using frequency and proportion was used for the quantitative design, while thematic analysis was used for the qualitative design.

#### **RESULTS**

The results are written and categorized into two parts, namely: Quantitative (yes/no questionnaire) and Qualitative (Focus Group Discussion). The quantitative data was not computed for the researchers were not able to gather respondents who availed for the program due to no availers in the community, and continued with the collected data. The researchers used focus group discussions for the qualitative part to expound on the reasons behind the participants' responses to the yes/no questionnaire done during the quantitative aspect of the study. The researchers then did a thematic analysis which resulted to government logistics as the master theme for both PWD and BHW discussions.

# **DISCUSSION AND CONCLUSION**

In the study, although the researchers were not able to gather answers from the availers of the program, the non-availers of the program considered most of the stated factors affecting their availment of the Expanded Z-MORPH program. The determined factors linked to government logistics as the main contributing factor. This play an important role in resolving these concerns since they are the one managing PhilHealth, and for they have implemented a national policy about disability addressing most of the factors.



### 4.2.7.e

# Prosthetics and Orthotics Service in Nepal: A Cross Sectional Study

#### Parajuli Pralhad Prasad

Hospital and Rehabilitation Centre for Disabled Children, Banepa, Nepal

#### **BACKGROUND**

Assistive device helps in mobility and disability correction. This study was designed to assess the situation of prosthetic and orthotic condition in Nepal and the beneficiary's satisfaction till 2016.

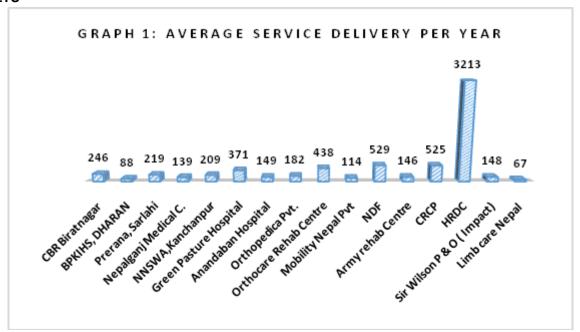
#### AIM

Mobility is the first step to access basic rights including access to food, shelter, education, job/income, equal opportunities and equal citizenship. This study provides the guidance to government and non-government agencies for promoting effective service catering Pattern in Nepal.

#### METHOD

The study was conducted throughout the country in Nepal. A complete enumeration method was used hence; all the prosthetic & orthopedic workshops and randomly selected beneficiaries were enrolled in the study. 16 orthopedic workshops and 25 randomly selected beneficiaries were enrolled.

### **RESULTS**



According to the National Population Census, 2011 total no. of persons with physical disabilities is 186,457 of which 140000 (75%) are potential to use the appliances. Only 24% of potential cases had access to the appliances. 68% of the workshop lies in the capital city. 48% of the appliances are manufactured and distributed by Hospital and Rehabilitation Centre for Disabled Children (HRDC) alone (graph 1). According to the standard of the World Health Organization, the required number of trained human resources (prothestist, orthotist) in Nepal should be 530. However, only 24 trained technicians are currently available. The average cost of appliances in Nepal goes beyond the capicity of the ordinary people. HRDC provid it to the actual cost. Only 76% of the beneficiaries were satisfied with the quality of appliances, of which 91% were from HRDC.

# **DISCUSSION AND CONCLUSION**

There is huge gap in between the trained human resources and demand of beneficiaries. Trained human resources with well equipped infrastructure is requirred. Decentralized orthopedic workshops will increase the access to benefecaries.



# 4.2.7.f

# Interdisciplinary Community Attachment to determine Prevalence of Disability and Rehabilitation Needs in Selected Villages in Rwanda: CBR Baseline

<u>Jean Baptiste Sagahutu</u>, Anne Kumurenzi, Maurice Kanyoni, Anne Kamweru, Robert Hakorimana, Juliette Gasana

University of Rwanda, College of Medicine and Health Sciences, Kigali, Rwanda

#### **BACKGROUND**

The initial report of Rwanda on the implementation of the United Nation Convention on the Right of Persons with Disabilities (UNCRPD) revealed that Rwanda has no comprehensive CBR programme evolved into a multi-sectoral and multi-discipline strategy to address the broader needs and inclusion of Persons with Disabilities. One of the reasons is the lack of the baseline information regarding the epidemiology of disabling conditions. Therefore, it is difficult to plan and implement strategically the program.

#### AIM

To establish the interdisciplinary team-work among Occupational Therapy, Prosthetics & Orthotics, and Physiotherapy and students at University of Rwanda; and to determine the profile and rehabilitation needs of persons with disabilities in selected area in Rwanda.

#### **METHOD**

Purpossive sampling was used to select from District, Sector, Cell, to Villages. Seven Villages were selected in guidance with community leaders. Community sensitization and door to door survey was conducted by the interdisciplinary team included community members and students from Prosthetics & Orthotics, Occupational Therapy and Physiotherapy Departments, College of Medicine and health Sciences, University of Rwanda. The Washington Group Short Set of Questions on Disability was used for screening Persons with Disabilities (PWDs). The individual assessment was also performed to identify the activity limitations, participation restriction, and rehabilitation needs using instrument developed based on the International Classification of Functioning Disability and Health (ICF) by interdisciplinary team of students, lecturers and practitioners.

# **RESULTS**

The most barriers to participation were geographical terrain and negative attitudes. The most frequent needs were social and educational support. PWDs reported Orthopaedic, Physiotherapy, Occupational Therapy, and speech therapy as needed rehabilitation services.

### **DISCUSSION AND CONCLUSION**

The most barriers to participation were geographical terrain and negative attitudes. The most frequent needs were social and educational support. PWDs reported Orthopaedic, Physiotherapy, Occupational Therapy, and speech therapy as needed rehabilitation services.



# Advanced IC Orthotics: Lower Limb Neurological

### 4.3.1

# The Role of AFOs with Resistive Moment and Evaluation Methods in Gait Rehabilitation for Individuals with Stroke

Hiroshi Hashimoto<sup>1</sup>, Sumiko Yamamoto<sup>2</sup>, Koji Ohata<sup>3</sup>, Yosuke Nishimoto<sup>4</sup>

<sup>1</sup>Pacific supply Co. Ltd., Osaka, Japan. <sup>2</sup>International University of Health & Welfare, Tokyo, Japan. <sup>3</sup>Kyoto University, Kyoto, Japan. <sup>4</sup>Kawamura Gishi Co. Ltd., Osaka, Japan

#### **Abstract**

Lower limb orthoses, especially Ankle-Foot Orthoses (AFOs), play an important role in gait rehabilitation for individuals with stroke. Most conservative AFOs restrict the motion of ankle joints to maintain stability during gait. However, the gait analysis with 3-D motion capture systems has revealed that the imperfect rocker function are observed during the gait with stroke, which leads to declined ability of walking. Therefore, it is important to select appropriate AFOs to reconstruct the rocker function.

An AFO with resistive moment was developed to reconstruct the first and second rocker based on the knowledge of gait analysis. It has been widely used for intensive gait trainings to facilitate the motion of the ankle in clinical settings in Japan. Moreover, a new measuring instrument, that has electrodes for EMG, load cells, a digital goniometer, an accelerometer, with a video camera, has begun to be used with the AFO to evaluate the outcome of the rehabilitation process in clinical settings.

This advanced instructional course, by a multidisciplinary team, is aimed to give an overview of the gait analysis of stroke and the role of the AFOs, and to show how the AFOs reconstruct the gait. It also demonstrates how to evaluate the gait and the design of the interventions by using the measuring instrument and how to fit and adjust the AFOs individually.

### Statement of the objective / learning objectives

To understand the characteristics of the gait of stroke, the role of AFOs in gait rehabilitation, and how to evaluate the gait and design of the interventions in clinical settings.



# Free Paper Session Sports & Physical Activity

# 4.3.2.a

# **Experiences of a Mobility Clinic for People with Limb Loss**

<u>Sarah Anderson</u>, Lisa Chaffey, Michael Dillon La Trobe University, Melbourne, Australia

#### **BACKGROUND**

Mobility following amputation is reduced and people with limb loss are often discharged from rehabilitation programs with some degree of mobility limitation.[1] Mobility clinics are designed to extend gait and mobility training beyond rehabilitation programs. No research has been undertaken into participants' experiences of these multidisciplinary, experience-based, clinics. Research in this area is needed to ensure clinics meet intended goals, including understanding the motivation and experience of attendees. Insights may improve mobility clinics and inform strategies to encourage greater participation.

#### AIM

To explore the motivation of people with limb loss to attend a mobility clinic, the experience of participation, and their perception of the clinic's benefits.

#### **METHOD**

Semi structured interviews were undertaken with nine mobility clinic attendees. All interviews were transcribed verbatim and data was thematically analyzed using Nvivoxx by two researchers. Emergent themes were member checked via follow up 3 months after the interviews.

#### **RESULTS**

Three themes emerged from the data.

- 1. Facing the challenge outlined how participants had underlying aspects of facing challenges in their lives following amputation or living with amputation. The impact of their amputation was felt across many aspects of participants' daily lives and challenged participants' views of a "normal" life.
- 2. Valuing Peers highlighted the importance of peers in the educational experience. Peers provided formal and informal support as well as learning opportunities during the clinic. Participants reported feeling as if they belonged to the group, and they could give and receive advice.
- 3. Improving mobility provided insight into the paucity of training participants had to participate in which had largely focused on gait skills. The additional skills that participants required were largely self-taught. Participants saw this clinic as a method of increasing knowledge about mobility and their use of their prostheses.

# **DISCUSSION AND CONCLUSION**

The mobility clinic was attractive to those who liked challenges and was an invaluable source of learning for those wishing to improve their mobility. Participants reported changes in mobility and that the importance of peer learning cannot be underestimated. Future clinics should ensure that peer education is supported, and activities cater for a range of skills and fitness levels.

#### **REFERENCES**

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# **ACKNOWLEDGEMENTS**

Funding for this project was provided by Össur ehf, R&D, Medical Office, Iceland.



# 4.3.2.b

# Effect of Prophylactic Knee Bracing on Muscle Forces during Unexpected Perturbations

Raneem Haddara, Vahidreza Jafari Harandi, <u>Peter Vee Sin Lee</u> University of Melbourne, Parkville, Australia

#### **BACKGROUND**

The quadriceps and hamstrings muscle imbalance have been previously associated with anterior cruciate ligament (ACL) injury.[1, 2] Quadriceps are known as the ACL antagonists while the hamstrings are the ACL agonists. Prophylactic knee braces are knee braces that are designed to mitigate this and reduce the risk of injury. To determine the effectiveness of these braces, subjects were unanticipatedly perturbed during walking with and without the braces. Muscle forces of the landing leg (post-perturbation) were calculated and reported.

#### AIM

To determine if the braces reduce quadriceps force (ACL antagonist) and increase hamstrings force (ACL agonist) and thus reduce risk of ACL injury.

#### METHOD

One healthy male (age: 25y; height: 1.86 m; mass: 80.1 kg) with no previous injury history participated in this study. All testing procedures were approved by the relevant Human Research Ethics Committees (Melbourne University). Trials were completed without and with a brace(POD K8, Australia). The trials were performed using the Computer Assisted Rehabilitation Environment (CAREN) (MotekforceLink, Netherlands). The participant had 45 markers placed on his lower limbs, pelvis, and torso. He walked at a speed of 1.1 m/s for 5 minutes before the perturbations were administered. The perturbation comprised of a sudden increase in the left leg speed to 2.31m/s with a maximum acceleration of 3.9 m/s<sup>2</sup>.

#### **RESULTS**

The brace decreased the quadriceps muscle forces per kg from 37.45 to 23.42 N/kg (Figure 1a) and increased the hamstrings forces from 9.03 to 12.54 N/kg (Figure 1b).

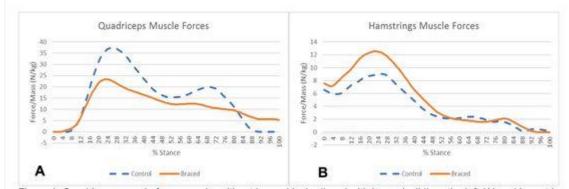


Figure 1. Quadriceps muscle forces per kg without brace (dashed) and with brace (solid) on the left (A) and hamstrings muscle forces per kg without brace (dashed) and with brace (solid) on right (B), n=1.

#### **DISCUSSION AND CONCLUSION**

The brace showed promising preliminary results in decreasing the muscle imbalance by reducing quadriceps forces by 14.04 N/kg and increasing hamstrings forces by 3.52 N/kg. However, more subjects need to be analyzed to determine true statistical significance.

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### 4.3.2.c

# Effect of Toe Displacement Trajectory of a Running-Specific Prosthesis on Sprinting Behavior

#### Ken Endo

Xiborg Inc., Tokyo, Japan. Sony Computer Science Laboratories, Tokyo, Japan

#### **BACKGROUND**

As represented by the Paralympic Games, recent athlete running on a running specific prosthesis(RSP) performs remarkably. Nevertheless, as the number of runners is still small, and as fabrication of carbon fiber reinforced plastics (CFRP) is both complicated and expensive, data regarding effect of running-specific prosthesis shape on running behavior are still limited. Since we closely develop a RSP with world-top runners, we examine how toe displacement trajectory of a RSP affects athletes' running behavior.

#### ΔIM

Examine effect of toe displacement trajectory of a running-specific prosthesis comparing two type of prostheses on running behaviour.

#### **METHOD**

Fixing the upper part of a RSP and loading vertically from its bottom on a slider, it deforms while storing energy like a spring. Due to a specification of RSP shape, its toe moves not only in upward but also in anterior direction. We hypothesize larger anterior displacement generates force to push a swing leg forward at the end of stance phase. On the other hand, small anterior displacement generates more force to push the body upward. Össur Cheetah Xtreme [1] and Xiborg [2] Genesis are used for comparison study. 4 athletes run 60m 3 times on each RSP and data are corrected via motion capture system at the top speed.

#### **RESULTS**

Figure 1 shows maximum hip flexion moment and mechanical work done by vertical ground reaction force(GRF) per one gait cycle toward center of mass of body during running at the top speed on two different RSPs. These data are normalized by body weight and height. Athletes generate less hip flexion moment with Össur Cheetah Xtreme. This is because GRF generates a force to push the swing leg forward. On the other hand, GRF does more mechanical work in vertical axis with Xiborg Genesis. This is because the RSP generates more force in its vertical direction, which results in pushing body upward rather than pushing the swing leg forward.

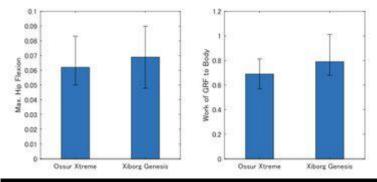


Figure 1. Maximum hip flexion moment and work done by GRF toward center of mass of body during running on two different RSPs.

## **DISCUSSION AND CONCLUSION**

Össur Cheetah Xtreme has larger displacement in anterior direction than Xiborg Genesis by 11% when it loaded with 1,000N. Therefore, as a results, these results confirms our hypothesis that larger anterior displacement helps swing leg motion with generation of smaller hip flexion moment, while smaller anterior displacement generates more mechanical work toward athletes' body. As the study focuses only toe displacement, the other body motions are ignored and still difficult to evaluate total performance.

# **REFERENCES**

- [1] Össur Cheetah Xtreme (https://www.ossur.jp/prosthetic-solutions/products/sport-solutions/cheetah-xtreme)
- [2] Xiborg Genesis (http://xiborg.jp/en/genesis/)



# 4.3.2.d

# **Confirmation Bias Affects User Perception of Orthopedic Devices**

Mark Geil<sup>1</sup>, Brittany Balsamo<sup>2</sup>
<sup>1</sup>Kennesaw State University, Kennesaw, USA. <sup>2</sup>Georgia State University, Atlanta, USA

#### **BACKGROUND**

Both prosthetic and orthotic joints have evolved to include dynamic stiffness adjustment, microprocessor control, and active motors. Advanced devices present a challenge when measuring outcomes during their use. The potential effects of cognitive biases make it difficult to determine whether outcomes change because of the function of the devices, or because the advanced technology has caused users to expect the devices to function better. Confirmation bias occurs when perceptions of a stimulus are affected by expectations about the stimulus.[1]

#### **AIM**

This study examined the expectations and outcomes of healthy young adults wearing knee braces to determine if: 1) their opinions would favor the brace they thought was more advanced, and 2) if their gait would change.

### **METHOD**

Eighteen healthy young adults aged 18-26 years participated in this IRB-approved study. We told the participants that a manufacturer was testing a new prototype knee brace, and showed them a fabricated flyer describing the "computerized" brace. Participants then completed a survey indicating expected preference for the "computerized" brace in various categories. In reality, the two braces were identical Mueller Adjustable Hinged Braces. We altered the appearance of one by adding a USB port, switch, LED light circuit, and by altering the color of the straps. Next, we measured their walking gait in both braces (in random order) using a motion analysis system. After the gait trials, participants repeated the survey.

#### **RESULTS**

In general, participants expected the "computerized" brace to perform better before they actually used it, with 61% expressing an overall preference for that brace, compared to 18% who thought they would prefer a standard brace. In walking trials, there were no significant differences between braces for any outcome measure. Many results were identical or almost identical. For example, self-selected walking speed was within 1 mm/s. Time series graphs showed consistency throughout the gait cycle, not just at local maxima. There were also no significant differences between limbs in either condition. Following the walking trials, participants' preference for the "computerized" brace increased. The Overall Preference factor exhibited the greatest difference between the Pre-trial and Post-trial questionnaires. While 61% of the participants showed overall preference for the "computerized" brace on the pre-trial questionnaire, this increased 21% (to 83%) post-trial.

# **DISCUSSION AND CONCLUSION**

These results confirm the presence of cognitive biases associated with user perception of an orthopedic device. Walking did not change, though users thought it was improved in a brace they thought was advanced. It is possible that walking could have changed in an impaired population, while in this population of healthy subjects, gait was presumably already optimized. The study underscores the importance of blinding when using self-reported outcomes and the need to consider a placebo effect when comparing orthopedic devices.

### **REFERENCES**

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### 4.3.2.e

# A Qualitative Analysis of Barriers and Facilitators to Physical Activity for Individuals with a Lower Limb Amputation in the UK

Zoe Schafer, <u>Natalie Vanicek</u> University of Hull, Hull, United Kingdom

#### **BACKGROUND**

A growing body of evidence supports the benefits of physical activity for people with a lower limb amputation (LLA). However, participation rates in physical activity are low for people with limb loss.[1] Previous research has sought to understand the perceived barriers and enablers to participation in sport, exercise and/or physical activity, in populations such as Dutch community-dwelling individuals and athletes,[2] American men with transtibial osteomyoplastic amputations [3], and American military veterans.[4,5]

#### AIM

The aim of the present study was to understand the barriers and facilitators to participation in sport, exercise and/or physical activity for people living with limb loss in the UK.

### **METHOD**

Nine participants, with varied levels and causes of amputation, responded to semi-structured, open-ended questions in a focus group setting. They were screened according to their physical activity levels (as defined by the WHO physical activity guidelines) and interviewed as two groups: physically active (n=6; mean age=65 years) or inactive (n=3; mean age=55 years). Probing questions included contributing factors towards their current level of activity; motivating and demotivating reasons to exercise; support and opportunities for exercise; and satisfaction with prosthetic rehabilitation. Focus groups were transcribed verbatim and member-checked. Thematic analysis of the qualitative data was completed according to Braun and Clarke (2006).

#### **RESULTS**

Similar findings were noted between the physically active and inactive groups, for both perceived barriers and facilitators to participation in physical activity (Figure 1). Exercise facilities were deemed poor and ill-suited to the needs of people with an LLA. High costs of accessing exercise facilities and a poor "value-for-money" experience were also reported. Strong motivators to exercise included opportunities for socialisation with family/friends and resuming "normality".

#### Poor access and availability of suitable Inadequate facilities for exercising Lack of readily available information provision Inadequate prosthetic function and poor fit Prosthetic and (including residual limb problems) Barriers intact limb Injuring the intact limb concerns Lack of motivation Psychological Ps Self-consciousness including concerns factors regarding the perceptions of others Social factors Returning to Feeling 'normal' again Facilitators 'normality'

# DISCUSSION AND CONCLUSION

More barriers to exercise were reported than facilitators. The lack of readily available advice about

Figure 1. Barriers and facilitators to exercise identified in both focus groups

participation was an important limitation, which could be mitigated during the important post-operative phase.[3] Exercise classes were reported as a facilitator among older veterans in the USA.[5] Such provision could also help promote social interaction and feelings of "normality". Our findings support the implementation of low-cost, group-based exercise sessions within the community, and more proactive and early sharing of advice for exercise participation.

## **REFERENCES**

- [1] Bragaru et al, Sports Med 2011.
- [3] Crawford et al, J Prosthet Orthot 2016.
- [5] Littman et al, J Rehabil Res Dev 2014.
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- [4] Littman et al, Disabil Health J 2017.



# 4.3.2.f

# Are Mobility and Quality of Life Closely Linked in Lower Limb Amputees?

<u>Sarah Anderson</u>, Michael Dillon La Trobe University, Melbourne, Australia

#### **BACKGROUND**

Improving mobility has been shown to have a positive influence on quality-of-life.[1] Programs designed to improve mobility have the potential to significantly improve quality-of-life; particularly given that mobility is one of the few influencing factors that is readily modifiable.[2] Organisations have sought to improve quality-of-life through the introduction of mobility clinics for people with limb-loss which aim to increase mobility of a person with limb-loss through participation in activities designed to improve confidence, balance, strength and prosthetic skill.

#### **AIM**

The aim of this project is determine changes in mobility score and determine if a relationship exists between mobility and quality of life.

### **METHOD**

Participants who had self enrolled in a mobility clinic completed an online survey which contained the PlusM, SF 36v2 along with demographic and other outcome measures. Participants completed the survey three times. Once before the clinic, one one week following the clinic and then three months following the clinic. A linear regression was used to identify the relationship between PlusM score and the physical component score of the SF36v2.

#### **RESULTS**

Nine participants (50% response rate) completed all three surveys and were include in the study. All participants were prosthetic users, the cause of amputation varied, 1 persons had an amputation due to diabetes, 2 were congenital, 2 were as a result of infection or illness and, 4 were as a result of trauma. There were 7 people with transfemoral level amputations. All 9 participants were employed, and mean income reported was in excess of AUD \$100,000 per annum.

N=9	Mean (SD)	Range
Age (yrs)	42.1 (7.23)	33-56
Time since amp (yrs)	9.13 (8.86)	1.17-24.5
Gender	3 Male, 6 Female	

Results of the statistical analysis will be presented.

# **DISCUSSION AND CONCLUSION**

The physical component score of the SF36v2 and the PlusM mobility scores were not related. This surprising finding suggests that either mobility plays less of a role in the physical component score than originally suggested or that other areas of function contribute more to quality of life or quality of life measures. Further research is warranted in this area.

# **REFERENCES**

[1] Wurdeman, Prosthet Orthot Int 2017.

[2] Quigley, Prosthet Orthot Int 2016.

## **ACKNOWLEDGEMENTS**

Funding for this project was provided by Össur ehf, R&D, Medical Office, Iceland.



# Symposium Other

### 4.3.3

# Prosthetics & Orthotics in 2030 – How will Material Science and Design Transform the Possible?

Catherine Holloway<sup>1,2</sup>, Masa Inakage<sup>3</sup>, Lucas Paes de Melo<sup>4</sup>, Mark Miodownik<sup>5</sup>

<sup>1</sup>University College London (UCL), London, United Kingdom. <sup>2</sup>Global Disability Innovation Hub, London, United Kingdom.

<sup>3</sup>Keio University Graduate School of Media Design, Tokyo, Japan. <sup>4</sup>AMPARO, Berlin, Germany. <sup>5</sup>University College London, London, United Kingdom

#### **Abstract**

The symposium will explore what the international P&O community will be talking about at ISPO 2030. It will draw on the expertise of leading experts in Design, AT, and Material Science to explore and give examples of the probable and the possible: what does this mean for P&O? How will digital methods (4D printing) change how we design, develop and deliver P&O's? How will data help drive design? How interactive and responsive will P&O become? How will an increasing user interaction impact the design process? How will all of this impact the skills gap?

We will explore the probable by revealing opportunities and challenges of trialling new products within service through the example of AMPARO which uses material science innovation to transform delivery service of prostheses in Kenya through the AT2030 programme, particularly in the developing world, and then look to the near future. New materials and 4D printing allow us to design bespoke liners which can sense. We will explore what this means for the P&O sector. Finally, we take a futuristic look, inspired by advances in design at what is possible for 2030 and how we can harness the enthusiasm and ingenuity of the new generation of designers working alongside the medical profession to push the boundaries of what is possible.

This symposium is supported by the British Council as part of the Tokyo 2020 Cultural Programme and by the AT2030 Programme which is funded through the UK Department for International Development.

# Statement of the objective / learning objectives

It will offer a futuristic look, inspired by advances in design, at what is possible for 2030 in the P&O field.



# Free Paper Session Prosthetics: Lower Limb Transtibial - Socket

### 4.3.4.a

# Mechanical Behavior Evaluation of Novel Prosthetic Devices for Transtibial Amputees Produced by Additive Manufacturing Composites

Maria Rojas-Ugalde<sup>1,2</sup>, Miguel Araya-Calvo<sup>1</sup>, Ignacio López-Gómez<sup>1</sup>, Sebastian Corrales-Cordero<sup>1</sup>, Olga Sánchez-Brenes<sup>1</sup>

<sup>1</sup>Laboratorio de Ergonomía Aplicada, escuela de Ingeniería en Diseño Industrial, Tecnológico de Costa Rica, Cartago, Costa Rica. <sup>2</sup>Maestría en Sistemas Modernos de Manufactura, Escuela de Ingeniería en Producción Industrial, Tecnológico de Costa Rica, Cartago, Costa Rica

### **BACKGROUND**

Three-dimensional manufacturing technology has the potential to fabricate prosthetic components with a complex and personalize geometry without affecting the manufacturing cost. The mechanical capacities of 3D printed materials should be assessed before applying this manufacturing method on lower limb prosthetic components.

#### AIM

The goal of this study was to evaluate the mechanical performance of novel prosthetic devices produced with composite materials by additive manufacturing process.

#### **METHOD**

Computational model of prosthetic device for transtibial amputee (socket, pylon, foot) was developed using computer aid design and three-dimensional scanning. A finite element analysis (FEA) was performed according to ISO 10328 and ISO 22675 standards to evaluate the mechanical behavior of the prosthetic devices, followed by an iterative optimization of the design. To define the optimal printing configuration and materials for each component compressive and flexural testing were developed, using design of experiments as a statistical methodology. The device was fabricated using additive manufacturing technology based on continuous filament fabrication (CFF), several experimental mechanical tests on the prototypes were executed.

#### RESULTS

Compressive and flexural testing results showed that the higher mechanical properties were achieved using 24% of reinforcement with concentric and equidistant printing configuration. Using these results, optimized designs were evaluated for toe-off and heel-strike static stances using FEA. The maximum stress found for the socket and pylon was 22.6 MPa and 39.1 MPa respectively for toe-off stance, and maximum stress found for the foot was 54.5 MPa for heel-strike stance. The maximum stress found in dynamic computational analysis was 33.4 MPa for the pylon, this value does not exceed the material proportional limit. Experimental mechanical static test on Pylon prototype was done also, the maximum deformation found was 0.4 mm for toe-off stance and the maximum force achieved before rupture was 3345 N for toe-off.

# **DISCUSSION AND CONCLUSION**

Maximum stress found in static condition using FEA was lower than the proportional limit of the corresponding material. Dynamic computational analysis of the Pylon does not show evidence of fatigue degradation under 10<sup>6</sup> cycles. Experimental mechanical tests of the Pylon satisfy the requirements defined in ISO 10328. Additive manufacturing technology based on CFF is verified as a possible manufacturing process for lower limb customized prosthetic devices.

## **REFERENCES**

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## **ACKNOWLEDGEMENTS**

Authors acknowledge support from VIE, Posgrados, Mechanic Materials laboratory, Center Research and Extension of Materials Engineering, Tecnologico de Costa Rica.



### 4.3.4.b

# Using of PVA/NaCl Hydrogel in Prosthetic Liner Application to Reduce Perspiration Between Residual Limb and Liner

Sadeeq Ali<sup>1</sup>, Nadzirah Binti Abdul Razak<sup>2</sup>
<sup>1</sup>Oslo Metropolitan University, Oslo, Norway. <sup>2</sup>University Malaya, Kuala Lumpur, Malaysia

#### **BACKGROUND**

Perspiration inside the prosthetic liner often leads to skin problems on the residual limb such as skin irritation, odour, and dermatitis. Many prosthetic liners are available in the market and manufacturers claim no dermatological problems occur with these liners. However, perspiration is still one of the most common problems in prosthetic liner users. The current evolution of materials in the review of biomedical applications has aimed to improve the functional properties of biomaterials to enhance interaction with biological systems.

#### AIM

The aim of this study is to study the fabrication and characterization of polyvinyl alcohol (PVA)/ sodium chloride (NaCl) hydrogel foam as perspiration absorbent medium in prosthetic liner application.

### **METHOD**

PVA/NaCl hydrogel foam was obtained by making solutions containing Polyvinyl alcohol, sodium chloride, glycerin and was prepared in deionized water PVA/NaCl hydrogel foam was prepared by using the freeze-drying technique and cured using UV-rays and then sandwich between the silicon. Different testing techniques were applied, Fourier Transform Infra-Red spectroscopy (FTIR), Scanning Electron Microscopy (SEM), Tensile Testing, Dynamic Mechanical Analysis (DMA), Contact angle and Swelling behavior were checked to better understand the properties of the materials of the PVA/NaCl hydrogel foam. These testing techniques were applied when PVA/NaCl hydrogel foam was sandwich with silicon pallet and without silicon pallet.

#### **RESULTS**

The mixture of the PVA and sodium chloride with the plasticizer through the freeze-drying technique produces a porous hydrogel foam and exhibits outstanding hydrophilic properties with a contact angle between <5°-10° and the UV cured samples have higher structural integrity and absorb water up to 30% of the original weight with respect to time. The tensile test showed that UV Cured PVA/NaCl un-inserted is 13 times stronger compared to UV Cured PVA/NaCl inserted with a silicon sheath.

# **DISCUSSION AND CONCLUSION**

The entire properties showed by the PVA/NaCl hydrogel foam has revealed its appropriateness as an excellent perspiration absorbent medium in prosthetic liner application. PVA/NaCl hydrogel foam will reduce sweating problems in prosthetic liners users. Using of PVA/NaCl together with silicon will provide a better liner compared with the recent available liners.



## 4.3.4.c

# The Effects of Perforated Prosthetic Liners on Residual Limb Health: A Case Series

Ana Gallego<sup>1</sup>, Joe McCarthy<sup>1</sup>, Michael McGrath<sup>1</sup>, Alan Kercher<sup>2</sup>, <u>Saeed Zahedi</u><sup>1</sup>, David Moser<sup>1</sup>
<sup>1</sup>Blatchford, Basingstoke, United Kingdom. <sup>2</sup>Endolite North America, Miamisburg, USA

### **BACKGROUND**

Replacement sockets are a significant time and financial burden on prosthetic services.[1,2] Some of the most commonly reported socket problems include excessive sweating and wounds/infections on the residual limb.[3,4] Elevated Vacuum Suspension (EVS) has been shown to aid residual limb wound healing [5,6] by applying negative pressure to the affected area. Perforated prosthetic liners allow sweat to be transported away from the skin and permit the negative vacuum to be applied directly to the residual limb surface.

#### AIM

Highlight the benefits of prosthetic socket technologies to residual limb health.

#### **METHOD**

Case studies were collected from patients with a history of sweating and residual limb health problems. Each was provided with a perforated, sweat management prosthetic liner to be used with either pin-lock suspension (Silcare Breathe Locking, Blatchford) or EVS (Silcare Breathe Cushion, Blatchford). The patients attended regular clinical visitations of a period of three months, during which their residual limb wounds were assessed.

### **RESULTS**

The different cases highlight the effectiveness of liner perforations, EVS and the combination of the two technologies to aid residual limb wound healing, for broad demographics. One case described a patient assessed as K1-K2 mobility level, who commonly used a wheelchair, with a long standing, seeping wound on her residual limb. She was prescribed a perforated cushion liner with suction suspension to allow moisture transfer. Other cases describe more active amputees with persistent blistering, irritated by exercise and activity, including a male who cancelled a surgical intervention after substantial improvements with a perforated pin-lock liner. All cases reported the wounds to be healed after approximately three months.





Figure 1. Photos illustrating a residual limb wound 'before' and 'after' the use of the perforated liner technology.

#### **DISCUSSION AND CONCLUSION**

The residual limb is arguably the most crucial element of success prosthetic treatment. There is growing evidence that the combined use of perforated, sweat management liners with EVS allows the successful healing of residual limb wounds, while still permitting prosthetic use.

# **REFERENCES**

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- [4] Dudek et al. Arch Phys Med Rehabil 2005.
- [6] Hoskins et al. Prosthet Orthot Int 2014.



## 4.3.4.d

# Natural Fiber with Leaf Extract (PSPO Sock) as an Alternative Material to Cotton Used in Philippine School of P&O

<u>Krisha Kate Tansiongco</u>, Alexander Abellon, Nicko Sean Cantiga, Iris Cecile Ambatali, Marichelle De Castro University of the East Ramon Magsaysay Memorial Medical Center, Inc., Quezon City, Philippines

#### **BACKGROUND**

Inadequate ventilation within the prosthetic socket can cause skin problems to amputees. Prosthetic sock serves as a barrier between the skin and liner. However, the commonly use prosthetic cotton sock is less permeable and absorbent, and retains sweat which promotes bacterial growth. These led the researchers to create PSPO sock made from natural fiber with leaf extract as an alternative to cotton as it has proven to have good properties.

#### AIM

To produce an alternative material to cotton in producing prosthetic socks and to compare the difference of PSPO and Cotton socks in terms of antibacterial, air permeability, and absorbency properties.

#### **METHOD**

Researchers used a Quantitative Quasi-Experimental design to fulfill the objectives of the study. Production and testing of the materials were all conducted in Department of Science and Technology. PSPO sock production was divided into five different stages: Gathering of raw materials, Decortication, Spinning, Knitting, and Dyeing. Samples underwent three different material tests: air permeability, absorbency, and antibacterial property. Mann Whitney U Test was used to test the difference in air permeability wherein the significance level was set as p=0.05 with confidence interval=95%. On the other hand, descriptive analysis was used to analyze the difference in absorbency and antibacterial properties.

#### **RESULTS**

PSPO sock showed statistically higher air permeability (p value <0.05) than Cotton sock with a value of 295.5 cm³/s/cm² and 112.7 cm³/s/cm² respectively as seen in the table. PSPO still showed faster absorbency than Cotton, as it took only 0 sec for the water droplet to be absorbed on the surface of the PSPO sock compared to Cotton which took 60 secs as seen in the table. Lastly, both PSPO sock and Cotton sock showed no difference in antibacterial property against Staphylococcus Aureus as both have 0 mm zone of inhibition and negative inhibitory activity.

PARAMETERS	Number of Specimen	PSPO Sock	Cotton Sock
Air Permeability (cm <sup>3</sup> /s/cm <sup>2</sup> )	10	296	113
Absorbency (s)	5	0	60+
Anti-bacterial (mm)	1	0	0

Table 1. Summary of the Results Comparing PSPO and Cotton Sock

# **DISCUSSION AND CONCLUSION**

PSPO sock is more absorbent and permeable than in Cotton sock. Knitting structure also influenced the result of the study. However, antibacterial property of both samples did not inhibit the Staphylococcus Aureus. Further material testing, use of industrial machinery for knitting, and use of pad-dry or printing method in obtaining antibacterial property are recommended to lessen the bias and to meet all the important properties before testing to actual patients.

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# 4.3.4.e

# **Mechanical Testing of Textured Prosthetic Sockets**

Julia Quinlan<sup>1</sup>, Jessica Yohay<sup>1</sup>, Vasanth Subramanian<sup>1</sup>, Brad Poziembo<sup>2</sup>, <u>Stefania Fatone</u><sup>1</sup> Northwestern University, Chicago, USA. <sup>2</sup>Prosthetic Design Inc., Dayton, USA

#### **BACKGROUND**

Textured prosthetic sockets produced using the SQUIRT-Shape fused deposition modelling system [1] may provide improved suspension, comfort and fit by adding texture to the inner wall of the socket. However, there are no standards to test effectiveness of socket suspension. Additionally, limited information is available on the effect of texturing on friction, which is needed for good suspension, and tensile strength, which is likely influenced by how well layers are bonded.

#### AIM

The aim of this study was to assess the effect of socket texturing on coefficient of friction (COF), ultimate tensile strength (UTS) and suspension in longitudinal and transverse planes.

#### METHOD

Socket samples were printed from polypropylene copolymer with 14 different texture patterns and their behavior was compared to conventionally used reference materials (raw polypropylene copolymer sheet, a thermoformed smooth polypropylene copolymer socket and a SQUIRT-Shape Socket with original default texturing). Standardized tests [2, 3] (Figure 1A, 1B) were used to assess UTS and COF of material samples and we developed custom material testing set-ups [4] (Figure 1C, 1D) and methods to investigate longitudinal and

rotational suspension of prosthetic sockets on mock residual limbs under two conditions: passive suction with a one-way valve and active suction with a vacuum pump at 20 mmHg.

# **RESULTS**

Static COF for textured material ranged from 0.271 to 0.422 and kinetic COF from 0.208 to 0.332. UTS for textured sockets ranged from 3.97 to 14.32 MPa. Longitudinal

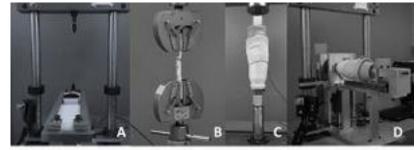


Figure 1 Testing set-ups for Coefficient of Friction (A), tensile strength (B), longitudinal (C) and rotational testing (D).

displacements for textured sockets ranged from 2.617 to 3.834 mm for passive suction and 2.060 to 3.458 mm for active vacuum. Torque for textured sockets ranged from -21.12 to -35.21 Nm for passive suction and -23.59 to -40.86 Nm for active vacuum. Socket texturing significantly affected COF, UTS and suspension in longitudinal and transverse planes compared to the reference materials. As expected, textured samples exhibited smaller UTS when compared to raw sheet material, with more aggressive texturing weakening the socket more than less aggressive texturing.

## **DISCUSSION AND CONCLUSION**

While it might be judicious to avoid aggressive textures when printing sockets, the minimum acceptable UTS of socket materials is unknown. While static COF was higher for textured samples, kinetic COF was lower. When suspension was assessed using a more realistic scenario, some textured sockets improved suspension in both planes compared to a smooth socket. This is likely due to compression of the socket creating greater engagement between material surfaces than possible with standardized testing.

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Funded by the US Department of Defense award #W81XWH-16-1-0485.



# Free Paper Session Prosthetics: Lower Limb - Gait

### 4.3.5.a

# Mechanical Work Performed during Step-to-Step Transition in Amputee Gait: A Promising Way to Help Understanding Metabolic Cost while Walking?

Céline Lansade<sup>1</sup>, Hélène Pillet<sup>2</sup>, Coralie Villa<sup>3</sup>, Gérard Chiesa<sup>1</sup>

Institut Robert Merle d'Aubigné, Valenton, France. Institut de Biomécanique Humaine Georges Charpak, Paris, France. Institution Nationale des Invalides - CERAH Centre d'Etudes et de Recherche sur l'Appareillage des Handicapés, Créteil, France

#### **BACKGROUND**

Although prosthetic components are improved to restore comfortable and secured gait, amputees present abnormal gait pattern with substantial compensations that result in greater energy cost. Metabolic energy cost appears as a relevant indicator of gait's quality. The referent method implying measurement of exhaled gas is conflicting with fast clinical exam. Mechanical work, easily obtained with a conventional gait exam, could help to understand

metabolic energy expenditure.[1-3] However, current literature is limited by the sample size.[4]

The aim of this study is to quantify the mechanical work during stepto-step transition performed by patients according

# Table 1: Comparison between healthy subjects and patients concerning walking speed and mechanical works during step-to-step transition (PLimb = Prosthetic limb; Climb = Contralateral limb)

Mean (std)	Non amputee N=24	Partial foot amputee		Transfemoral amputee			
N=7	N=29	N=9					
PLimb	CLimb	PLimb	CLimb	PLimb	CLimb		
Walking velocity (m/s)	1,39 (0,12)	1,10 (0,22)	1,08 (0,28)	0,92 (0,33)			
W <sub>braking</sub> (J/kg)	-0.17 (0.08)	-0,07 (0,03)	-0,21 (0,08)		-0.12 (0.11)	-0.02 (0.04)	
W <sub>propulsion</sub> (J/kg)		0,05 (0,04)	0,18 (0,09)	-, -	,	0,07 (0,05)	0,23 (0,18)

to their level of amputation in order to help to explain the variations of metabolic energy cost during amputee walking.

## **METHOD**

AIM

45 patients with partial foot (PF), transtibial (TT) or transfemoral (TF) amputation have been included in the study. The gait analysis exam was realized on level ground. Each patient used his own usual prostheses and adopted his self-selected walking speed. Using the method developed by Donelan,[5] mechanical power was approximated as the dot product of the Cg velocity and the ground reaction forces applied on each lower limb. The mechanical work corresponding to step-to-step transition work was obtained using the time integral of mechanical power profile during the two double supports called respectively W<sub>braking</sub> and W<sub>propulsion</sub>. A control group of 24 asymptomatic subjects was used as a reference.

# **RESULTS**

Average walking gait velocities chosen by amputees decreases as the amputation level increases. Mechanical work during the first and the second double supports for each lower limb are presented in Table 1 for patients according to the level of amputation compared with healthy subjects.

# **DISCUSSION AND CONCLUSION**

As already stated in the literature, our results showed that the double stance phase is a crucial phase of mechanical power exchange. Mechanical work absorbed and generated by the prosthetic limb during step-to-step transition is smaller compared to the controlateral limb's one. It confirmed the great asymmetry of mechanical work between both lower limbs during amputee walking.[3,4] This study opens the way to a better understanding of amputee gait pattern and to the quantification of prosthetic components performance.

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# 4.3.5.b

# Can Whole Body Center of Mass Kinematics be useful for Prosthetic Control?

<u>Clément Duraffourg</u><sup>1,2</sup>, Xavier Bonnet<sup>1</sup>, Hélène Pillet<sup>1</sup>

<sup>1</sup>Institut de Biomécanique Humaine Georges Charpak, Paris, France. <sup>2</sup>Proteor®, Dijon, France

#### **BACKGROUND**

The adaptation of the behaviour of microprocessor controlled prostheses depends on walking condition identification. To improve both the accuracy and the delay of detection of the condition, authors have proposed to use whole body kinematic.[1] In the robotic field the center of mass (COM) is often consider as representative of the whole body and used for control [2] thus it should be useful for prosthetic control.

### **AIM**

The aim of this study was to evaluate the ability of the COM velocity to discriminate between conditions including level, uphill and downhill ambulation of people with transfemoral amputation.

### **METHOD**

Data from 21 people with transfemoral amputation walking on level ground, uphill and downhill on slopes of 5% and 12% at self-selected speed [3] were used in this study. The whole body kinematics were assessed with an optoelectronic system Vicon at 100 Hz and combined with segmental inertial data to obtain whole body COM kinematics. COM velocity (vCOM) was expressed in the VICON reference frame as a function of the percentage of the prosthetic gait cycle, and normalized. We performed one way repeated measures ANOVA analysis on sagittal plane vCOM on the mean, and values at heel strike and at mid stance (35% gait cycle).

#### **RESULTS**

An example of the evolution of vCOM in the different situations is shown on Figure 1. Anova analysis showed significant differences between all situations for all three parameters computed from vertical component of vCOM (max p-value = 0.011). Mean antero-posterior velocity significantly (p<0.01) decreased in 5% slopes regardless of the orientation (up or down), and the decrease was significantly greater on 12% slopes (p<0.01).

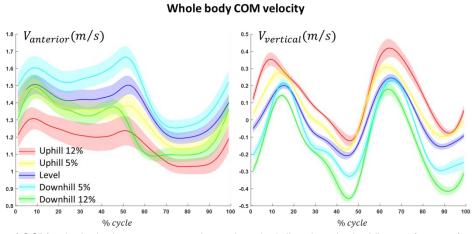


Figure 1. Example of COM velocity in the antero-posterior and vertical directions in the Vicon reference frame. The corridors represent ±1 standard deviation.

## **DISCUSSION AND CONCLUSION**

To the author knowledge, there is no study reporting the velocity of the COM during slope ambulation of people with transferoral amputation. Even if the tendency of vertical vCOM evolutions in slopes could be expected, the present study allowed to quantify these variations. The results confirmed that vCOM variations could be used for situations differentiation even for slopes as low as 5% (3°).

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The authors thank Proteor® for its financial support, as well as the CERAH and the IRR Nancy for data collection.



# 4.3.5.c

# Gait Analysis of Amputee Patients Walking with a Canadian Prosthesis

Mourad Faiz, Celine Lansade, Gérard Chiesa Institut Robert Merle d'Aubigné, Valenton, France

#### **BACKGROUND**

Canadian Prostheses (CP) are used for the most proximal amputations of the lower limbs such as hip disarticulation, hemipelvectomy and short transfemoral. Amputations in the pelvic area are rare [1] (1 to 2% of amputations) and their causes are mainly tumoral, vascular and traumatic. Few studies have investigated the gait pattern of patients with CPs and they were essentially case reports.[2, 3]

#### AIM

The aim of our study is to characterize the walking parameters of patients with a CP on a significant database and to evaluate the parameters of influence on the gait quality.

### **METHOD**

This is a prospective cross sectional study of patients with a CP who were followed at the Robert Merle d'Aubigné Institute in Valenton with a well adapted prosthesis and who are used to walk with it. Recruitment started from September 2017 and ended in January 2019. The study protocol includes a six minute test and a Gait Analysis in our laboratory equipped with a Vicon optoelectronic system and an AMTI force platform. The analysis were performed by only one person to avoid the inter-individual variability.

**RESULTS** 

We recruited 35 patients (sex ratio=0.54). The mean age was 48.3 years (Std 17.9). The mean time since amputation was 16.9 years (std 18.4). The causes of amputations were essentially tumoral (n=21) and traumatic (n=7). We recruited no vascular patients. The amputation levels were: hip disarticulation (n=30) hemipelvectomy (n=3) and short transfemoral (n=2). The majority of patients (41.9%) walked without walking sticks, 35.4% walked with one walking stick and 22.5% with two sticks. The main spatio temporal parameters and the six minutes test are described in Table 1. All of our patients used vaulting of the healthy size during the stance phase as a mechanism to facilitate the prosthetic side step. They also used the hip

TABLE 1

		Prosthetic side (Std)		Sound side (Std)
Step length (cm)	(cm)	0.56 [0.15]		0.57[0.12]
Percentage of stance phase	(%)	59.98[5.24]		73.28[4.69]
Range of motion of ankle joint (sagittal)	(*)	12.81[4.04]		29.44[9.5]
Range of motion of knee joint (sagittal)	(*)	24.12[14.42]		54.82[7.46]
Range of motion of hip joint (sagittal)	(*)	25.48[7.74]		57.3[11.63]
Range of motion of pelvic tilt	(*)		21.5[5.7]	
6 minutes test	(mn)		295.3[96.6]	

# **DISCUSSION AND CONCLUSION**

Our study, shows variability of the gait pattern depending on age, prosthetic material characteristics, etiology, comorbidities. Our results shows a healthy side vaulting higher than that described in the literature for more distal amputation levels, as well as a significant increase in pelvic sagittal plane inclination during the walking (hip-hiking), which is a characteristic strategy of the gait pattern of high level amputees.

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hiking of the prosthetic side during the swing phase.



# 4.3.5.d

# Reciprocating Gait Prosthesis for the Individual with Bilateral Hip Disarticulation

<u>Takashi Nakamura</u>, Hiroki Imai, Yumi Hama, Reiko Kondo National Rehabilitation Center for Persons with Disabilities, Saitama, Japan

#### **BACKGROUND**

Rehabilitation of the individuals with high-level lower limb amputation provides one of the greatest challenges for a rehabilitation team. For individuals with the bilateral hip disarticulation, incorporating a reciprocating gait orthosis within the prosthetic design has proven to allow successful standing and assisted ambulation for several patients. In an attempt to provide reciprocating gait, some swivel mechanisms have been mounted beneath the socket, however this produces a most unnatural style of walking.

#### ΔIM

This study provides a new design and gait training process of reciprocating gait prosthesis for the bilateral hip disarticulation amputee.

#### **METHOD**

The subject was a 24 years old male amputee with bilateral hip disarticulation. His hip prosthesis consisted of the locked knee (3R31, Otto bock), SACH ankle joints and the hip joints (TH-01C, Teh Lin) which were locking joints with stride control function. The hip joint were modified to improve stride control. Removal of the extension spring of the hip joint allows free flexion of the hip joint to obtain a range of motion in the sagittal plane.

#### **RESULTS**

Figure shows the sequence of one gait cycle. The gait is initiated in the following manner. Body weight was transferred to the support leg by inclining the body to one side. The contralateral limb becomes clear of the ground, then the swing limb proceeded from extension to flexion by gravity. Subsequent training from the physiotherapist, who has much experience about reciprocating gait training of paraplegic patients, produced an efficient gait.

The subject could independently don and doff the prosthesis, rise from a bed to a standing position, achieve reciprocal gait and return to a seated position without any assistance. A cable linking the knee-lock release mechanism to the socket operated the release mechanism only when the hip junctions had flexed. The knee yielding mechanism worked efficiently for the gentle sitting.

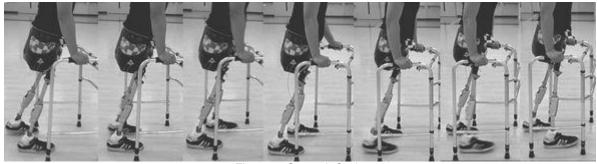


Figure 1. One gait Cycle

## **DISCUSSION AND CONCLUSION**

It is imperative that clinicians pay considerable attention to customizing seating systems and wheelchair fittings to achieve independent mobility, and the wheelchair provision is an easy solution for the locomotion. Although the disability of the bilateral hip disarticulation is severe in terms of both function and independence, the proposed simple prosthetic design that can overcome these factors will have a major impact on the lifestyle of bilateral hip disarticulation amputees.

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### 4.3.5.e

# The Utility of the Two-Minute Walk Test as a Measure of Mobility and Function in Community Ambulating Lower Limb Amputees

Anat Kristal<sup>1</sup>, Robert Gailey<sup>1</sup>, Ignacio Gaunaurd<sup>1,2</sup>

<sup>1</sup>Department of Physical Therapy, University of Miami Miller School of Medicine, Coral Gables, USA. <sup>2</sup>Department of Veterans Affairs Medical Center, Miami VA Healthcare System, Miami, USA

# **BACKGROUND**

Prosthetic ambulation is an essential goal in rehabilitation programs of people with a Lower Limb Amputation (LLA).[1] Outcome measures with normative data related to the walking of people with a LLA, can assist with the evaluation, goal setting, and treatment. The 2-Minute Walk Test (2-MWT) has become favorable as a measure of walking ability because it is simple, and easy to administer.[2] Currently there are no normative values of the 2-MWT for community ambulating LLA.

### **AIM**

1) To establish the normative values for the 2-MWT distance and gait speed in community ambulating LLA, 2) To describe the differences in data between groups based on gender, functional level, level of amputation, and cause of amputation.

## **METHOD**

A convenience sample of 103 LLA; either unliteral transfemoral or transtibial completed were recruited. All participants completed a demographic questionnaire and had their anthropometric measurements recorded by a physical therapist (PT). A certified prosthetist determined participants' functional level. The 2-MWT course had a rectangular shape with dimensions of 15 m x 0.58 m. A licensed PT administered the test according to a standardized protocol.[3] Independent student's t-test was used to examine the differences between genders and levels of amputation. One-way ANOVA was used to examine differences based on functional level and cause of amputation.

#### **RESULTS**

Significant differences in the 2-MWT distance and gait speed were found between genders (p<.05), functional levels (Table 1), level of amputations and causes of amputation (p<.05). Men walked farther and faster than women (p<.05). Functional level K4 performed better than K3 (p<.05) and K3 performed better than K2 (p<.05). Transtibial amputees performed better than TFA (p<.05) and The traumatic group performed better than the disease group (p<.05).

Table 1: 2-MWT performance based on the functional level

	K2 (n=8)	K3 (n=70)	K4 (n=25)
2-MWT Distance (m)* <sup>†§</sup> Mean±SD (range)	83.9±25.6 (49-119)	138.4±28.5 (52-197)	177.8±31.1 (124-259)
2-MWT Gait Speed (m/min)* <sup>†§</sup> Mean±SD (range)	42.3±12.8 (25-60)	69.4±14.3 (26-99)	89.0±15.7 (62-130)

Significant level *p*<.05. \* Significant difference between K2 and K3. <sup>†</sup> Significant difference between K2 and K4. <sup>§</sup> Significant difference between K3 and K4.

#### **DISCUSSION AND CONCLUSION**

This study reports the preliminary normative values of the 2-MWT distance and gait speed in community ambulating unilateral lower limb amputees (LLAs). Future research with a larger sample including all k-levels will further determine the descriptive profile of the 2-MWT performance in unilateral LLAs. Establishing normative values for the 2-MWT in people with LLA will further assist clinicians in creating individualized rehabilitation treatment programs and constructively communicate progress to patients.

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The study was supported by the Department of Defense/Veterans Affairs Joint Incentive Fund: Mobile Device Outcomes-based Rehabilitation Program (MDORP).



# 4.3.5.f

# Reliability of the Functional Lower-Limb Amputee Gait Assessment for Classification of Observational Gait Deviations in Lower Limb Amputees: Pilot Study

Anat Kristal<sup>1</sup>, Robert Gailey<sup>1</sup>, Jennifer Lucarevic<sup>1</sup>, Sheila Clemens<sup>2</sup>, Ignacio Gaunaurd<sup>1,3</sup>

Department of Physical Therapy, University of Miami Miller School of Medicine, Coral Gables, USA. <sup>2</sup>Department of Physical Therapy, Florida International University, Nicole Wertheim College of Nursing & Health Sciences, Miami, USA. <sup>3</sup>Department of Veterans Affairs Medical Center, Miami VA Healthcare System, Miami, USA

#### **BACKGROUND**

Gait deviations are common characteristics of lower limb amputee gait [1] and are associated with knee osteoarthritis (OA),[2] low back pain [3] and increased metabolic costs during walking.[4] Physical Therapists (PTs) would benefit from an objective, efficient, clinically friendly approach to Observational Gait Analysis (OGA) that identifies the most prominent gait deviations, to assist with interventions and monitoring of change over time. The Functional Lower-limb Amputee Gait assessment is a recently developed OGA instrument that assesses six critical gait events.

#### AIM

To establish the interrater reliability of three gait deviations of the FLAG assessment between five PTs.

### **METHOD**

Videos of unilateral Lower Limb Amputees (LLAs), walking at a self-selected speed, were analyzed by five PTs. The five PTs sat in a large conference room and together viewed videos on a large screen to determine subject gait deviation(s). The following gait deviations were evaluated: 1) decreased knee flexion, 2) decreased toe load, 3) other deviations, 4) no deviations. Each PT was blinded from each other. A two-way random effect Intraclass Correlation Coefficient (ICC) for an absolute agreement for multiple raters was used to determine the inter-rater (ICC<sub>2,k</sub>) reliability. Phi correlations were used to examine the relationship between the gait deviations.

## **RESULTS**

Significant moderate to good negative correlations were found between no deviations and decreased toe load (r=-.55, p<.001), and between no deviations and decreased knee flexion (r=.54, p<.001). A significant moderate positive correlation was found between no deviations and other deviations (r=.50, p<.00). Decreased knee flexion was found to have the highest co-occurrence with the other deviations. Lastly, ICC's calculated for the preliminary version of the FLAG assessment was 0.85.

# **DISCUSSION AND CONCLUSION**

The inter-rater reliability of the three gait deviations of the FLAG assessment was excellent indicating a strong level of agreement among the PT raters when assessing the presence of gait deviations in people with unilateral lower limb amputation. The FLAG provides a clinical systematic approach to observational gait analysis in people with LLAs. It allows for a method of classification of the most clinically relevant gait deviations which are modifiable in the rehabilitation setting.

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# **ACKNOWLEDGEMENTS**

The study was supported by the Department of Defense/Veterans Affairs Joint Incentive Fund: Mobile Device Outcomes-based Rehabilitation Program (MDORP).



# Free Paper Session Outcome Measurements - General

### 4.3.6.a

# Measuring General Benefits of Medical Technology Products Exemplified by users of Bone-Anchored Transfemoral Prostheses

#### Kerstin Hagberg

Sahlgrenska University Hospital, Gothenburg, Sweden. Sahlgrenska Academy, Gothenburg University, Gothenburg, Sweden

# **BACKGROUND**

A measure of patient-reported benefits generated by medical technology (medtech) products has been lacking. Recently, a generic measure, MedTech20®,[1] was introduced to capture medtech products attributes that affect the QoL and to supplement other outcomes in health economic assessments. A prosthesis is a medtech product. In bone-anchored prostheses (BAP), the attachment device connecting the BAP to the implant, is another product.

#### AIM

To describe outcome of the MedTech20<sup>®</sup> from the perspective of users of bone-anchored transfemoral prostheses.

# **METHOD**

In a mailed survey individuals treated with the OPRA-implant [2] in Sweden, using BAP since >1yr and able to complete questionnaires in Swedish, Norwegian or English were included and asked to answer MedTech20<sup>®</sup>. In this questionnaire, the degree of agreement (in 7 levels) to 20

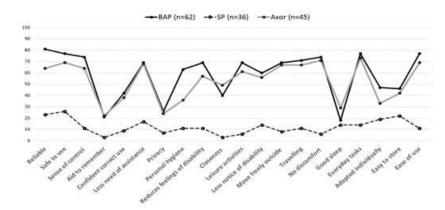


Figure 1. The percentage of participants who stated "agree a lot" to "completely agree" on each of the 20statements included in the MedTech20<sup>®</sup> Questionnaire for the BAP, the SP and the Axor device, respectively.

statements of attributes of a medtech product is collected. A preference-based index (0-1) describing the benefit of the product from the societal perspective can be calculated. Participants were asked to answer MedTech20<sup>®</sup> with regard to three products: the BAP, the previous socket-suspended prosthesis (SP) and the Axor attachment device.[2] The Regional Ethical Board approved the study.

#### **RESULTS**

Response rate was 76% (62/82). The 62 participants (66% men, mean age 57 yrs, 90% unilateral transfemoral amputation) had in Md 11 (1-29) yrs of experience of BAP. The mean MedTech20® Index was 0.655 (Sd 0.188) for BAP (n=62), 0.267 (Sd 0.179) for SP (n=36) and 0.582 (Sd 0.213) for Axor (n=45). Pairwise index value differences between BAP vs SP and BAP vs Axor were statistically significant (p<0.05). Figure 1 illustrates the amount of participants that "agreed a lot" or higher on each statement.

# **DISCUSSION AND CONCLUSION**

Outcome from MedTech20<sup>®</sup> in individuals with BAP demonstrated higher benefits of the BAP as compared to the SP. Moreover, results indicated lower sense of security for the Axor device than for the BAP. Generalization of the results to other users of socket-prostheses is not recommended due to selection bias and the risk for recall bias. To conclude the MedTech20<sup>®</sup> seems to be a promising generic tool to add in evaluations of P&O devices to catch users' perspective.

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#### **ACKNOWLEDGEMENTS**

The Swedish Government research grant (ALFGBG-773581) funded the study.



### 4.3.6.b

# **Exploring Current Expectations of the Prosthetist's Role in Australia**

Renee Mackenzie<sup>1</sup>, Meg Morris<sup>2</sup>, Gregory Murphy<sup>1</sup>

<sup>1</sup>La Trobe University, Bundoora, Australia. <sup>2</sup>Healthscope Northpark Private Hospital and Centre for Sport and Exercise Medicine Research, Bundoora, Australia

#### **BACKGROUND**

The role of the clinical prosthetist in Australian healthcare has evolved substantially over the past century. As the role has changed over time, it is likely the expectations surrounding this professional's behavior and scope of practice have also changed. Organisational Role Theory [1] provides a framework to consider the variation in expectations that may exist regarding this clinical professional's role and behavior.

#### AIM

This research aimed to explore current expectations of the prosthetist's role and to identify if conflicting expectations existed between six key participant groups involved in the provision of prosthetic devices.

#### METHOD

The Prosthetist Role Expectations Scale (PRES) is a valid and reliable measure,[2] comprised of 72 items divided into 11 subscales describing prosthetist behaviour. Responses are recorded on a 6-pt Likert scale from 'very strongly agree' to 'very strongly disagree'. Ethical approval was granted to recruit prosthetists, orthotists, technicians, prosthetic clients, rehabilitation specialists and physiotherapists within Australia. Descriptive statistics were calculated for each subscale and item. Items and subscales that showed differences between groups were further reviewed by One-way Analysis of Variance and Tukey's post hoc testing.

#### **RESULTS**

1064 surveys were distributed with a 25% response rate. Consensus between groups was indicated by mean scores that did not categorically oppose each other on the Likert scale. This was observed in 10/11 subscales and 65/72 items. Conflict between groups was indicated by categorical on the Likert scale and further explored for statistical significance between groups. Significant differences were found between groups for the Independent Prescription subscale. Rehabilitation specialists showed an average score of 'disagreement', whereas the other groups showed a mean score of 'agreement' with items in this subscale. The difference between the specialists and prosthetists (p=.003), orthotists (p=.008), technicians (p=<.001)

% Respons		
67%		
10%		
7%		
3%		
4%		
9%		

Table1. Percentage response from participants

and amputees (p=.003) was significant at the .05 level. A further seven items in the independent prescription, shared prescription, referral, adjustment/ advanced communication subscales showed conflicting expectations between groups, four of these were statistically significant (p=<.0001).

### **DISCUSSION AND CONCLUSION**

Agreement across groups in areas of interdisciplinary functioning, research and device-specific clinical tasks/communication may be reflective of clarity in the literature describing these activities. Conversely, ongoing role changes or variable language in literature describing referral, prescription and communication concerning sensitive issues may be indicative of the reported areas of conflict/confusion between groups. The first application of the PRES provided insight into the current expectations of the role of the prosthetist and identified areas of both consensus and conflict.

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# 4.3.6.c

# Diagnostic Accuracy of GMFCS-FR Tagalog Version for Filipino Children with Cerebral Palsy Administered by Barangay Health Worker

April Ann Marie Manantan, Adelaine Martinne Antonio, Jidjpeter Gregor Jaradal, <u>Audrey Sanchez</u>, Joseph Lorenz Soriano

University of the East Ramon Magsaysay Memorial Medical Center Inc., Quezon City, Philippines

#### **BACKGROUND**

Cerebral Palsy (CP) is amongst the leading cause of movement disorders in pediatrics. Only 1% has access to assistive devices. Accurate classification of a child's functional mobility aids in gaining access to health insurance services. A widely used classification system for CP is the Gross Motor Function Classification System – Family Report (GMFCS-FR) Questionnaire. GMFCS is rarely used outside western countries because of the conflict on language barriers. Thus, different studies have been conducted to translate the tool.

#### AIM

To develop a Tagalog version of GMFCS-FR, which can be utilized more easily in rural areas where medical professionals are scarce. To determine the diagnostic accuracy of the tool administered by a barangay health worker (BHW) in children with CP.

#### **METHOD**

The GMFCS-FR was translated from English into Tagalog after the CanChild guidelines. Eighteen patients with CP registered in the PSPO Charity Clinic were included in the study. Five subjects were included in each age band except for 2-4 years old and 12-18 years old where only four subjects were successfully recruited. GMFCS-FR scoring was done via phone interview administered by a BHW. After which, the patients were scheduled for clinic visit where GMFM-88 was administered by a pediatric PT. Specificity and sensitivity for each level and age band were computed to determine the diagnostic accuracy.

#### **RESULTS**

Good to excellent (50-100%) accuracy was observed in all functional levels across all age bands despite consistently poor sensitivity (<50%) and good to excellent specificity (50-100%). Specificity has been the major reason for high accuracy exhibited by the tool. Primary reason for poor sensitivity was there were not enough perfect matches. The PT has been observed to consistently ascribe higher function to subjects (i.e. GMFCS IV) than what is ascribed by the BHW (i.e. GMFCS V). However, there was only one level discrepancy in the ratings of the BHW and the PT except for two subjects.

# **DISCUSSION AND CONCLUSION**

Similar outcomes were found in related studies. These studies suggest that the child performs at his maximal capabilities because of equipped environment and expertise of medical professionals in facilitating movements. The Tagalog translation of GMFCS-FR was accurate despite of the sensitivity since the aim of the GMFCS-FR was to capture the usual performance rather than the best. The questionnaire may be the most viable solution to health service challenges such as scarcity of medical professionals in rural areas.

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# **ACKNOWLEDGEMENTS**

UERMMMCI Research Institute for Health Sciences; Nippon Foundation; Exceed Prosthetics & Orthotics; CanChild.



### 4.3.6.d

# Validation of Electromyographic Wireless Module During Flexion and Extension Exercises in Lower Limb Muscles

Erick Guzmán<sup>1</sup>, Francisco Alvarado<sup>2</sup>, Rebeca Romo<sup>2</sup>, Hugo Vélez<sup>2</sup>
<sup>1</sup>Universidad Autónoma de Guadalajara, Guadalajara, Mexico. <sup>2</sup>Universidad de Guadalajara, Guadalajara, Mexico

# **BACKGROUND**

Around the world, one billion people is considered to have a disability,[1] musculoskeletal diseases are the most common.[2] Exoskeletons, active orthoses, and prostheses are devices that assist and improve the quality of life,[3-5] literature presents different projects where all of them can be controlled with the help of an electromyographic device. Unfortunately, portable electromyograms cost around \$20,000 USD and are not commonly used to control active devices.[6]

#### AIM

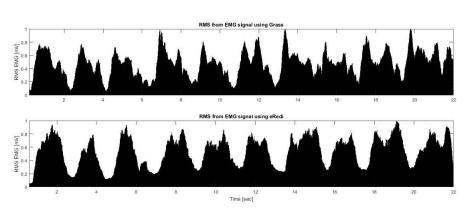
Development and validation of a 5 volts wireless modular electromyogram capable to measure from 1 to 10 different muscles during motor activitie considered to be used for the control of devices that improve the correct biomechanic from the human body.

#### **METHOD**

Twenty-six healthy subjects (18 male, 8 female,  $21 \pm 2.07$  yrs (mean  $\pm$  SD) participated in this study after giving written informed consent. The skin in each subject was prepared over three of the major groups of muscles in the lower limb (quadriceps, hamstring, and gastrocnemius). For this experiment, myoelectric signals were recorded during 3 different exercises (10 reps each one), using two devices in parallel, a multi-channel EEG from Grass Technologies Comet (configured as EMG) and an electromyographic wireless module previously developed and called eRedi. In both devices, data was filtered (10-400 Hz), sampled (1000 Hz), and processed (root mean square, area and correlation).

## **RESULTS**

Figure 1 presents an example of the root mean square (RMS) and the area calculated and applied to the signals acquired from both systems for 22 seconds. Es easy to identify in the figure the ten contractions made by the volunteers during one of the tests in both devices. Also, there was not a significant difference in the amplitude, all values are under 1mV during maximum



contraction. After this, an algorithm was developed to calculate the 25%, 50%, and 75% area from the RMS signal, this has presented similarity in the current processed data. Is difficult to determine a correct correlation due the signals where measured over the same muscular group but in different positions. However, this does not represent a big relevance because the signals are considered that will be used in the future to control a mechanical device.

# **DISCUSSION AND CONCLUSION**

Until now, the signals present a similar behavior with respect to a professional equipment, but more analysis and validation is required. The prototype presented could be a first step to control different systems of prostheses, orthoses, or exoesqueletons. The development of these kind of projects is important, especially for people that is starting their research in this field. A reliable hardware could let the users to concentrate their efforts in the development of a more accuracy software.

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# 4.3.6.e

# The Diagnostic Validity of a Screening Tool for Vestibular Dysfunction in Community Ambulators with Unilateral Lower Limb Amputation

<u>Jennifer Lucarevic</u><sup>1,2</sup>, Robert Gailey<sup>1</sup>, Ignacio Gaunaurd<sup>1,3</sup>, Kyong Jae Kim<sup>1</sup>, Christopher Bennett<sup>1</sup>, Allison Symsack<sup>4</sup>, Paul Pasquina<sup>4</sup>, James Moore<sup>1</sup>, Michael C Schubert<sup>5</sup>, Edward Brooks Applegate<sup>6</sup>
<sup>1</sup>University of Miami, Coral Gables, USA. <sup>2</sup>California State University Dominguez Hills, Los Alamitos, USA. <sup>3</sup>Miami Veterans Affairs Healthcare System, Miami, USA. <sup>4</sup>Henry M Jackson Foundation for the Advancement of Military Medicine, Bethesda, USA. <sup>5</sup>Johns Hopkins University School of Medicine, Baltimore, USA. <sup>6</sup>Western Michigan University, Kalamazoo, USA

#### **BACKGROUND**

The vestibular system provides important information to maintain upright balance and prevent falls. Evaluation of vestibular function and vestibular sensory integration requires specialized training that may be outside the perceived knowledge base of healthcare providers involved in amputee rehabilitation. There is a need to develop a vestibular system screening tool to identify LLA who would benefit from referral to a vestibular specialist for further evaluation and testing.

#### $\Delta IM$

The purpose of this study was to develop a screening tool and report the sensitivity, specificity, and predictive value for identifying LLA with vestibular dysfunction.

#### METHOR

A convenience sample of community ambulators with unilateral LLA were recruited from a national conference sponsored by the Amputee Coalition. Eligible participants provided self-reported medical history including demographic characteristics, inner ear symptoms, and medical history. All participants performed FEC Balance while wearing a sensor attached at the third sacral vertebra.

Performance-based and self-reported and variables of prosthetic postural steadiness, sensory integration, age, inner ear symptoms and comorbidities were included in the ProPSI Screening tool. Separate ROC analyses were performed to determine a cut-scores where the sensitivity was approximately equivalent to the specificity for identifying LLA with vestibular dysfunction.

# **RESULTS**

The sensitivity, specificity, positive and negative predictive values, and likelihood ratios are summarized in Table 1. When  $\geq 2$  referent criteria are met, the ProPSI had a sensitivity of 70% and specificity of 76% to screen LLA with vestibular dysfunction. Meaning it was able to identify 70% of LLA with vestibular dysfunction (true positives), and 76% of LLA with normal vestibular function (true negatives). The LR+ and LR- of ProPSI  $\geq 2$  referent criteria is 2.92 and 0.39 respectively.

Test	Referent	SN	SP	PPV	NPV	LR+	LR-
FEC Balance	ML a <sub>rms</sub> ≥ .0036	63	60	57	67	1.6	0.62
Time < 30 sec	26	91	70	60	2.9	0.81	
Self-report	SISQ ≥ 3	48	64	52	60	1.3	0.81
Age ≥ 52	63	67	61	69	1.9	0.55	
	≥2 criteria	70	76	70	76	2.9	0.39

Table 1. Sensitivity, Specificity, Predictive Value, and Likelihood Ratios

## **DISCUSSION AND CONCLUSION**

The Prosthetic Postural Steadiness and Sensory Integration (ProPSI) was developed as a screening tool to help healthcare providers involved in amputee rehabilitation identify if they should refer a patient to a vestibular rehabilitation specialist. This sensitive and specific screening tool incorporates self-report and performance-based criteria that can be used individually or combined to screen LLA for vestibular dysfunction.

#### **ACKNOWLEDGEMENTS**

This work was funded by Department of Defense & Department of Veterans Affairs Joint Incentive Fund "Mobile Device Outcome-based Rehabilitation Program".



## 4.3.6.f

# Interdisciplinary Approach in Rehabilitation of Children after Upper Limbs Prosthetics

Alina Kuzyakina<sup>1,2</sup>, Maria Avksentieva<sup>2</sup>
<sup>1</sup>Motorica, Moscow, Russian Federation. <sup>2</sup>Institute of leadership and healthcare management, I.M. Sechenov First Moscow State Medical University (Sechenov University), The Ministry of Health of the Russian Federation, Moscow, Russian Federation

#### **BACKGROUND**

According to modern data, 4 out of every 10,000 live-born children are born withhout the upper limb, therefore they potentially require prosthetics. Prosthetic technologies are rapidly developing, but there is almost no data on the structure of rehabilitation services for upper limb prosthetics and the management of rehabilitation assistance.

#### AIM

The following research aims to evaluate of the effectiveness of a multidisciplinary approach in rehabilitation of children after upper limb prosthetics.

#### **METHOD**

55 prosthetics of the upper limbs (for children from 3 to 15 years old) have been performed from September to November 2018. Immediately after prosthetics, all children underwent an individual complex of rehabilitation based on a multidisciplinary approach (an hour class with an ergotherapist, an hour class with a kinesiotherapy instructor, and an hour class with a clinical psychologist). The success of the rehabilitation program was assessed with the test "9-Hole Peg Test", conducted before the start of the rehabilitation program and after its completion.

### **RESULTS**

Currently, all 55 clinical cases have been evaluated - in all 55 cases after the 3-hour rehabilitation program, there was a significant improvement in the results of the test:

- reduction of the time required to complete the task by 30-55%:
- increase of the movements accuracy the number of errors and drops of pegs decreased by 1.3-2

In addition, according to the subjective assessment of the patients, their confidence in the movements significantly increased.

In the future we plan to expand the sample size to create a statistically reliable justification for the use of a multidisciplinary approach in the rehabilitation of this group of patients.

#### **DISCUSSION AND CONCLUSION**

Based on the data obtained so far, it can be assumed that a multidisciplinary rehabilitation program (an individual hourly session with an ergotherapist, an hour session with an kinesiotherapy instructor, and an hour class with a clinical psychologist) can significantly improve the patient's skills with the prosthesis, reduce the number of errors in the capture of the object and increase speed of the task execution.



# Free Paper Session Prosthetics: Upper Limb - Design

### 4.3.7.b

# Development of Wireless Motorized Functional Arm Prosthesis using Robot Technology Devices

Akio Nakagawa Kobe Gakuin University, Kobe, Japan

#### **BACKGROUND**

Several kinds of myo-hands are used but their use is limited because of high cost. The body powered cable controlled hook prosthesis has been used as a standard functional prosthesis. A skilled prosthetist can fabricate the prosthesis and the user needs training. OT has to have enough experience to check the prosthesis and to train the users. In recent years, robot technology has been developed widely. The actuators and the control devices became small, cheap and easy to use.

#### AIM

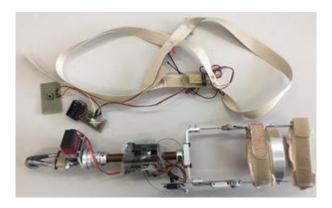
The research is to use cheap robotic devices to build the hook prosthesis into wireless and motorized system, and make it at a low cost, easy to fabricate the prosthesis and easy for the users and OTs to use.

### **METHOD**

The RC servo motor generates higher torque in a small housing than before and sold at a cheap price. The wireless transmitter-receiver IC with a built-in micro-computer and basic program is commercially available in these years. It doesn't require any knowledge about computer nor programming to use. The authors built the motor and control system as an additional system for the conventional wire-controlled hook prosthesis. The prosthetists fabricate the functional arm prosthesis without the cable. Required skill is to fabricate a cosmetic arm prosthesis then add the motor and wireless control system. The other way is to replace the cable with the motor and the control system.

# **RESULTS**

The wireless motorized hook prosthesis eliminated to use a cable and solved several problems related to the cable. It became possible for the users to operate the hand since the first time they started to use. The operation is easy at any arm position and the hook movement is not affected according to the position. The sensor could be placed at any part of the body and any type of sensor could be used. OTs don't need to adjust the cable running nor to do checkout the prosthesis related to the cable. The system could be expanded to control the elbow on-off for AE prosthesis and to control the pro-supination unit for bi-lateral amputees.



#### **DISCUSSION AND CONCLUSION**

The results showed that it doesn't need any skilled technique to fabricate and users don't need any initial training. The added motor and wireless system are cheap, it will not be expensive in a future commercially available model. The demerits are as follows: Weight increase of motor and batteries. The user should charge these two batteries. It could be used not only by users in the advanced countries but also be used by amputees in under developing counties.



### 4.3.7.c

# Development of a Novel Prosthesis for Upper Limb Amputees: User Oriented Electric Wireless Prosthetic Hand

Yukiyo Shimizu<sup>1,2</sup>, Takahiko Mori<sup>3</sup>, Kenichi Yoshikawa<sup>2</sup>, Daisuke Katane<sup>2</sup>, Hiroyuki Torishima<sup>4</sup>, Yuki Hara<sup>5</sup>, Arito Yozu<sup>2</sup>, Hirotaka Mutsuzaki<sup>2</sup>

<sup>1</sup>University of Tsukuba Hospital, Tsukuba, Japan. <sup>2</sup>Ibaraki Prefectural University of Health Sciences Hospital, Ami, Japan. <sup>3</sup>Shonan Institute of Technology, Department of Electrical and Electronic Engineering, Fujisawa, Japan. <sup>4</sup>Omiyagishi Laboratory, Omiya, Japan. <sup>5</sup>Department of Orthopaedic Surgery, University of Tsukuba, Tsukuba, Japan

#### **BACKGROUND**

Myoelectric hands are useful tools for upper limb amputees in activities of daily living (ADLs). However, conventional prosthetic hands have some problems such as their high costs and heavy weight. In addition, they need to detect muscle activities in stumps. Therefore, they are not applicable in amputees with short stumps or paralyzed limbs. It is also difficult for patients with sensory disturbance in their stumps.

### **AIM**

We have developed a novel wireless electric prosthetic hand that functions without myoelectricity. The aim of this study was to compare this novel prosthetic hand with a conventional myoelectric hand (Ottobock).

### **METHOD**

Ten healthy participants were enrolled in this study. The clinical evaluation of each hand was performed using the Simple Test for Evaluating Hand Function (STEF) and Action Research Arm Test (ARAT). Additional tests based on ADLs, such as grasping a ball, pinching an eraser, pinching a battery, holding a canned coffee, and holding an umbrella, were also performed. Each hand was fixed to a participant's forearm, muscle activity sensors for the myoelectric hand were attached to the wrist extensor and flexor, and the online button for our prosthesis was put on each torso. Before the measurement for each hand, participants practice until they were able to hold STEF balls.

## **RESULTS**

In both tests, the scores obtained using our novel prosthesis were better than those obtained using the Ottobock hand. Pinching a small pin in STEF and a small 6-mm ball in the ARAT and holding an umbrella could be performed only with the novel prosthesis. In addition, the preparation time for the measurement in the novel hand is significantly shorter than in the Ottobock myoelectric hand.

# **DISCUSSION AND CONCLUSION**

We have developed a novel wireless prosthetic hand that enables better gripping, pinching, and holding compared with the conventional myoelectric hand. This hand does not need to detect muscle activation in stumps, therefore, it might be effective for even patients with severe sensory disorders in their stumps or phantom limb pain. The wireless button could provide users with more instinctive use of the prosthetic hand.



### 4.3.7.d

# Targeted-Muscle Reinnervation and Osseointegration for Treating a Patient with Bilateral Above-Elbow Amputation: World First-Case Report From Surgery to Prosthetic Fitting

Andrea Giovanni Cutti<sup>1</sup>, Guido Staffa<sup>2</sup>, Maurizio Fontana<sup>2</sup>, Oskar Aszmann<sup>3</sup>, Rickard Branemark<sup>4</sup>, Erik Andres<sup>5</sup>, Stefan Reinelt<sup>5</sup>, Alessandro Dondi<sup>6</sup>, Daniele Dallai<sup>6</sup>, Thomas Macchiavelli<sup>1</sup>, Pericle Randi<sup>1</sup>, Alice Frey<sup>7</sup>, Birgit Bischof<sup>7</sup>, Daniela Wustefeld<sup>5</sup>, Michaela Buhl<sup>7</sup>, Rinaldo Sacchetti<sup>1</sup>

<sup>1</sup>Centro Protesi INAIL, Vigorso di Budrio, Italy. <sup>2</sup>AUSL Romagna, Faenza, Italy. <sup>3</sup>Medical University Vienna, Vienna, Austria. <sup>4</sup>Massachussetts Institute of Technology, Boston, USA. <sup>5</sup>Ottobock, Duderstadt, Germany. <sup>6</sup>Ottobock, Budrio, Italy. <sup>7</sup>Ottobock, Vienna, Austria

### **BACKGROUND**

Bilateral loss presents a dramatic reduction of body integrity and functionality. Prosthetic replacement must enable simple but effective help in the basic ADLs and allow the patient some level of independence. Here we report of a 29-year-old female patient with right-side shoulder disarticulation and left-side very-proximal transhumeral amputation whom we treated with Targeted Muscle Reinnervation to generate intuitive myosignals [1] and left-side osseointegration to ensure maximum glenohumeral mobility.[2]

### **AIM**

The details of surgery, prosthetic rehabilitation, pearls and pitfalls and early functional outcomes of this difficult case are presented.

### **METHOD**

After amputation, a conventional myoelectric prosthetic fitting failed due to the cumbersome control and the socket-imposed restriction of the left-side shoulder. Given the patient's determination, realistic expectations, strong family support, neuroma pain and left-side dominance a new strategy in prosthetic rehabilitation was initiated two years later. First a bilateral TMR in a single session was performed. After 4 months, she underwent the first stage of osseointegration (S1), with the implantation of a fixture in the left humerus. After 5 months the second osseointegration surgery (S2) was completed, with the exposure of the implant. Right and left-side myoelectric prosthetic fitting followed.

# **RESULTS**

The right-side TMR involved anterior and posterior deltoid, latissimus dorsi, and pectoralis major, resulting in 5 usable signals for prosthesis control plus the upper-trapezius (non-reinnervated). The left-side TMR involved biceps, triceps and coracobrachialis, with two usable EMG signals for prosthesis control. EMG signals could be clearly detected bilaterally after 7 months.

After S2, the patient retained full glenohumeral range-of-motion of the shoulder joint with excellent force. Prostheses construction and training were spread over 7 months, about 1 visit/month, 3-4 days each, stating with the right-side. The right-side prosthesis included an HTV silicone inner socket & flexible epoxy outer socket, an Ottobock 12S6 shoulder, Dynamic-Arm TMR elbow, wrist rotator and Variplus hand, with an innovative harness (body-jacket). The left-side prosthesis included custom self-sticking EMG sensor-holders and the same active components of the right side.

### **DISCUSSION AND CONCLUSION**

The unique treatment reported here requires strong commitment by the patient, her family and by the multidisciplinary clinical team. Both pain and the abutment skin-penetration point required specific management. The patient is using both prostheses in daily life, reports extreme confidence in control and tremendously benefited for the unrestricted left shoulder. The combination of TMR, osseointegration, advanced commercially-available prostheses components and focused rehabilitation set a new pathway for patient management.

# **REFERENCES**

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# 4.3.7.e

# The Impact of Innovative Prosthetic Technologies on Surgical Considerations - New Options of TMR, Osseointegration and Robotic Surgery in Amputee Rehabilitation

Jennifer Ernst, Gunther Felmerer

Division of Plastic Surgery; Department for Trauma Surgery, Orthopedics and Plastic Surgery, University Medicine Göttingen, Göttingen, Germany

#### **BACKGROUND**

Recent technological advancements and innovations in prosthetic devices require refinements in amputation surgery to fully reap the benefits of these technology breakthroughs. To address limitations, surgically targeted muscle reinnervation (TMR), osseointegration and robotic surgery are promising to help address the limits of current prosthetic control and socket suspension.

#### **AIM**

Surgical refinements beyond the initial amputation and postsurgical management provide improvements in signal acquisition and rendering, socket suspension and rehabilitation of amputees.

### **METHOD**

Patients with short upper residual limbs and previous problems with prosthetic fitting were selected. After examination by an interdisciplinary team of surgeons, technicians, therapists and engineers within a specialized outpatient clinic for amputees, appropriate and available prosthetic solutions and surgical possibilities of the revision surgery were evaluated. Multiple microsurgical selective nerve transfers (TMR), osseointegration and further surgical interventions as a robotic harvested free muscle flap were performed to improve prosthetic fitting and following rehabilitation of the amputees. Patients were monitored closely by the interdisciplinary team.

#### **RESULTS**

Six patients (6 male, 0 female; 5 non-dominant hand, 1 dominant hand) - two glenohumeral, three transhumeral and one transradial amputees were included into the observational study. All received multiple selective nerve transfers. Three are currently fitted successfully to their final myoprosthesis and successfully control six degrees of freedom. One transhumeral is still in prosthetic rehabilitation. In one transhumeral amputee a refined targeted muscle reinnervation protocol was combined with one step osseointegration. The transradial amputee received a robotic harvested free muscle flap to improve soft tissue coverage of the transradial residual limb. The architecture of the muscle and three selective nerve transfers created three additional myosignals.

# **DISCUSSION AND CONCLUSION**

The application of refined surgical procedures in amputation revision surgery may allow for new human-machine-interfaces and open new options to benefit from emerging prosthetic technologies. The prosthetists, engineer and surgeon will need to educate themselves in these new technologies in order to select the appropriate options, identify the limitations and improve their patients' lives.

# **ACKNOWLEDGEMENTS**

We thank Prof. Branemark & Prof. Braatz for supporting the osseointegration procedure.



# 4.3.7.f

# Developing a National Survey to Determine User Interests in Options to Restore Touch Perception Following Upper Extremity Limb Loss

<u>Fantley Clay Smither</u>, Karen Andrews, Kristin Zhao, Tyson Scrabeck, Ryan Lennon, Colin Colby Mayo Clinic, Rochester, MN, USA

#### **BACKGROUND**

Restoring touch perception for individuals with upper extremity limb loss is a very ambitious task. It is important to understand how individuals with upper limb loss feel this would be best achieved.

#### AIM

We aimed to create a national online survey to assess upper limb prosthetic users' opinions of sensory feedback.

#### **METHOD**

A survey was developed to obtain data from prosthetic users in the United States. Participants were asked to rank the perceived acceptability and effectiveness of noninvasive sensory feedback to areas of intact sensation not typically involved in sensory feedback (the arm). We focused on four main types of haptic information: object contact, proprioception, surface texture and grasp force. We also asked how best to convey those senses with a variety of stimuli. After analyzing the responses from 8 local individuals, the survey was refined further and transformed into an anonymous online survey. Invitations were sent out from national prosthetic companies with an email link.

#### **RESULTS**

142 unique responses were obtained with the online survey. There was strong interest by individuals with upper limb loss in sensory feedback with prosthetic limbs. The most popular pairing of haptic information with sensory stimulation was grasp force paired with gentle vibration. The users were also asked to grade themselves in tasks and then analyze which of these tasks would be improved by sensory feedback. The tasks that most individuals agreed would benefit most from sensory feedback were zipping a jacket, tying shoes, buttoning a shirt and using a cup. Interest in sensory feedback was also plotted against demographics. There was no difference in interest between sexes or for different employment statuses, but there was a statistically significant decline in interest in sensory feedback and stimulation options with increased years of prosthetic use.

# **DISCUSSION AND CONCLUSION**

The results from this national survey of upper extremity prosthetic users from the United States shows there is strong interest in developing sensory feedback systems. It is important to start with the feedback from individuals with upper extremity limb loss to determine their needs to improve or guide the design of haptics systems. This data suggests that there may be more interest in sensory feedback with a prosthesis from people with recent limb loss.



# 4.3.7.g

# Variable Compliance Transradial Prosthetic Socket Allowing Full Anatomical Range of Motion Using Stiff Motion Counters in a Breathable Soft Matrix

Jonathan Kuniholm<sup>1,2</sup>, Zachary Meyer<sup>1</sup>
<sup>1</sup>StumpworX LLC, Portland, OR, USA. <sup>2</sup>Open Prosthetics, Durham, NC, USA

#### **BACKGROUND**

Half of arm amputees reject prosthetic arms, usually because of comfort. Self-suspended sockets severely limit range of motion. Traditional monolithic sockets made with composites and silicone liners create heat and moisture management and skin breakdown issues. These sockets are uncomfortable under load, and are much less functional as a result. Rather than seek marginal improvements in socket technology, the prosthetic industry is in need of a radical new socket design to address these shortcomings and improve performance and acceptance.

#### AIM

Socket design has changed little in decades and is sorely (pun intended) in need of updating. This research sought to address the deficiencies of current sockets not through incremental changes, but by challenging the socket itself.

#### **METHOD**

Inspired by modern athletic shoe design and materials, a new design for the socket was created by deconstructing the socket functionally. Helical 'counters' that restrict relative motion of the terminal device in specific directions were designed to maintain intimate contact with the residual limb, at the same time as they do not touch each other or restrict joint motion, and can be tightened with a lacing system. Each counter is self-supporting against two directions of loading, but must otherwise be secured. Flexible hinges are integrated with a backplate and reel closure system, as well as a 'soft counter' to tie the hard counters together and cushion the residual limb.

#### **RESULTS**

Multiple prototypes of the variable compliance socket have been constructed. Preliminary results suggest that it is possible with these principles to create a transradial socket that can bear higher tensile and compressive loads comfortably than any standard socket design, either self- or harness-suspended, while preserving anatomical range of motion. The helical counters have been created using a 3d printed core with a carbon fiber lamination, as well as through direct 3d printing with carbon filament. The deconstructed design allows significantly improved comfort and moisture management. Through the integration of the backplate and with the reel closure system doing double duty as a flexible



hinge, the transradial design is secure enough to be self-suspended. Tensile load bearing capability is improved with a harness. While this design is body-powered, a flexible sleeve with electrodes would allow a myoelectric version.

#### **DISCUSSION AND CONCLUSION**

The capabilities of this new design with respect to range of motion and load bearing capability are a significant improvement over monolithic carbon fiber designs. The arm can be worn for much longer more comfortably, and anecdotally improved compliance and acceptance with the single patient (the corresponding author) for whom it was created. We believe that the design should be further explored, and tried on a wider patient population, to include different levels of amputation and lower limb amputees.

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### **ACKNOWLEDGEMENTS**

Supported in part by a grant to Open Prosthetics by the Fetzer Institute, and by StumpworX LLC of Portland, OR.



# Free Paper Session Developing Countries

#### 4.3.8.a

# Effectiveness of Rehabilitation Management System in Improving the Quality of Physical Rehabilitation Services in Nepal

Yeti Raj Niraula<sup>1</sup>, Raju Palanchoke<sup>1</sup>, Chiara Retis<sup>2</sup>
<sup>1</sup>Humanity & Inclusion, Kathmandu, Nepal. <sup>2</sup>Humanity & Inclusion, Phnom Penh, Cambodia

#### **BACKGROUND**

Physical rehabilitation needs in Nepal are growing because of non-communicable disease, ageing, road and disaster-related injuries. Prosthetic and orthotic services within Physical Rehabilitation Services (PRCs) are limited in number and efforts have been done to strengthen their clinical and managerial capacities to increase efficiency and sustainability. Since no quality assurance and planning tool was available to support managers, the Rehabilitation Management System (RMS) has been developed with the support of Humanity & Inclusion.

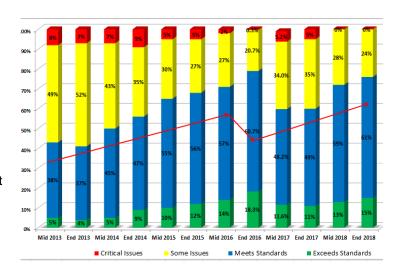
#### AIM

The aim of this study is to assess the effectiveness of the "Rehabilitation Management System" tool in improving compliance with standards in 5 PRCs supported by Humanity & Inclusion in Nepal.

#### **METHOD**

The tool is made of a set of 56 standards organized in 6 scorecards covering domains such as service users, service outputs, staff equipment, finances and management.

Compliance is measured by teams through a scoring system from 0 (critical issues) to 3 (standard is exceeded). After each scoring, priority issues are identified by each PRC and plans for improvement are implemented. Scoring, planning, implementation and reevaluation through a new scoring are carried out regularly by PRCs. Data from 11 scoring of 5 PRCs from 2013 to 2018 were collected and changes in compliance analyzed for each domain.



#### **RESULTS**

Compliance with standards for 5 PRCs increased steadily since the first scoring, from 38% of standards met at roll out to 61% of standards met in the last scoring. The proportion of standards for which compliance exceed increased from 5% to 15%. The proportion of unmet standards steadily decreased, from 49% of compliance showing some issues to 24%; similarly, the proportion of standards with critical issues decreased from 8% to no critical issue at last scoring. The critical issues identified included weak user centered approach, confidentiality of information, limited accessibility, lack of guidelines for appropriate technology, occupational health and safety and others. The decrease in compliance between the 7th and 8th review corresponds to a change in the set of standards that were updated for better alignment with international frameworks.

#### **DISCUSSION AND CONCLUSION**

Each review helped identify areas of weak compliance to work towards improvement and set milestones for continuous growth. Hence, we can conclude that the RMS effectively contributed to a systematic and progressive development of management capacities of the rehab centers which in turns had a positive impact on the overall quality of physical rehabilitation services. Continuous monitoring of good practices and improvement of areas that still have issues are needed.

### **ACKNOWLEDGEMENTS**

Sincere thanks to USAID for funding the development of Rehabilitation Management System and its implementation in 5 PRCs.



#### 4.3.8.b

# Costing System Analysis to Meet Budgetary Needs for Disabilities Orthotic Prosthetic Services

Atikah Adyas<sup>1</sup>, Ii Solihah<sup>1</sup>, Payung Hasibuan<sup>1</sup>, Yopi Harwinanda Ardesa<sup>2</sup>

Jakarta I Health Polytechnic, Jakarta, Indonesia. <sup>2</sup>Surakarta Health Polytechnic, Surakarta, Indonesia

#### **BACKGROUND**

The national basic health research 2013 revealed a disability rate of 11%, i.e. an increase injury 7.5 to 8.2%. Since 2014, the patients in lab clinic Jakarta I Health Polytechnic have increased. Around 100 patients are in waiting list, while others must carry out routine checks. The services performed because of getting aid from donors. Cost of Orthotic Prosthetic Services (OP) need for continuity services. Research review in low-income countries indicates OP policies have not considered demographic and socio-economic factors.

#### AIM

This study aims to develop costing system analysis of Orthotic Prosthetic Services. It will obtain product determination, and production flow; costing formula and average costs; correlation between costing with budgeting and dominant variables.

#### **METHOD**

The study was conducted in two steps. Firstly, it was done in Jakarta I Health Polytechnic i.e. focus group discussion to faculty members, followed by content analysis to determine product and flow of production; document reviewed of one year (2015) cost transaction, identified cost centers of support service units and cost center of service units, developed template costing instruments,

Table 1. The costing formula and unit cost OP according to grouping product (in Indonesian Rupiah, 1 USD = IDR 13,000)

No.	Production unit	Q	Formula Unit Cost							
			Formulai 2 Total cost		Formula 2 Total cost - investment cost		Formula 3 Total cost - (salary and investment)			
			Total Cost	Unit Cost	Total Cost	Unit Cost	Total Cost	Unit Cost		
1	OGATAS	144	948.717.692	6.588.317	748.620.856	5.198.756	619.173.084	4.299.813		
2	PAGATAS	36	942.092.944	26.169.248	741.933.700	20.609.269	612.485.928	17.013.498		
3	OGAWAH	144	942.094.725	6.542.324	741.935.481	5.152.330	612.487.709	4.253.387		
4	PAGAWAH	48	942.094.725	19.626.973	741.935.481	15.456.989	612.487.709	12.760.161		
5	SPITIK	48	942.094.725	19.626.973	741.935.481	15.456.989	612.487.709	12.760.161		
Average OP cost				15.710.767		12.374.867		10.217.404		

continued with costing analysis used double distribution method. Secondly, it held in Surakarta Health Polytechnic. The purposive sampling to 42 respondents of faculty members was interviewed by using questioners that has been tested for validity. Multivariate analysis was conducted to find the most dominant variable for budgeting.

# **RESULTS**

The study produces costing system analysis of OP that consist of laboratory clinic as production unit, orthotic prosthetic devices as output product, grouping product based on limb area: OGATAS (orthotic of upper body motion), OGAWAH (orthotic of lower body motion), PAGATAS (prosthetic of upper body movements), PAGAWAH (prosthetic of lower body movements), SPITIK (Spinal orthotic), and flow of production will be structured by the grouping product. There are 3 costing formula and average cost as shown in table 1. The most fabricated product is orthotic with lowest cost IDR 4,253,387; average cost grouping product IDR 10,217,404. Multivariate analysis formula 3 indicated there was a significant relation between costing system analysis and budgeting (BHP or consumable p = 0.038), average cost p = 0.020, orthotic cost p = 0.006). The dominant variables associated with budgeting is average cost (p = 0.020).

#### **DISCUSSION AND CONCLUSION**

The number of limb defects in Indonesia increase. This is related to Indonesia's geographic that prone to natural disaster. Costing system analysis for disabilities orthotic prosthetic services formulate the guidance and instrument costing template. The cost of consumables and orthotic need more attention. With some data adjustments, this costing system could be used by OP study program to calculate and propose budgetary need for laboratory clinic (formula 3). It also can be used for private clinic (formula 1 or 2).

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### **ACKNOWLEDGEMENTS**

I would like to thank the Ministry of Research and Technology's and Ministry of Health which has funded this research.



#### 4.3.8.c

# 40 Years of ICRC Physical Rehabilitation Programme – a Global Analysis of Male and Female Users Accessing Services Since 1979

Cornelia Anne Barth<sup>1,2</sup>, Catherine Blake<sup>2</sup>, Andreas Wladis<sup>3</sup>, Prashant Bhandarkar<sup>4</sup>, Cliona O'Sullivan<sup>2</sup>

International Committee of the Red Cross (ICRC), Geneva, Switzerland. <sup>2</sup>University College Dublin, Dublin, Ireland. <sup>3</sup>Linköping University, Linköping, Sweden. <sup>4</sup>WHO Collaboration Centre, Mumbai, India

#### **BACKGROUND**

The ICRC's physical rehabilitation programme (PRP) supports structures in countries during and after conflict and is one of the leading actors in the provision of physical rehabilitation services in low- and middle-income countries (ICRC 2017). The PRP-developed electronic database 'patient management system' (PMS) is currently used in 38 of 145 physical rehabilitation centres (PRC). To date no global analysis has been carried out on the characteristics of persons seeking out rehabilitation services in ICRC supported structures.

#### ΔIM

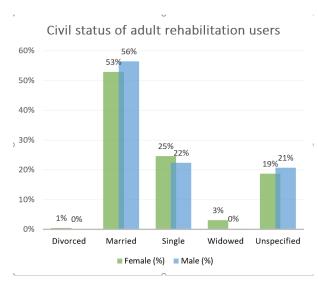
The objective of this study was to analyze demographic factors and injury characteristics of male and female rehabilitation service users accessing ICRC supported structures and present key findings.

#### **METHOD**

PRC using 'PMS' were invited to participate, receiving project information and instructions for data download, anonymisation and password protection. A total of 31 PRC from 14 countries signed and shared data via E-mail or ICRC internal file-sharing channels. A data protection and sharing agreement was signed between the ICRC and academic partners. De-identified data from 1979-2018 were cleaned, merged and aggregated by sex and age. Descriptive statistics, independent t and chi square analyses were carried out by a consortium of researchers, physiotherapists and medical statisticians using Microsoft Excel 2013 and R Studio for windows (version 3.5). The primary endpoint was identification of gender differences in adult and minor service users.

### **RESULTS**

287'274 individuals were included (27% female). Mean age was 26.1±20.6 years; females 5.3 years younger than males (t=60.1:p<0.001). Overall 17% were aged <5 years (41% female), 22% aged 5-17 (37% female), 56% aged 18-65 (19% female) and 5% aged >65 years (31% female),(X2=12080:p<0.001). A third (33%) presented with amputation (11% female), 53% of these caused by landmines (5% female). 14% presented with cerebral palsy (38% female), 7% polio (34% female), 7% fractures (21% female), 6% paraplegia (30% female) or tetraplegia (17% female). 4.5% club foot (39% female) and 4% hemiplegia (32% female). Of the 18-65 year olds, 31% of women were unemployed, 21% housekeepers, and 9% farmers. In contrast, 21% of men were unemployed, 19% non-qualified workers, 18% farmers and 9% military. Proportionately more adult females were single, widowed and divorced than males  $(X^2 6880:p<0.001)$ .



### **DISCUSSION AND CONCLUSION**

Fewer females than males attended PRC overall. Proportionately more females were in the youngest and oldest and in the single, widowed and divorced groups. Fewer females presented with amputation, while more presented with other health conditions. This worldwide analysis of rehabilitation user data warrants further investigation of underlying reasons for gender-related and other differences. Subsequent analyses intend to explore gender dimensions, service provision challenges, outcomes and predictors for emerging rehabilitation needs in ICRC, conflict, low-resource settings.

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#### **ACKNOWLEDGEMENTS**

The authors would like to thank the ICRC, Linköping University and UCD for contributing to the funding of this project.



#### 4.3.8.d

# Losing and Regaining Dignity - Voices from Spinal Cord Injured People in Cambodia

#### Pia Nolstedt

Karolinska Institutet, Department of Public Health Sciences, Division of Global Health, Stockholm, Sweden

#### **BACKGROUND**

A spinal cord injury (SCI) is considered one of the most severe injuries and often leads to physical impairments and limitations. People with SCI experience lower well-being and tend to score lower in all domains considered important for quality of life, such as physical, social and mental health. However, limited research regarding the experience and living situation of persons with SCI in low-income countries such as Cambodia, is available.

#### AIM

The aim of this study was to gain a deeper understanding of the life situation of people who have acquired SCI in Cambodia, through qualitative interviews and analysis.

#### **METHOD**

Ten people with a SCI participated in semi-structured qualitative interviews. Data was collected in Battambang, Cambodia where rehabilitation patients were identified using purposive sampling. Inclusion criteria were persons over 18 years, diagnosed at least three years with complete or incomplete SCI causing paraplegia or tetraplegia. Semi-structured qualitative interviews were conducted concerning relationship with family and community; future hopes and worries; barriers and facilitators to coping with SCI. Interviews were conducted in Khmer; translated and transcribed into English by field translator. A professional translation service specialised in disability related issues re-translated interviews to assure accuracy. Transcripts were analysed using content analysis to identify condensed meaning units, codes, categories and a main theme.

#### **RESULTS**

Three sub-themes and one overall theme were identified (Table1). First sub-theme, exclusion and isolation from society, refers to how SCI can lead to a person's rejection from society, both for the injured and family. Second sub-theme, the need for fellowship and belonging, refers to the importance of relationship with friends, relatives and community, which often were lost following injury. Third sub-theme, hopes and concerns for the future, refers to the long-term perspective of living with SCI related to mental and physical health, life expectancy and ability to provide for self and family. The sub-themes revealed a main theme, losing and regaining dignity. These illustrated how dignity in many different ways is lost for persons with SCI in Cambodia, but that it is possible to regain some amount of dignity.

Main Theme								
Losing and regaining dignity								
Exclusion and	heme 1 l isolation from iety	Sub-the The need for fe belon	ellowship and	Sub-theme 3 Hopes and concerns for the future				
Category 1	Category 2	Category 1	Category 2	Category 1	Category 2			
Social and	Losing	Being different	Inspiration	Striving to become	Living condition			
cultural attitudes	opportunities	from others	and support	independent	and survival			

Table1: Main theme, sub-themes and categories

# **DISCUSSION AND CONCLUSION**

The study demonstrates how dignity of persons with SCI in Cambodia is lost and difficult to regain. This is a multidimensional problem, comprising both social, cultural, environmental and personal levels. Negative perceptions about disabilities, cultural prejudice and religious beliefs lead to stigmatisation of persons with SCI. A first step is providing practical adaptations for home environment and access to basic medical supplies. There is a need to recognise people with SCI in society and enforce their basic human rights.

#### **ACKNOWLEDGEMENTS**

This study received a grant from the Swedish International Development Cooperation Agency (SIDA) and its Minor Field Study (MFS) Program.



# 4.3.8.e

# Design and Testing of a Low-Cost, Passive Prosthetic Knee with a Rotary Hydraulic Damper

Nina Petelina<sup>1</sup>, V.N. Murthy Arelekatti<sup>1</sup>, W. Brett Johnson<sup>1</sup>, Matthew Major<sup>2</sup>, Amos Winter<sup>1</sup>MIT, Cambridge, USA. <sup>2</sup>Northwestern University, Chicago, USA

#### **BACKGROUND**

Studies have estimated that there are over 230,000 of transfemoral amputees in India alone.[1] Over 47% of people with amputation reported severe socio-economic stigma resulting in change or loss of occupation.[2] Currently available prostheses provide stability, however they do not provide able-bodied kinematics, one of the most important requirements for developing countries.[1] Affordable designs of knee joints use friction-based dampers that result in a jerky walking pattern, which can be made smoother using fluid-based dampers.

#### **AIM**

The aim of this project is to design a low-cost passive knee prosthesis with a rotary hydraulic damper that

enables transfemoral amputees to walk with close to able-bodied kinematics over level ground.

# **METHOD**

To determine the appropriate damping coefficient for the design, gait data from a participant wearing a fully characterized transtibial prosthesis [6] was used, because it provided close to ablebodied kinematics while accounting for the effects of a passive prosthetic foot. The

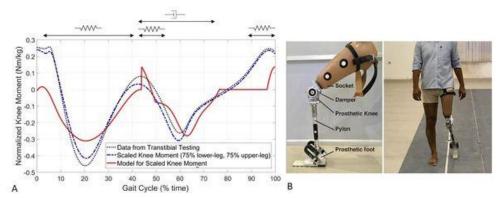


Figure 1. A) Normalized knee moment target and replication for able-bodied kinematics. The black line is data from a transtibial amputee using a fully characterized foot.[6] The blue curve is scaled knee moment from varied inertial parameters of the lower and upper legs. The red curve is the combination of springs and damper that replicates the modified normative moment profile, with  $R^2$ = 0.64. B) Prosthetic knee prototype with a hydraulic damper and a fully characterized prosthetic foot.[6]

target knee moment was computed through inverse dynamics using typical inertial parameters for transfemoral prostheses. The damping coefficient that could best replicate the target knee moment was then computed.[3, 4]. Shear-based rotary hydraulic dampers were built with the different damping coefficients, including the optimal value.[7]. The dampers were tested with a prototype knee in overground walking trials in India to collect qualitative feedback from transfemoral amputees.

### **RESULTS**

Testing in India showed that amputees were able to walk with the prototype with little training. The dampers were able to provide smooth transition between stance and swing phase as well as prevent excessive heel rise. However, amputees walked at slower speeds than expected, which resulted in them preferring lower damping values than our predicted optimal values.

# **DISCUSSION AND CONCLUSION**

The designed knee prototype tested on transfemoral amputees in India enabled smooth walking transitions and prevented hyperflexion during swing phase. Qualitative feedback from participants allowed us to further refine the damper model by adjusting the knee moments as a function of walking speed. A motion analysis study is currently being conducted to further validate our framework for the design of the prosthetic knee mechanism.

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#### **ACKNOWLEDGEMENTS**

Funding provided by MIT Tata Center, NSF Career Award (no.1653758), and Indo-US NIH Grant (# 9208498).



# **Posters**

# Free Paper – Poster Presentation Orthotics: Lower Limb Neurological

#### 5.001

# Effect of a New Articulated Ankle Foot Orthosis with Plantarflexion Resistance on Gait: A Case Series of 2 Hemiplegic Patients

Aliyeh Daryabor <sup>1,2</sup>, Mokhtar Arazpour <sup>3</sup>, Gholamreza Aminian<sup>3</sup>, Mina Baniasad<sup>4</sup>, Sumiko Yamamoto <sup>5</sup>

Student Researcher in International University of Health and Welfare, Tokyo, Japan. <sup>2</sup>PhD student, Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Science, Tehran, Islamic Republic of Iran. <sup>3</sup>Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Science, Tehran, Islamic Republic of Iran. <sup>4</sup>Mechanical Engineering Department, Sharif University of Technology, Tehran, Islamic Republic of Iran. <sup>5</sup> International University of Health and Welfare, Tokyo, Japan

### **BACKGROUND**

Ankle-foot orthoses (AFOs) have been described to have positive effects on the gait biomechanics in stroke patients. The plantarflexion resistance of an AFO

is considered important for hemiplegic patients, but the evidence is still limited.

#### AIM

To investigate the immediate effect of an articulated AFO with plantarflexion resistance on kinematics and kinetics of lower-limb joints in two stroke patients

#### **METHOD**

The articulated AFO with the adjustment of plantarflexion resistive moment was designed. The spring generates a plantarflexion resistance of the ankle joint at the initial stance phase. The efficacy of orthosis was evaluated on two patients with stroke in 2 conditions: without an AFO and with the AFO.

#### **RESULTS**

Regarding the spatial-temporal parameters including walking velocity, cadence, stride length and single support time, immediate improvement was observed during walking of one subject with AFO compared with barefoot walking, but no deference was observed between two conditions in other subject. When both patients walked with the AFO, the angular change of dorsiflexion of the paretic ankle joint increased in gait cycle. The AFO also was able to reduce the paretic knee extension in the single-support phase of the stance by 2.93°% in subject A and 1.9°% in subject B.

### **DISCUSSION AND CONCLUSION**

AFO affect not only the movement of the ankle joint but also the movements of the knee joint. These changes indicate improvement of the first and the second rockers and swing phase gait but not third rocker function. Further Adjustable screw

Spring

Shot

Cam

Fastening Screw

Metal plate

Figure 1. A schematic diagram of the ankle joint of new AFO.

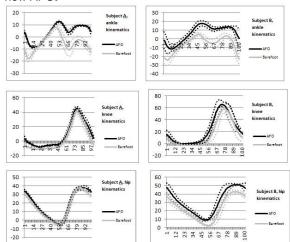


Figure 2. The sagittal kinematic data at the ankle, knee, and hip joints of subjects A and B.

investigation is recently underway to compare its effect with other AFOs on the gait parameters of hemiplegic patients.

# **ACKNOWLEDGEMENTS**

This study was supported by the Iran National Science Foundation, Grant Number 95849762.



# Offloading Plantar Foot Ulcers with Combi Cast Orthosis

<u>Louise Roser</u> Team Olmed, Stockholm, Sweden

#### **BACKGROUND**

Unstable insulin and blood sugars as a result from diabetes, affects the entire body over time. Complications increase the risk of developing severe foot ulcers.[1] Systematic reviews present Total Contact Cast as the most successful clinical and pressure reducing technique when treating plantar foot ulcers. The evidence concerning removable orthosis and shoes are limited by a low level of evidence, suggesting of more research in the future.[2]

#### AIM

The aim of the study was to collect and analyze baseline data from patients with plantar foot ulcers treated with a combi cast orthosis (CCO) (Figure 1).

#### METHOD

Twelve patients (10 men and 2 women) were included in the study. Information concerning the wound development was gathered during their medical appointment at the wound care clinic. Inclusions criteria where patients with pressure ulcers that went through a full treatment program until healed. Patients were prescribed a rigid orthosis manufactured in plastic gypsum and fiberglass = CCO. The CCO consist of an individual made insole, a rocker with removable Velcro's™ on the anterior side. The intention was to where it both in- and outside. For hygiene and different weather conditions the patient where also prescribed a weather cover to be use with the CCO.

#### **RESULTS**

The average time of treatment was 139 days (r = 45-351). Majority of the ulcers were located under Metatarsophalangeal (MTP) 1. Healing complications were registered in 8 patients during their follow up. Three out of the patients required chirurgical interventions due to reduced circulation during the treatment. Additional five of the patients indicated compliance complications. The average treatment time among those 8 patients with compliance problem was 17 % longer, (169 days), compared to the average time.

# **DISCUSSION AND CONCLUSION**

One of the major reasons for adequate clinical wound healing with TCC is the exclusion of compliance obstacles.[2] Large variation was noted in this study regarding the healing time. The outcome indicates that removable devices are not appropriate for all patients when treating foot ulcers. The location of the ulcer seems to affect the outcome although that 67 % of the wounds were located under MTP 1. Further data is required for more and stronger conclusions.

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Figure 1. CCO.



# Case Collection using a Smartphone Application for AFO Damages

Rina Ishiwata<sup>1</sup>, Takamichi Takashima<sup>2</sup>, Keiji Takahashi<sup>3</sup>, Katsuhiro Konishi<sup>4</sup>, Takanori Aikawa<sup>1</sup>, Takenobu Inoue<sup>1</sup>

National Rehabilitation Center for Persons with Disabilities, Tokorozawa, Japan. <sup>2</sup>Nagano University of Health & Medicine, Nagano, Japan. <sup>3</sup>Prosthetics & Orthotics Technical Services Group, Wakayama, Japan. <sup>4</sup>Sawamura Prosthetics and Orthotics Service Co., Ltd., Kobe, Japan

#### **BACKGROUND**

To provide more durable and safer orthotics with limited budget, it is necessary to make standard and improve provision system based on the overview of usage and repairing. AFO is the most commonly used and soon will be worn away or occasionally breaks. In Japan, we have a statistic score of repairing of orthotics but no means getting the overview of repairing in detail. Therefore, we developed the smartphone application for AFO damages and have started Japanese nationwide case collection.[1]

#### AIM

To get the overview of AFO damages and find distinctive damages to focus.

#### **METHOD**

Orthotists are asked to take pictures of AFO damages and input related information using the application. Mandatory items are types of AFO, main damage location, detail of main repair process etc. Optional items were duration of use, weight of the user, activity level, etc. Case collection has been conducted twice (total in one year) and it is ongoing till March 2020. Collected cases are categorized into several groups with similar damage. A table putting the weight on the columns and the duration of use on the rows was made for each group and the cases are mapped with activity level.

#### **RESULTS**

311 cases were collected at the end of February 2019 (12 cases, repairing for adaptation, were excluded from the analysis). Breakdown were strap deterioration 135, sole attrition 75, metallic part damages 43 (stirrup and/or foot plate 25, joint 16, other 2), plastic parts damages 36, and others 10. For the metallic parts, 27 out of 43 were that of double-upright AFO. 20 out of 27 were occurred at a stirrup and/or a foot plate (Figure 1). 18 out of 20 damages occurred within 3 years (legal durable years in Japan for adult). The all users whose double-upright AFO were damaged were 40 kg or more and the users' activity levels tend to be high ( $\star \star \star$ :8,  $\star \star$ :5,  $\star \star$ :5).

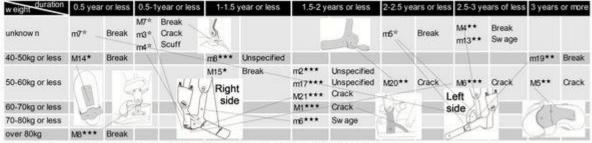


Figure 1. Damages of stirrup and/or foot plate with double-upright AFO (20 cases)

(★★★: active-ambulator, ★★: household-ambulator, ★: training-room-ambulator, ☆: activity level unknown)

# **DISCUSSION AND CONCLUSION**

Previous study [2] also reports more damages are occur at stirrups (17 out of 24) than joints or uprights. This could be caused by thinness and less hardness of stirrups compared to uprights made of different material. The result shows a necessity to find ways to reduction of stirrup damages focusing on uses with high activity level whose weight is 40kg or more. Thus, the table made by collected cases promises to give the overview of damages to focus.

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### **ACKNOWLEDGEMENTS**

This work was supported by JSPS KAKENHI Grant Numbers JP17K13110, AMED 16dk0310009j0003.



# Comparison of Ankle–Foot Orthosis with Stiff and Flexible Footplates to Improve Push Off in a Child with Cerebral Palsy

Ryo Yonetsu<sup>1</sup>, Junya Suzuki<sup>2</sup>, Manabu Yamagata<sup>3</sup>, Akiyoshi Saito<sup>2</sup>, Satoshi Fuchioka<sup>4</sup>
<sup>1</sup>Kanagawa University of Human Services /School of Rehabilitation, Yokosuka, Japan. <sup>2</sup>Kawamura Gishi Co., Ltd /R&D Division, Daito, Japan. <sup>3</sup>Kitamura Chemicals Co., Ltd /Osaka Sales Department, Osaka, Japan. <sup>4</sup>Osaka Prefecture University /Graduate School of Comprehensive Rehabilitation, Habikino, Japan

#### **BACKGROUND**

Ankle–foot orthosis (AFO) is frequently prescribed for ambulatory children with cerebral palsy (CP) to improve their gait patterns. AFO can correct the first and second ankle rocker function; however, an incomplete third rocker during the pre-swing (PSw) phase remains a major issue.[1,2] To overcome these limitations, a new AFO that can recreate dorsiflexion of the metatarsophalangeal joint was produced experimentally using soft carbon fiber reinforced plastics.

#### AIM

The aim of this preliminary study was to assess the effects of this newly developed AFO on gait in a child with CP

#### **METHOD**

The study participant was a 7-year-old boy with spastic hemiplegic CP. This study was approved by the Osaka Prefecture University Research Ethics Committee (2015-117). By using a motion analysis system that was

synchronized with a force plate and electromyography (EMG), two gait tasks were performed five times by the participant while walking using the a conventional AFO and a newly developed AFO. Subsequently, temporal, kinetic, and kinematic data were collected. Unpaired t-test was used to compare the sample data. Statistical significance was set at p=0.05.

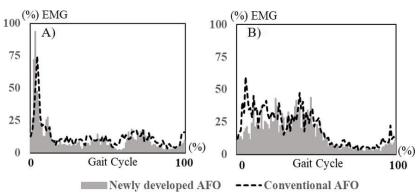


Figure 1. Tibialis anterior (A) and gastrocnemius (B)

EMG muscle activity during the gait cycle

# **RESULTS**

The peak vertical ground reaction force (GRF) during the PSw phase was significantly different between

the conventional (9.2±0.4 N/kg) and newly developed AFO (10.0±0.2 N/kg) (p<0.01). With regard to ankle angular movement, the newly developed AFO significantly increased ankle dorsiflexion at the stance phase compared with the conventional AFO (p<0.05). As for EMG activity, muscle activity on the gastrocnemius during the roading response phase decreased on using the newly developed AFO compared with when using the

conventional AFO, whereas muscle activity on the tibialis anterior during the same phase increased momentarily on using the newly developed AFO (Figure 1).

#### **DISCUSSION AND CONCLUSION**

Our newly developed AFO could facilitate higher peak vertical GRF in the PSw phase, indicating that the participant's push-off movement improved. Moreover, angular ankle movement and EMG activity suggest that the newly developed AFO would help correct the first and second rocker function. The concept of our AFO is to recreate dorsiflexion of the metatarsophalangeal joint, which was a different AFO configuration that used in previous studies.[2,3] We believe that the newly developed AFO may effectively improve gait.

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#### **ACKNOWLEDGEMENTS**

This research was supported by Japan Science and Technology Agency(AS3015032S).



# Effect of Improved Walking Speed using a Walking Aid to Support Hip Joint upon Lower Limbs of Stroke Patients

<u>Tomoki Nakatani</u>, Junji Taguchi, Masako Tsutsumi, Naruhito Hasui Takarazuka Rehabilitation Hospital, Takarazuka, Japan

# **BACKGROUND**

Previous studies clarified that stroke patients could improve their continuous walking distance and energy cost significantly by doing walking training at a high speed. At our hospital, we often use the elastic band (T – Support; Fig 1) as a walking aid to improve walking speed. It can assist the motion of the flexion of the hip joint, resulting in the improvement of walking speed. However, the changes of lower limb function of wearing the elastic band remain unclear.

#### AIM

The purpose of this study was to examine the changes of the lower limb function of stroke patients when they wear the elastic band and do training with improved walking speed.

#### **METHOD**

17 patients with primary stroke who were able to walk on their own were enrolled. Factors of walking to be measured were walking speed and the stride length during a 10-meter walk when they did/didn't wear the elastic band, as well as the moment of ankle plantar flexion during the late stance phase and the muscle activity of calf muscles. An electrode was attached to the paralysis side of the lateral head of gastrocnemius muscle with sampling frequency at 1000Hz to calculate the muscle activity during the late stance phase. Wilcoxon matched-pairs signed-ranks test was used for statistical analysis and a significant level was set at 5%.

# **RESULTS**

Factors of walking at the time when the patients did/didn't wear the elastic band were determined as follows: walking speeds were 0.68/0.60m/sec; the stride length were 0.44/0.41m; the moment of ankle plantar flexion was 3.7/3.0Nm; and the muscle activity of calf muscles was 157.0/138.0%. A statistical significance was observed in all these items.

# **DISCUSSION AND CONCLUSION**

Previous studies clarified that improvement of walking speed in the healthy adults depends on the moment of ankle plantar flexion and the muscle activity of plantar flexor during the late stance phase. In this study, it was suggested that the stroke patients, improving

Figure 1. T - Support

walking speed wearing the elastic band can increase the moment of ankle plantar flexion and the muscle activity of calf muscles during the late stance phase and improve the lower limb function.

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# Selection of the Most Suitable Ankle Foot Orthosis in Hemiplegic Patients with Stroke

<u>Satomi Iwasawa</u><sup>1</sup>, Masahiro Satake<sup>2</sup>, Yuki Kawata<sup>1</sup>, Kazuto Kikuchi<sup>3</sup>, Yutaka Furukawa<sup>4</sup>, Yoshino Terui<sup>2</sup>, Yuusuke Kimoto<sup>5</sup>, Ryouhei Suzuki<sup>6</sup>

<sup>1</sup>Akita Prefectural Center for Rehabilitation and Psychiatric Medicine, Daisen-city, Japan. <sup>2</sup>Akita University Graduate School of Health Sciences, Akita-city, Japan. <sup>3</sup>Akita National Hospital, Yurihonjo-city, Japan. <sup>4</sup>Akita City Hospital, Akita-city, Japan. <sup>5</sup>Akita Rehabilitation Academy, Akita-city, Japan. <sup>6</sup>Ogachi Central Hospital, Yuzawa-city, Japan

#### **BACKGROUND**

There are many types in ankle foot orthosis (AFO). We can find a lot of studies about the effect of the AFO, however there are few studies about the selection of the most suitable AFO for hemiplegic patients with stroke.

#### ΔIM

This study aimed to choose the most suitable AFO with the gait analysis, walking speed, walking endurance and walking variability using several types of AFO for hemiplegic patients with stroke.

#### **METHOD**

Forty patients with stroke participated.

We measured root mean square of acceleration (RMS), 10m maximum speed (MWS), 2min maximum walking distance (2MWD) and stride time variability (CV) wearing three types of AFO (flexible AFO (LH), AFO is fixed at 0°dorsiflexion (FIX), AFO with plantar stop & free dorsiflexion (FD)) and barefoot.

RMS represents fluctuation of trunk during walking and smaller value indicates that gait is better. So we classified into LH group (LHG), FD group (FDG) and FIX group (FIXG) using minimum RMS. And we examined in each group, whether AFO that showed minimum RMS corresponded to the AFO that be selected from the MWS, 2MWD and CV.

#### **RESULTS**

10 subjects were included in LHG, 15 in FDG, and 15 in FIXG.

RMS, in LHG, during LH gait was significantly smaller than barefoot (p<0.05). In FDG, during FD gait was significantly smaller than barefoot, LH and FIX (p<0.01, p<0.01, p<0.05). In FIXG, during FIX gait was significantly smaller than barefoot and LH (each p<0.01).

MWS, in FDG, during FD gait was significantly faster than barefoot (p <0.01). In FIXG, during FIX and FD gait were significantly faster than barefoot (p <0.01, p <0.05).

2MWD, in FDG, during FD and LH gait ware significantly longer than barefoot (p<0.01, p<0.05). In FIXG, during FIX and FD gait were significantly longer than barefoot (each p <0.01).

CV, there was no significant difference depending on the type of AFO. However, in FIXG, during FIX and FD gait tended to be smaller than barefoot.

# **DISCUSSION AND CONCLUSION**

This study suggested that these measurements were useful in the select of the the joint angle of the AFO is fixed or free dorsiflexion in hemiplegic patients with stroke. However, it was difficult to select the flexible plastic AFO of short type.



# The Effect of Modified AFO against Claw Toes on a Person with Stroke - A Case Study

Yosuke Nishimoto

Kawamura Gishi Co., Ltd., Hyogo, Japan

#### **BACKGROUND**

The prevalence rate of claw toes in persons with stroke in the maintenance period has been reported as high as 60 to 70%). It is observed during terminal stance. One of its causes is shortening of the flexor digitorum longus muscle. The long-term usage of ankle-foot orthoses (AFOs) with limited dorsiflexion may cause this shortening.

#### AIM

The aim of this study is to investigate the effects of an AFO with free dorsiflexion and plantar flexion resistance of the ankle joint and free dorsiflexion and limited plantar flexion of metatarsophalangeal(MP) joints.

#### **METHOD**

The case is of an 80 year-old male after stroke. He can walk with a plastic AFO and a cane. Pes equinovarus and claw toes were observed. He complained of pain with the claw toes. An ankle joint with free dorsiflexion and plantar flexion resistance with an oil damper was used as an AFO. The foot plate was split and re-connected for free dorsiflexion and limited plantar flexion of the MP joints. This AFO was used for three months. The range of ankle joint and MP joints were measured. No intervention was

#### **RESULTS**

performed except for this AFO.

During walking, increased dorsiflexion of the MP joints was observed and pes equinovarus was reduced. Claw toes attenuated when sitting all of the toes contacted on the ground and the pain on claws was reduced. Some attenuation was seen in the pressure trace of the 2nd toe PIP joint back side. The passive range of motion of the MP joints had been 10 degrees, and was increased to 30 degrees. The gait speed was also improved. The dorsiflexion angle at heel off improved from 3 to 6 degrees.



Figure 1. Before intervention

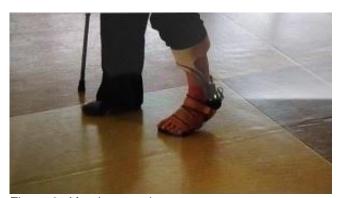


Figure 2. After intervention

### **DISCUSSION AND CONCLUSION**

This AFO enabled the MP joints and the ankle joint to dorsiflex more than with the plastic AFO, leading to reduction of the claw toes due to stretching of the flexor digitorum longus at late stance. These results may also contribute to improved forefoot locker and gait speed. In conclusion, this AFO may be effective to improve claw toes of persons with stroke.



# The Effects of an Elastic Strap for Gait Training of a Person with Stroke in the Recovery Rehabilitation Stage

#### Yasuhiro Fujimoto

Kawamura Gishi Co., Ltd., Daito-shi, Japan. Takarazuka Rehabilitation Hospital, Takarazuka-shi, Japan. Pacific supply Co., Ltd., Daito-shi, Japan

#### **BACKGROUND**

Japanese guidelines for the management of stroke treatment recommend usage of braces in the acute stage to reconstruct gait. Thijssen et al. reported that an orthosis with an elastic strap was effective for increasing gait speeds, step lengths, and decreasing energy costs for persons with stroke on the chronic stage.[1] However, its effect on the recovery stage, especially with a KAFO or an AFO, is still unclear.

#### **AIM**

The aim of this case study is to clarify the effects of an elastic strap with or without braces for a person with stroke in the recovery stage.

#### **METHOD**

The subject was 70-year old male with right hemiplegia due to stroke. He used a KAFO and .progressively an AFO for gait training and was discharged. Six conditions were set; with the strap (T-support, Kawamura gishi Co.,Ltd., Fig 1) under three conditions (#1: with a KAFO (unlocked) after one month from onset, #2: with an AFO after two months from onset, and #3: without brace after four months from onset) and without the strap under the same three conditions. Gait speeds (under all conditions), ankle moments of force (under #1 and #2), the myoelectricity of tibialis anterior and gastrocnemius (under #3) were measured and videos were recorded.

#### **RESULTS**

Gait speeds were improved under condition #1 (30.5m/min) and #2 (44.6m/min) with the strap. Ankle moments also increased under condition #1 (7.6Nm for the first peak and 3.5Nm for the second peak) and under #2 (6.2Nm for the first peak and 1.4Nm for the second peak) with the strap. The EMGs showed systematic activities of muscles under condition #3 in comparison with without the strap. Improved knee stability during stance was observed in videos.



Fig 1. (A) The front, (B) back, and (C) side view of the elastic strap used in this study.

#### **DISCUSSION AND CONCLUSION**

The strap may have contributed to the stability during stance and smoothed the transition to swing, leading to increased gait speed and ankle moments. Without the brace, the strap may assist the swing of the affected limb to systematic muscle activities. These results suggest that the usage of an elastic strap, with or without braces, may be effective for gait training for persons with stroke in the recovery stage.

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# Experience of using Long-Legged Orthosis with Electronically Controlled Knee Joint for Hemiplegic Patients ~ Single Case Study

<u>Koichi Tashiro</u>, Koji Teruya, Narisige Wakisaka, Kenji Hidaka, Masahide Endo Sakura Jyuji Fukuoka Hospital / Medical corporation Fukuoka cherry blossom cross, Fukuoka, Japan

#### **BACKGROUND**

Using braces are important, and braces are often using for treatment of stroke patients. However, fixing the knees may reduce walking efficiency, by using knee ankle foot orthosis (KAFO). It has been developing that KAFO attached electronically controlled knee joint (EAM-knee KAFO; Pacific Supply) which can adjust the partial motion restriction and guidance of knee joint during walking. Using EAM-knee KAFO may improve walking efficiency, for stroke patients.

#### AIM

Comparing before and after using EAM-knee KAFO of walking. We research about walking speed, stride length, and loading fore-foot of terminal stances and we verify the effectiveness of it.

# **METHOD**

We used a single case study design; our patient was Brunnstrom Recovery Stage III, Functional Ambulation Categories 3. Using EAM-knee KAFO for the patient 20 minutes per a day, through a week. The way of operation is to fix the knee when the patient is walking, except the phase of terminal stance to mid-swing. When the phases of terminal stance to mid-swing, we induce the movement of the knee. We compared walking speed and stride length, before and after using EAM-knee KAFO, by using ankle foot orthosis. Furthermore, we used the insole monitor PIT (Reif) to research about the loading of average fore-foot (%) and amount of changing.

#### **RESULTS**

Walking speed and stride length were increased. Fore-foot loading were increased each days, and the average were 17.5±8.2%. We were able to confirm the sustainable effectiveness, which shows the beginning of fore-foot loading were 7.6%, ending of fore-foot loading ware 25.4%.



Figure 1. Results of walking speed and stride

### **DISCUSSION AND CONCLUSION**

Using EAM-knee KAFO, which is able to adjust the partial motion restriction and increasing the loading of fore-foot. Increasing the fore-foot of loading is the one of the factors, that improves walking speed and stride length. Therefore, using EAM-knee KAFO improves walking efficacy.



# Free Paper – Poster Presentation Orthotics: Lower Limb Orthopaedic

#### 5.010

# **Development of Orthosis in 3D Printers**

<u>Jose de Jesus Mayagoitia Vazquez</u>, Israel Miguel Andres, <u>Sergio Luis Orozco Villaseñor</u>, Irving Martinez Chavez, Jorge Avila Arias CIATEC AC, Leon, Mexico

#### **BACKGROUND**

An orthosis is a support or other external device applied to the body to modify the functional or structural aspects of the musculoskeletal system. 3D printing is the reproduction of volumetric objects from a CAD design or scanning in three dimensions by adding material. 3D printing in the original sense of the term refers to processes in which material is accumulated sequentially on a platform.

#### **AIM**

To design and development of orthoses for patients who have suffered a musculoskeletal injury and its prescription requires the use of a splint or orthosis.

#### **METHOD**

The affected part of the patient is analyzed with a 3D scanning equipment, this represents the basis of the structure that will make up the orthosis of the affected limb. Subsequently, a point cloud file that describes the scanned region is obtained and by using computer-aided design tools (CAD / CAE) this file is converted into a solid format that describes the morphology to be treated. The designed orthosis adapts perfectly to the anatomy of the affected part. Finally, the file is transformed into a compatible format for 3D printing and with the appropriate material for the intended area.

#### **RESULTS**

The development of the device is supported by a doctor with specialty in traumatology and orthopedics, always taking into account the type of injury that presents the patient and the critical areas of the anatomy of the body of the lesion to be treated. The design of the orthosis is made based on the dimensions and morphological characteristics of the patient. Subsequently, the file is transformed into a compatible format for 3D printing, and with the appropriate material for the area destined for the orthosis, printing is done in three dimensions.

#### **DISCUSSION AND CONCLUSION**

Orthoses increase their effectiveness and comfort if they are manufactured in a particular way for each individual, since it is specially made based on the unique and unrepeatable lesion and morphology of each patient, leading to a more propitious recovery for people.

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#### **ACKNOWLEDGEMENTS**

Centre of applied Innovation in Competitive Technologies (CIATEC A.C.) for supporting the research.



# Preliminary Study of the Force Generated in the Custom-Made Lower Leg Fracture Brace With and Without Patella Tendon Identification

#### Chotika Suvipalawat

Sirindhorn School of Prosthetics and Orthotics (SSPO), Bangkok, Thailand

#### **BACKGROUND**

Fracture bracing is a conservative treatment benefit for the regeneration of bone tissue role in the healing of fracture area and in the remodeling stage.

#### AIM

This research aimed to study the force generated along devices of lower leg fracture brace and investigate immediate and short-term of mentally and physical effects in comparison between with and without patella tendon identification.

#### **METHOD**

This study is conducted to facilitate the satisfactorily and physically affected to six participants after testing with devices and analyze the amount of average pressure at the calf circumference and plantar pressure. It divided into two experiment by using FSA software. The first stage, the pressure was measured at the calf and plantar area of the foot while using PTB brace with patella tendon weight-bearing and hydrostatic compression. The second stage, the pressured was measured after removing the patella tendon weight-bearing and then applying plies-sock to increase the compressive force at calf circumference. The second objective getting from the interview, then interpreting by using a Visual Analog Scale (VAS) score.

#### **RESULTS**

No statistically significant difference (r = -.277, p = .298.)of the compressive force between the PTBandHC device and the HC device while controlling the off-loading pressure at the plantar surface area. This result might be affected by the limitation of the subjects. Nevertheless, the HC device provided more comfort than the PTBandHC device, referring from the questionnaire that was informed by all of six healthy participants.

Note - PTBandHC Device: Patella tendon brace with patella tendon weight-bearing area and hydrostatic compression.

HC Device: Remove the patella tendon weight-bearing area while having hydrostatic compression.

# **DISCUSSION AND CONCLUSION**

The results show the benefits of not having PTB area that provide more comfort to all participants. The confounding factors of the concept of fracture brace with only hydrostatic compressive device achieve unloading force similarly with PTBandHC device. This information can be implied to the effect of the compressive force that is not necessary to be high at the patella tendon area in order to get less pressure at the foot.

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#### **ACKNOWLEDGEMENTS**

We would like to express the sincere attitude to the SSPO for all the support and encouragement.



# Hip Orthosis for the Rehabilitation of Hemiparetic Stroke Patient with Hip Fracture

#### Kathy Mak

Princess Margaret Hospital, Hong Kong, Hong Kong

#### **BACKGROUND**

Hip fracture is common in post- stroke patient and the paretic side is being affected most frequently. Balance and cognitive impairment which are the associated deficits make these patients prone to high risk of fall. Lower limb orthosis are proved to improve certain gait deviations. However, practically an orthosis up to hip level can be a challenge to handle for the stroke patient with hip fracture, in view of the heavy weight of orthosis and impaired upper limb function.

#### AIM

To design an effective hip orthosis for stroke patients with hip fracture and the effect on the rehabilitation.

#### **METHOD**

In the scissor gait with hip adduction, the sufferers can be tripped by themselves and fall. Ideally to enable hip abduction, knee extension and ankle in neutral position would be beneficial for walking. Conventional hip- knee-ankle orthosis with heavy weight, and its complicated lock and unlock mechanism can be an obstacle for the patients.

Taking the conventional hip abduction brace for post- operation use as a blue print, a custom- made hip abduction brace is designed. In order to minimize the weight, the waist band covers about two-third of the waist; the hip joint extends to the supracondylar region; the thigh part which is a strap comprises soft material.

#### **RESULTS**

The newly designed hip abduction brace is applied to the hemiparetic stroke patient with hip fracture for rehabilitation. The lower limb muscle power is 4 on sound side and 2 on hemiparetic side. The Barthel Index increased from 27 to 36/100 and MFAC =2. Scissor gait is observed in the patient, in which heel-strike takes place in front of another foot. With the application of brace, satisfactory outcome is obtained. The orthosis provides enough force to reduce the hip adduction angle, so previous scissor gait improved while using the hip abduction orthosis. The walking stability is increased as the walking base is widened. The patient shows good adaptation to the brace. The hip orthosis can be handled with ease. More clinical test can be carried out to compare the difference with and without the brace.

# **DISCUSSION AND CONCLUSION**

The newly designed hip abduction orthosis shows the characteristics of light weight, easy- to handle and providing enough force to abduct hip joint. The rehabilitation can be facilitated. While only provided with mild sound side support from the patient, one assistant for long term care would be possible upon continuous training, which relieves the burden of the caregiver to take care of the stroke patient. The newly designed hip abduction orthosis effectively improves walking stability and may reduce fall risk.

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#### **ACKNOWLEDGEMENTS**

I would like to show my gratitude to the team of the Orthopaedics Rehabilitation ward.



# Comparison of Pressure Distribution and User's Satisfactions between Conventional and CAD-CAM Foot Orthosis in Pes Cavus: A Case study

#### Chonthicha Chaemkhuntod

Sirindhorn School of Prosthetics and Orthotics, Bangkok, Thailand

#### **BACKGROUND**

Pes cavus is one of a common foot problem, characterized by an excessively high medial longitudinal arch of the foot. The use of foot orthoses in pes cavus is to provide stability, distribute the weight, and increase the contact area and comfort. Nowadays, the computer-aided design and computer-aided manufacturing (CAD-CAM) technology are one of the methods to produce the foot orthosis however, the study on the effectiveness of this method is still scarce.

#### AIM

This study aims to compare the effectiveness of the foot orthosis provided by the CAD-CAM method and conventional foam impression method in terms of plantar pressure distribution and user satisfaction.

#### **METHOD**

A 49 years old female, presented with pes cavus, hind-foot varus and mid-foot and forefoot pain was included in this study. The patient was fitted with two different methods of custom made foot orthosis which are a conventional method using foam impression and CAD-CAM method in proper sport's shoes. The outcome measure of pressure distribution during walking was assessed by Foot Sensory Array (FSA) and a self-reported Client Satisfaction with Device of Orthotics and Prosthetic Users' Survey (CSD-OPUS) were used to assess the user satisfaction of the foot orthosis.

#### **RESULTS**

- I. The result of foot plantar pressure distribution in dynamic walking, at early to mid-stance phase, heel peak pressure without orthosis is 21 psi,17 psi with CAD-CAM, and 11 psi with conventional foot orthosis. In late stance, patient mainly bears the weight at metatarsals head. Metatarsal head peak pressure without orthosis is 23 psi while CAD-CAM orthosis is reduced to 18 psi and 13 psi for conventional foot orthosis. For pressure distribution at the medial longitudinal arch area was observed in conventional foot orthosis more than CAD-CAM foot orthosis and barefoot respectively.
- II. The result of patient satisfaction from Client Satisfaction with Device of Orthotics and Prosthetic Users' Survey (CSD-OPUS) rated 1-5 from not satisfy to very satisfy show that patient-reported satisfaction rate of 5 in conventional foot orthosis and 4.6 CAD-CAM foot orthosis.

### **DISCUSSION AND CONCLUSION**

CAD-CAM and conventional foot orthosis can help to re-distribute the excessive pressure over the medial longitudinal arch of foot. However, the conventional foot orthosis can maximize the peak pressure at the medial longitudinal arch area more than the CAD-CAM foot orthosis. A self-report of user satisfaction demonstrate higher satisfaction rates in Conventional foot orthosis more than CAD-CAM. This study suggests that for pes cavus a conventional is more effective than CAD-CAM foot orthosis.

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# Successful Management of Skin Graft and Bony Prominence over Foot Area by Using Custom Made Silicone Socks and PTB-AFO

<u>Sarawanee Phaipool</u>, Kwannate Permpool, Bengt Soderberg Sirindhorn Prosthetics and Orthotics School, Bangkok, Thailand

#### **BACKGROUND**

The team has emerged the combination of 'Customize silicone sock with the PTB-AFO' to overcome the challenged of rehabilitation for skin graft all over the foot area with bony prominences problem and the ankle ROM limitation.

#### **AIM**

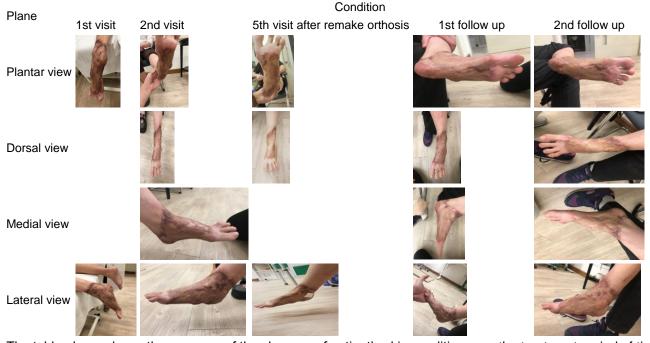
To share management experiences of patient who has skin graft and bony prominence problem at the foot. As well as the result of the management case has be shown.

#### METHOD

A 29 years old female was transferred to Sirindhorn School of Prosthetics and Orthotics clinic with the problem in her left foot due to the multiple fractures from car accident following with sensitive skin graft problem and foot deformities; accordingly, she was unable to bear weight on her foot and has difficulty to walk. The pressure underneath foot created abrasion over the bony prominence and sensitive skin. The custom made silicone was provided to elimination friction and promote skin graft curing together with PTB-AFO to allow the patient to walk independently by the offloading method.

#### **RESULTS**

The patient's skin graft was strengthening after 1 month follows up. She could walk independently without an assistive device while the limitation of ROM had decreased. Table below shows the comparison of foot condition change in every visit.



The table above shows the progress of the changes of patient's skin condition over the treatment period of time.

# **DISCUSSION AND CONCLUSION**

To avoid pressure over the plantar surface of the foot, one solution for Orthotist is to provide PTB-AFO for weight transfer from foot to Patella tendon bearing, yet it is not promoting skin graft healing. Thus providing them to customize silicone sock combination with PTB-AFO is significantly effective to unload from plantar pressure, prevent shear force, and intensify the skin graft problem.

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# A Literature Review on the use of Ankle-Foot Orthoses for Running

<u>Leanne Sanders, Melissa Yelle, Mr. Matt Leblanc</u> George Brown College, Toronto, Canada

#### **BACKGROUND**

Ankle-foot orthoses (AFO) are devices prescribed to assist individuals with upper and lower motor neuron disorders and muscle weakness to mitigate gait deficiencies.[1, 2] As surgical techniques improve, limb salvage procedures have increased the population of AFO users looking to return to their previous active lifestyles.[3] A recent shift in AFO design has included energy storage options to help individuals achieve more active lifestyles.[4, 1]

#### AIM

This review will explore the current demographics of AFOs used for running and discuss the effectiveness of emerging device designs and materials that impact the biomechanics of running.

#### METHOD

A comprehensive search of databases using search terms related to running and AFO's will be conducted. Peer reviewed articles that incorporate the use of AFOs while running with both qualitative and/or quantitative methods will be included.

#### **RESULTS**

A preliminary search identified 41 articles. Initial results show that strut stiffness did not significantly impact running parameters however, strut angle and bending axis did cause some biomechanical changes.[3, 5, 6] A case study demonstrated that the use of a carbon fibre orthosis facilitated a return to physical activity including running for a 17 year-old traumatic brain injury patient.[7] Research has also demonstrated the efficacy of a minimalist AFO design in providing foot clearance in swing to patients suffering from drop foot and it's success with running.[4]

# **DISCUSSION AND CONCLUSION**

Depending on the materials used and design characteristics, AFO intervention can have positive effects on running biomechanics. Consideration must be taken into account for client preference, and tuning of the orthotic device is especially important in activities like running where forces and moments are increased. Preliminary results have shown a direct link between AFO usage and a successful return to high impact activities, specifically running.

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# **ACKNOWLEDGEMENTS**

Gord Ruder, B.SC., M.Sc., C.O.(c), F.C.B.C.; Amy Richardson, B.SC., M.Sc., C.P.(c).



# A Temporal Comparison of CAD/CAM Versus Conventional Methods in the Rectification and Fabrication of Pediatric Ankle Foot Orthotics

Anika Campeau<sup>1,2</sup>, Jan Van Niekerk<sup>1</sup>
George Brown College, Toronto, Canada. <sup>2</sup>Rehabilitation Centre for Children, Winnipeg, Canada

#### **BACKGROUND**

Currently, there is a lack of research on the temporal parameters of CAD/CAM methods in comparison to other methods for the manufacturing of orthotics. In comparing the time required of both rectification methods for Thoracolumbosacral Orthotics, CAD/CAM required '93.3 min (34%)' [1] less time. Continuing research of CAD/CAM is necessary as a reported '24% of practitioners [are] us[ing] CAD/CAM regularly' [2] with the expectations that it will continue to rise.

#### AIM

The purpose of this study is to temporally compare the rectification and fabrication process of pediatric AFOs produced using CAD/CAM method versus conventional methods after negative anatomical shape captures were acquired.

#### **METHOD**

Certified Orthotists (CO(c)) and Registered Technicians (RTO(c)) at the Rehabilitation Center for Children in Winnipeg, Canada, collected data of the rectification and fabrication processes of rigid and articulating AFOs applying CAD/CAM and conventional methods using standardized timesheets. The participating staff had 5-30 years of conventional experience and 2 years experience with Vorum CAD/CAM Technology (Vancouver, BC). Vorum CAD/CAM Technology was used for negative anatomical shape capture scans, rectifications and carvings. Scans from 33 pediatric patients were used to rectify and fabricate: 6 unilateral and 8 bilateral AFOs conventionally, and 6 unilateral and 13 bilateral AFOs using CAD/CAM methods, totaling 52 AFOs.

#### **RESULTS**

The mean rectification and fabrication time per device of rigid and articulated devices was 6.49 hours using the positive plaster anatomical method and 4.11 hours using CAD/CAM. The percent difference between these methods indicates that the CAD/CAM method requires 36.67% less time per device compared to the conventional method. The most noticeable differences between methods were identified during the rectification processes conducted by the clinicians. The clinicians recorded a mean rectification time of 3.1 hours per device for the conventional method and 0.65 hours per device in CAD/CAM. The CAD/CAM method had the greatest time reduction during rectification of 79.04% compared to a conventional method per device.

#### **DISCUSSION AND CONCLUSION**

The clinicians and technicians had less experience with CAD/CAM method than conventional method, yet CAD/CAM methods required less time. This may be due to increased indirect time on specific tasks like waiting for the plaster to set during rectifications. This suggests that the temporal requirements may be reduced by using CAD/CAM methods to rectify and fabricate pediatric devices. Device quality was not compared between the methods in this study, but may be an area for further research.

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#### **ACKNOWLEDGEMENTS**

RCC for funding and participating, Gord Ruder, B.Sc., M.Sc., C.O.(c), F.C.B.C and Amy Richardson, B.Sc., M.Sc., C.P.(c).



# Plantar Pressure Distribution in Patients with Flexible Flatfoot: Measured by Platform System and In-Shoe System

Chih-Kuang Chen<sup>1,2</sup>, Simon Fuk-Tan Tang<sup>3,2</sup>, Alice Chu-Wen Tang<sup>4</sup>, Ho-M Wu<sup>5</sup>

Dept of PM&R, Chang-Gung Memorial Hospital, Taoyuan, Taiwan. <sup>2</sup>Chang Gung University, Taoyuan, Taiwan. <sup>3</sup>Dept of PM&R, Lotung Poh-Ai Hospital, Yilan, Taiwan. <sup>4</sup>Dept of PM&R, Taipei City Hospital, Yangming Branch, Taipei, Taiwan. <sup>5</sup>Dept of PM&R, Taipei City Hospital, Renai Branch, Taipei, Taiwan

#### **BACKGROUND**

Flatfoot is characterized with insufficiency of the medial longitudinal arch and flexible flatfoot is the most predominant type which leads to numerous clinical problems.

#### AIM

This study aimed at investigating the plantar pressure distribution in flexible flatfoot patients with platform system and in-shoe system.

#### **METHOD**

Nineteen flexible flatfoot patients and fifteen normal subjects were recruited. Foot Function Index (FFI) was used for subjective symptoms report, and higher scores indicated worse clinical condition. Plantar pressure were assessed with Emed-X system and Pedar in-shoe system. Student independent-t test was used for statistical analysis, and statistical significance was set at p<0.05.

#### **RESULTS**

The results showed that the total score of FFI was significantly higher in flexible flatfoot patients. Emed-X system revealed that there were significantly greater contact area, peak pressure, foot maximum force and force-time integral in the medial midfoot area in flexible flatfoot patients. While Pedar in shoe system showed that there was significant decrease of peak pressure in lateral rearfoot.

# **DISCUSSION AND CONCLUSION**

The findings of Emed-X system confirmed the crucial change of medial midfoot in flexible flatfoot patients, while the findings of Pedar in-shoe system illustrated the alteration of lateral rearfoot. These biomechanic features can be further applied in the orthosis design.



# Free Paper – Poster Presentation Orthotics: Spinal

#### 5.018

# Device of Spinal Orthosis for Early Gait Training for Elderly Vertebral Compression Fracture

<u>Yuko Yamasaki</u>, Hideo Watanabe, Shiro Hirayama Department of Rehabilitation, Shakaihoken Omutatenryou Hospital, Fukuoka, Omuta, Japan

#### **BACKGROUND**

Bed rest is often forced for 1 to 2 weeks after vertebral compression fracture, which is likely to lead to elderly person's disuse syndrome. In order to prevent this complication, gait training from early stage seems to be useful.

#### AIM

Devise a new spinal orthosis is needed for early gait training which has the function of sufficiently fixing the fractured vertebral body externally and restriction of the trunk movement.

#### **METHOD**

1.We made a new frame type spinal fixing orthosis which donning over the flexible spinal corset for gait training. 2.In order to verify the effect of this orthosis, the rigidity was measured by

the following methods.

Subject: male in the 20's

Preparation: new spinal orthosis, flexible corset, pressure sensor,

goniometer

Measurement method: The trunk angle and the pressure force at the time of trunk motion were measured for each subject with 1 no orthosis, 2 flexible corset, 3 new spinal orthosis 4 new spinal orthosis wearing over the flexible corset.

# **RESULTS**

1.Although the structure of this trunk orthosis is a metal frame type, its weight is about 1.2 kg. And it can also be used for other patients because the height and width of the orthosis can be adjusted by sliding bars. 2.The new spinal orthosis attached over the flexible corset was able to restrict the movement in five directions.

Figure 1. a new spinal orthosis

#### **DISCUSSION AND CONCLUSION**

Prevention of disuse syndrome due to long term bed rest of the elderly is important for maintaining ADL and IADL. The spinal orthosis devised for this purpose have good rigidity to anterior flexion, lateral bending and rotation. Additionally the feeling to wear the orthosis is not bad and put on and take off is also easy. This orthosis seems to be useful in the early gait training, therefore, recommended to be standing in the hospital.



# Compliance Control of Robotic Walk Assist Device via Integral Sliding Mode Control

Izhar ul Haq<sup>1</sup>, Syed Humayoon Shah<sup>1</sup>, Kamran Shah<sup>1</sup>, Nizar Akhtar<sup>2</sup>, Haider Ali<sup>1</sup> University of Engineering and Technology, Peshawar, Pakistan. <sup>2</sup>Pakistan Institute of Prosthetic and Orthotic Sciences, Peshawar, Pakistan

#### **BACKGROUND**

Millions of people around the world have walking disability which is seriously affecting their mobility and quality of life. Through-out the world significant population entered into ageing society which is one of the cause of walking disability.[1]. To regain full or partial walking capabilities, various types of assist devices are available, however, state-of-the-art walk assist devices provide limited functionality and patients need to have strong muscles to hold

#### AIM

To investigate a compliant control technique in order to overcome synchronization issue in human robotic combine motion.

#### **METHOD**

The proposed robotic walk assistive device (RWD) is modeled as second-order mass-spring-damper (MSD) system (as shown in below equation) which is a passive and compliant reference model for the RWAD.

$$\ddot{e} + f\dot{e} + d\dot{e} = h\ddot{n}$$

It is clear from above equation that fine tuning of damping coefficient f,  $\bar{d}$  and  $\bar{h}$  of the MSD reference model

plays a vital role in the compliance behavior, figure 2 shows block diagram of human and RWAD combine motion.

#### **RESULTS**

For simulation, it is assumed that human is not providing any torque initially and at a later stage (t=11 sec) it starts providing torque for a moment. Simulation results for model reference compliance control (MRCC) of RWAD for hip and knee joint are shown in Fig (2) and Fig (3) respectively. Figure (1) presents results of RWAD hip joint required position and actual position Hence, the RWAD is tracking the position

demand as it is. However, when human starts applying torque,

Fig 1: Block diagram of RWAD and Human compliance control comes in action and change position demand to compensate for this torque. Hence, walking action is completed in collaboration. In addition, compliance helps to synchronize RWAD motion with human.

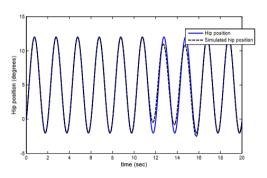


Figure 2.: Hip position

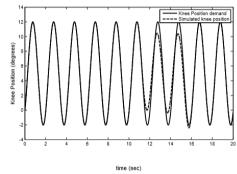


Figure 3: Knee position.

# **DISCUSSION AND CONCLUSION**

This study presents integral sliding mode-based compliance control scheme of RWAD. The model reference compliance scheme mimics the compliant behavior of mass-spring-damper system. The scheme intends providing 'assistance as needed' to the people with weak legs. Compliance control is employed for its relevance to the safety of user. It safeguards against excessive torques applied by RWAD. The key feature is to reduce the assisting torque if user has improved walking capability. The effectiveness of the scheme is demonstrated via simulation.



# Retrospective Cohort Study Comparing Three HALO Management Protocols and the Incidence of Adverse Events

<u>Yutaka Arai</u>, Steven Walker, Brian Delaney, Jessica Angus The Royal Brisbane & Women's Hospital, Brisbane, Australia

#### **BACKGROUND**

Fractures of the cervical spine are a common occurrence and have been managed in a HALO thoracic brace (HALO) since its introduction in 1959. Several HALO management complications have been reported in the literature; including pin loosening, ring migration and pin penetration. The Royal Brisbane and Women's Hospital's (RBWH) Orthotics Department has used two different styles of HALO brace with either standard or self-tapping pins and continues to modify the HALO management protocol.

#### AIM

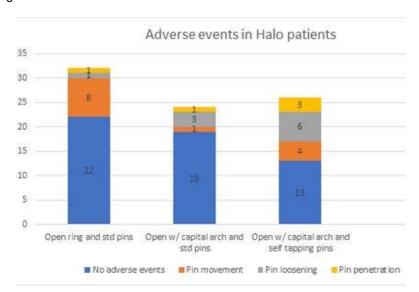
The purpose of this retrospective study is to compare the adverse events of three different HALO management protocols of over a 100 C-spine fracture patients of RBWH.

#### **METHOD**

A retrospective case series was undertaken which has, thus far, analysed the charts of 82 patients who were treated with HALO at RBWH. Inclusion criteria was set regarding HALO ring fitted and pins utilised. Patients were excluded if insufficient documentation existed to allow statistical analysis to take place. 32 patients were fitted with an open back ring with standard pins. 24 patients fitted with an open back ring with capital arch and standard pins. 26 patients fitted with an open back ring with capital arch and self-tapping pins. Results were then analysed to determine if pin type or HALO ring had a direct correlation to incidence of adverse event.

#### **RESULTS**

A total of 28 patients of the 82 reviewed (34.1%) experienced some degree of adverse event throughout their treatment. The most common adverse event was pin movement or slipping which occurred in 13 (15.8%) patients. This accounted for 46.4% of all adverse events. In patients fitted with the open back ring with capital arch and self-tapping pins, 13 of 26 patients (50%) experienced some degree of adverse event compared to 31.2% of patients fitted with the open back ring and standard pins and 20.8% of patients fitted with the open back ring with capital arch and standard pins.



# **DISCUSSION AND CONCLUSION**

The initial analysis of our preliminary data

indicates that the incidence of adverse events relating to pin loosening, movement or penetration are twice the rates reported by Van Middendorp et al. (2009). Further analysis is required, but indications are that self-tapping pins have a significantly higher risk of adverse events in our cohort of patients. It is our hypothesis that pin loosening is a precursor for pin penetration in patients wearing self-tapping pins.

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# Application of a Dynamic Spinal Brace to a Child with Fibrodysplasia Ossificans Progressiva Developing Acutely Progressing Scoliosis

Nobuhiko Haga<sup>1</sup>, Yusuke Shinoda<sup>1</sup>, Sayaka Fujiwara<sup>1</sup>, Hiroshi Mano<sup>1,2</sup>, Ryoko Sawada<sup>1</sup>
Department of Rehabilitation Medicine, The University of Tokyo, Tokyo, Japan. Department of Rehabilitation, Shizuoka Children's Hospital, Shizuoka, Japan

#### **BACKGROUND**

Fibrodysplasia ossificans progressiva (FOP) is a rare genetic skeletal disorder manifesting progressive heterotopic ossification in the skeletal muscles, fascia, tendons and ligaments, and congenital malformation of the great toes. Heterotopic ossification leads to deformity and loss of motion in the trunk and extremities, affecting normal activities of daily living. More than half of the patients develop scoliosis during childhood, and most of them lead to unbalanced curves, though appropriate treatment has not been established.

#### ΔIM

To present our preliminary experience of applying a dynamic spinal brace to a child with FOP developing acutely progressing scoliosis.

#### **METHOD**

A 5-year-old boy with FOP (R206H mutation in *ACVR1* gene) developed soft tissue swelling (flare-up) on his neck, which spread to his shoulder and back in a month. To prevent progression of this flare-up and formation of heterotopic ossification, corticosteroids and selective cyclooxygenase-2 inhibitors were prescribed. Two months later, right convex scoliosis was noticed, and acutely progressed. To prevent worsening of scoliosis and improve balance of the trunk, a Dynamic Spinal Brace (DSB) was prescribed and a lift was applied to his left shoe.

#### **RESULTS**

The brace mildly corrected his spinal curvature and the patient felt improvement of his standing balance. Though the follow-up period is only half a year, no apparent heterotopic ossification developed on his back, and the acute progression of scoliosis subsided. No skin trouble developed.

#### **DISCUSSION AND CONCLUSION**

Spinal curvature in FOP patients can lead to unbalanced posture and cause cardiorespiratory failure. Previous report on scoliosis in FOP described that spinal orthosis resulted in breakdown of the skin and failed to halt progression of the curve. DSB consists of a three-point support framework with a polycarbonate strut and contact surface with the trunk smooth and covered with a soft material. Though the follow-up period is limited, DSB might be effective to treat scoliosis in FOP.

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# **ACKNOWLEDGEMENTS**

This study was supported by the Health and Labor Sciences Research Grants for Research on Intractable Diseases, MHLW of Japan.



# Decompensation after Orthotic Application in AIS that Mimics Cobb Angle Reduction

MD Jeeyoung Kim<sup>1</sup>, MD Yangjoo Song<sup>2</sup>, MD Hyundong Kim<sup>1</sup> Inje University Busan Paik Hospital, College of Medicine, Inje University, Busan, Republic of Korea. <sup>2</sup>Veterans hospital, Busan, Republic of Korea

#### **BACKGROUND**

Cobb's angle reduction is considered as the most important factor in estimating the prognosis of effect using orthosis. Worsening of spine curve can be avoided when decompensation is properly detected and appropriately treated. However, studies of decompensation, one of the other factors that could affect prognosis, were reported mainly in case of surgical treatment, and insufficient in case of orthosis treatment.

To make sure that decompensation can affect prognosis of AIS, this study compared serial X-ray of 2 AIS patients, one had decompensation primarily and the other's decompensation was occurred at first wear of orthosis.

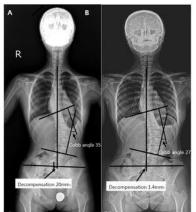
#### **METHOD**

Two patients with AIS visited rehabilitation outpatient clinic of university hospital who applied brace for preventing progression of scoliosis. Evaluations including time of menarche, Tanner stage, Risser stage, height,

length of spinal column, degree of vertebral rotation by Nash-Moe technique, curve pattern. Cobb's angle and decompensated or not were assessed before and right after the first application of brace. Follow up X-ray was performed 5 weeks after wearing period.

#### **RESULTS**

In Patient 1, Tanner stage was II, Risser stage was III and height was 155.3cm. The major curve was 35° of Cobb. Vertebral rotation was +2. Decompensation was measured as 20mm to the left side. After wearing Brace, inbrace X-ray was studied and the major curve reduced by 2°. Also decompensation was improved with 12 mm decrease. After 5 months, follow up exam showed major curve decreased by 6°. Decompensation also decreased by 6.6mm (figure 1).



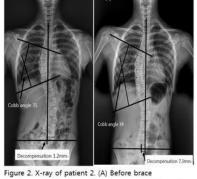


Figure 1. X-ray of patient 1. (A) Before brace

(B) After 6 months Boston brace treatment without brace (B) After 6 months Boston brace treatment without brace Table 1. Changes in parameters before and after treatment

	patient 1				patient2			
	Error State of	Initial in-brace	After treatment		- 1000000000000000000000000000000000000	100000000000000000000000000000000000000	After treatment	Chang of value
Cobb's angle (")	35	33	27	-8	35	18.5	34	-1
Decompensation(mm)	20	8	1.4	-18.6	1.2	5.5	7.3	+6.1

In Patient 2, Tanner stage was I, Risser

stage was I and height was 146.7cm. The major curve was 35° of Cobb. Vertebral rotation was +1. Decompensation was 1.2mm to the left side. After wearing Brace, in-brace X-ray showed the major curve reduced by 16.5°. However, decompensation was aggravated with 4.3mm increase. After 5 months, major curve increased by 15.5°. Decompensation also increased by 1.8mm (figure 2).

# **DISCUSSION AND CONCLUSION**

In case of patient 1, decompensation was observed initially, but we confirmed that Cobb's angle was decreased by correction of brace modification. In case of patient 2, decompensation was not observed initially, but Cobb's angle decreases and then increases again, because the decompensation occurred after wearing brace. Decompensation is important factor that must be considered in the manage of AIS using the orthosis. Following up X-ray and checking decompensation can be an important predictive factor of scoliosis progression.



# Free Paper – Poster Presentation Orthotics: Upper Limb

#### 5.023

# Does customized brace provide sufficient stability? Analysis of Contact Pressure in Traditional Wrist Cast and 3D-Printed Customized Brace

Hao-Ming Chang<sup>1</sup>, Cheng-Li Lin<sup>1</sup>, Tzu-Hao Wang<sup>2</sup>
<sup>1</sup>Department of Orthopedic Surgery, National Cheng Kung University Hospital, Tainan, Taiwan. <sup>2</sup>Kaohsiung Municipal Min-Sheng Hospital, Kaohsiung, Taiwan

#### **BACKGROUND**

Circumferential resin cast is one of common conservative treatment in wrist and hand injury despite of disadvantage including frowziness, dermatitis, pressure sores, and compartment syndrome. Recently, 3-dimensional (3D) fabrication wrist brace is promising because it could provide more breathable, satisfying orthosis. However, there is no published evidence comparing the stability and contact pressure between 3D customized wrist brace and resin cast.

#### AIM

This study tried to establish a 3D-printed customized brace model which could not only provide similar contact pressure and stability as resin cast, but more breathable, comfortable and convenient.

#### **METHOD**

We proposed a customized brace for wrist made by 3D printing machine with the healthy volunteers of digital model of forearm, wrist and palm. And then chose 6 regions on forearm as research targets (ROI; Region of Interest). Pressure sensors were carried out on these regions and applied with resin cast and customized brace. By measuring and analyzing the pressure on these regions, compare the fixation and find out the parameter of design. Wrist was placed respectively in neutral position, and arm sling when pressure was recorded. Satisfaction Questionnaires were obtained from all participants after usage of resin cast, and customized drilled/ undrilled brace.

#### **RESULTS**

In the first experiment, in resin cast, pressure of neutral position at 90 minutes and other following time point is not statistically significant (p-value > 0.05) by using Generalized Estimating Equation. Hence, we set 90 mins as our experimental time. In the second contact pressure experiment, customized wrist brace had lower contact pressure than resin cast in forearm area with statistical significance (p-value < 0.05). Performance of drilled and undrilled customized wrist brace is not statistically significant (p-value > 0.05). In the third experiment, after adjustment of tolerance of customized brace in forearm area (ROI 3,6), customized brace with tolerance of 0.3 mm had no statistical significance than resin cast (p-value > 0.05) by Friedman Test. The result of questionnaire is that customized wrist brace is better than resin cast in comfortability and convenience.

# **DISCUSSION AND CONCLUSION**

In this study, 3D customized brace with partial tolerance adjustment could provide similar contact pressure and stability as resin cast. In addition, there is no difference between braces drilled and undrilled with holes of 5 mm in diameter. Overall, 3D-printed customized wrist brace had better comfortability and convenience than resin cast.



# A Novel Artificial Muscle Type Dynamic Splint for Wrist Joint Disease using Darts Throw Motion

Mr Jun Nakayama<sup>1</sup>, Mr Kazunori Ogawa<sup>2</sup>, Mr Hisao Oka<sup>3</sup>
<sup>1</sup>Kansai University of Welfare Sciences, kasihara city, Japan. <sup>2</sup>Daiya Industry Co., LTD., Okayama city, Japan. <sup>3</sup>Graduate School of Health Sciences, Okayama University, Okayama city, Japan

#### **BACKGROUND**

In the recent years, darts throw motion (DTM) has been known as a functional motion direction of the wrist joint. However, reports on wrist joint splints with careful consideration of DTM are limited. Therefore, we devised a new artificial muscle-type dynamic splint incorporating the DTM.

#### ΔIM

To compare the automatic motion of the wrist joint using three-dimensional (3D) motion analysis to obtain reproducibility of the DTM splint.

#### METHOD

The splint is arranged with two McKibben-type rubber artificial muscles. To position the limbs, a dedicated fixture was created in order to make 90° flexion position of the elbow joint and middle forearm. Measurements were performed using the image analysis software (Sky com, Tokyo Japan) with a 3D motion analysis device (Opti track Japan: Motive). The wrist joint angle is calculated from the 60° palmar flexion (PF) based on the wrist radial angle (WRA) of the radial styloid process from the head of the index metacarpal finger and the lateral epicondyle of the humerus to the 60° dorsal flexion (DF).

#### **RESULTS**

Examination items are three-point angle (wrist ulnar angle [WUA]) of the ulnar styloid process (projection) from the base of the little metacarpal finger to the lateral humeral epicondyle; three-point angle (ulnar deviation [UD]) of the radicular and ulnar styloid processes from the index metacarpal finger; and three-point angle (radial deviation [RD]) of the ulnar (projection) and radial styloid processes from the base of the little metacarpal finger. In the DF direction, RD and WUA of the artificial muscle splint showed a significant difference (p<0.05; 30–60°) as compared with active motion. In the PF direction, the artificial muscle splint was significantly different from 30° (p<0.05) to 60° (p<0.01) for both UD and RD as compared with active motion. Furthermore, WUA showed a significant difference of 50° (p<0.05).

### **DISCUSSION AND CONCLUSION**

This splint is arranged with two McKibben-type rubber artificial muscles on both the volar and dorsal sides. Since the artificial muscles were used, adjustment of force and forced direction becomes easier than before. Based on the results of this study, this splint has been suggested to have a dart throw effect of >30° in the PF and >40° in the DF directions than automatic exercise.

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#### **ACKNOWLEDGEMENTS**

This work was supported by JSPS KAKENHI Grant-in-Aid for Scientific Research (B).



# The Effect of Customized Electric Wheelchair Control Device Aids Made by 3D Printing Technology

<u>Hee Seung Yang</u>, Da Hyun Ahn, Dong Young Ahn, Woo Sob Sim, Min Jo Veterans Health Service Medical Center, Seoul, Republic of Korea

#### **BACKGROUND**

Several disabled patients employ electric wheelchairs for daily activities and ambulation. Since tetraplegia (quadriplegia) patients suffer from severe hand dysfunction, an electric wheelchair cannot aid them completely. Electric wheelchair joysticks are often available as standardized ready-made products. Consequently, there are certain limitations to providing different complementary features for each patient's hand dysfunction. However, owing to advancements in science and technology, the 3D scanning and printing technology can overcome such limitations.

#### AIM

The objective of this study is to develop customized electrical wheelchair joysticks that aid tetraplegia patients with severe hand dysfunction, whereby patients' driving performance with electrical wheelchairs can be improved.

#### **METHOD**

During the period of September 1, 2018 to December 31, 2018, five tetraplegia patients using electric wheelchairs but not content with the original joysticks participated in this study. Patients' discomfort and issues regarding previously used wheelchair joysticks were individually identified. Through 3D scanning and modeling, customized electrical wheelchair joysticks were designed and developed. After using the customized joysticks for two weeks, the patients' driving abilities and satisfaction with the electric wheelchairs were evaluated. Modified power-mobility indoor driving assessment (PIDA), National Aeronautics and Space Administration task load index (NASA-TLX), and psychosocial impact of assistive devices scale (PIADS) were employed for evaluation.

#### **RESULTS**

Results for one of the five patients are excluded owing to the patient's medical issues.

Case 1 (KDH), Case 2 (LYH), and Case 3 (HDY): Modified PIDA scores have the highest values (patients can follow instructions easily, accompanied by a safe and successful first trial) in the pre-test and post-test. Modified PIDA time measurements indicate time reduction in the post-test as compared to the pre-test. NASA-TLX and PIADS values indicate greater satisfaction through usage of customized joysticks in the post-test.

Case 4 (PIS): Modified PIDA score has a higher value in the post-test (mean-value=4) as compared to the pretest (mean-value=3.33). Modified PIDA time measurement indicates time reduction in the post-test as compared to the pre-test. NASA-TLX and PIADS values indicate greater satisfaction through usage of customized joysticks in the post-test

# **DISCUSSION AND CONCLUSION**

By using customized joysticks, patients can improve their electric wheelchair driving abilities and can thereby experience greater satisfaction.

# **REFERENCES**

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# An EMG Gaming System for Myoelectric Prosthesis Control

<u>Go Nakamura</u>, Hidemasa Nakamura, Hibiki Takami, Yuichiro Honda, Futoshi Mizobe, Takaaki Chin Robot Rehabilitation Center in the Hyogo Institute of Assistive Technology, Kobe, Japan

#### **BACKGROUND**

To control myoelectric prosthesis voluntarily, it is required to conduct training. However, only a limited number of medical staffs can instruct in Japan. It is particularly difficult to conduct training for children because they get tired during training. Against such a Background, toys or games for training are necessary. The EMG systems such as MyoBoy system [1] have been already proposed, and these systems provide some games. However, it is insufficient choices of the games for attracting children.

#### ΔIM

The aim of this study is to increase motivation in children and keep the training as long as possible by attracting their interest.

### **METHOD**

Figure 1 shows the developed gaming system for myoelectric prosthesis control. The gaming system consists of a transmitter, a receiver and a tablet computer. The measured EMG signals are digitized in the transmitter and sent to the receiver. The receiver decodes the EMG signals. If the children generate EMG signals for closing/opening, the character of closing/opening becomes large (Fig. 1). The characters and Background images can be changed easily based on the each child's interests.

#### **RESULTS**

The developed gaming system has been used during training for a child. As an example of successful case, it is observed that a child who is tired of training is interested in our gaming system, and he resumes EMG control training again. In particularly, it seems that he is enjoying the characters which become large according to the amplitude of EMG signals.

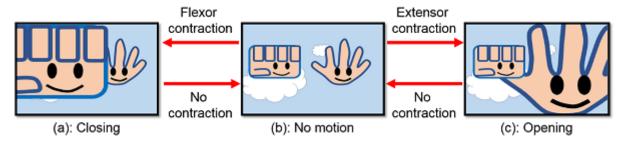


Figure 1. The developed gaming system for myoelectric prosthesis control

# **DISCUSSION AND CONCLUSION**

The developed gaming system is used while myoelectric hand training for children. It was confirmed that the developed gaming system can support myoelectric prosthesis training for children. In future works, the authors plan to check the training effectiveness using developed gaming system. In addition, we plan to investigate relationship between children's interests and sensory feedback such as visual or audio feedback.

# **REFERENCES**

[1] Otto Bock web page: <a href="http://www.ottobock.com/">http://www.ottobock.com/</a>



# Free Paper – Poster Presentation Prosthetics: Lower Limb Transfemoral

#### 5.027

# Different Traditional Alignmeet Techniques of Transfemoral Prosthesis and their Effects on Gait Parameters

Nizar Akhtar, Aqsa Ali

Pakistan Institute of Prosthetic and Orthotic Sciences, Peshawar, Pakistan

#### **BACKGROUND**

Alignment of components effects the comfort and gait functions of TF amputee. Some researchers claimed static alignment while others believe that matching Roll Over Shape (ROS) is the key to optimum gait. Some other researchers believe that symmetry, less energy consumption and stability are the keys for optimum alignment. It is still confusing for clinicians to decide which alignment method (MKA. TKA, German) require least magnitude of alignment changes to obtain optimal gait. Research is needed to high-light these alignment methods.

#### ΔIM

The main objective of this study is to investigate the effects of traditional alignment techiques (MKA, TKA, German) on optimum gait parameters.

#### METHOD

Two subjects were conveniently selected and fitted with TF prosthesis with three alignment conditions (MKA, TKA, German). A total of 19 retro refelective markers of 12 mm dia were placed over the anatomical landmarks of the body. Quantitative data was recorded of each subject while wearing prosthesis with three different alignment methods. Prior to data collection, both subjects were instructed to walk for about five minutes to accommodate the alignment changes of each method. The motion data was sampled at 120Hz using an eight camera motion captured system and data aquisition software. Motion data was synchronized to facilitate subsequest analysis.

#### **RESULTS**

Subjects were relatively similar in terms of amputation etiology (trauma), activity level (K3), residual limb length (32cm and 34.5cm), socket fit and socket type. Both participants considered their socket fir to be comfotable(mean comfort score: 8). MKA and TKA alignment produced almost same stride length (SL=1.41 m) on prosthetic side. German technique failed to produce near to normal value of stride length. The stride time with MKA alignment was closer to normal value (1.2 sec) as compared with other techniques. The velocity with MKA alignment was higher than other techniques (1.3 m/s), however, no alignment technique scored higher or eqaul to the normal velocity value(1.5 m/s). The stance phase duration with MKA was 64% which was closer to normal value (60%) compared with TKA (66%) and German method (68.4%).

#### **DISCUSSION AND CONCLUSION**

This study suggested a potential difference in gait parameters as a result of three different traditinal alignment techniques. MKA method might serve to produce useful biomechanical parameters to obtain optimal gait pattern. A limitation to this study was a case series with two amputees. A larger scale study is warranted to confirm the useful effects of MKA alignment. It is also suggested that a futire study sould also focus on exploring which activity level (K level) needs which traditional alignment.

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### **ACKNOWLEDGEMENTS**

The author would like to thanks the PIPOS administration for allowing the use of Biomechanics Gait Lab.



# Effectiveness of Locking Knee with Sitting Assist Prosthesis for Elderly Transfemoral Amputee with Poliomyelitis: A Case Report

<u>Izumi Takase</u>, Mitsunori Toda, Miki Tadatsu, Takaaki Chin Hyogo Rehabilitation Center, Kobe, Japan

#### **BACKGROUND**

Locking knee is one of the choices for low mobility grade elderly transfemoral amputees. However, when unlocked for sitting, conventional locking knee prosthesis could not support users. So, users have to do sitting motion with their residual leg and upper limbs. Locking knee with sitting assist could support the patient while lowering into a seated position. Here we present a case of elderly transfemoral amputee who achieved independent ADL and doing housework with this prosthesis.

#### AIM

To investigate the effectiveness of locking knee with sitting assist knee joint for low mobility grade elderly transfemoral amputation as a case report.

#### **METHOD**

A 68-year old female with poliomyelitis on left leg was admitted to our hospital for rehabilitation following right transfemoral amputation and contralateral supracondylar femoral fracture caused by traffic accident. Manual muscle testing was 3 in lower limb, and she was unable to stand with residual leg. The goal of rehabilitation was to achieve indoor walking and doing houseworks with prosthesis. She could stand with residual leg following 9-week intensive training, and the prosthesis using locking knee with sitting assist was prescribed for prosthetic training. The motion pattern of sitting-down movement with or without sitting assist function was evaluated using electromyograph and stabilometer.

#### **RESULTS**

She achieved indoor walking and independent ADLs with prosthesis and walker, left the hospital and went home. She uses her locking knee with sitting assist prosthesis all day, and she could do all the household chores including cooking and washing, which she used to do before amputation. Muscle activation in sitting motion showed 62% reduction in right triceps, and 40% reduction in left gluteus maximus with sitting assist knee compared to conventional locking knee without sitting assist. Center of pressure in sitting motion were kept almost body center with sitting assist, while shifted to residual limb with conventional knee in coronal plane. She felt that this prosthesis reduced the burden in sitting motion, and made her doing ADLs and housework easy.

# **DISCUSSION AND CONCLUSION**

Our results showed that sitting assist locking knee prosthesis could reduce the burden while sitting in elderly transfemoral amputees with muscle weakness in residual limb and upper limb, while conventional lock knee raises the concern for falling when unlocked for sitting. We might seek the possibility to achieve prosthetic walking and independent ADLs with locking knee with sitting assist even in patients with severe muscle weakness. Further evaluation in larger number of cases should be needed.



# Design and Optimization of a Hip Disarticulation Prosthesis Using Remote Central of Motion Mechanism

#### Li Xinwei

University of Shanghai for Science and Technology, Shanghai, China

#### **BACKGROUND**

Hip disarticulation is an amputation removing the entire extremity through the hip joint capsule. Statistics show that only 2.2% of all amputations at the hip disarticulation level. There is a little volume of published studies describing the developments and innovations of the HDPs. The mechanisms of the existing HDPs cannot simulate the anatomical structure of uninjured side leg to make the amputees walk naturally because the mechanisms almost don't rotate around the actual acetabulum of the amputated side

#### AIM

To design a novel HDP with remote center of motion mechanism turns rotating center of HDP back to the acetabulum which could get rid of the asymmetrical gait pattern and the problem of differential length between prosthesis and intact leg.

#### **METHOD**

The 1R-RCM is designed with a double parallelogram linkage, which connects two revolute joints to implement the motion as a rotation joint while maintaining the remote center of the rotation, motivated by its promising results in the field of the prosthesis. The design has several new features compared to current HDPs which rotate around an axis out of the pelvic socket or uncertain ones: (1) the HDP is restrained to rotate about acetabulum but not physically hinging to it, (2) a range of motion from -15° to 45° free of singularity, (3) stable support, and (4) compact, which make it suitable for HDP.

#### **RESULTS**

This paper presents a remote central mechanism for hip disarticulation prosthesis that satisfies the center of rotation constraint was proposed on the basic of analysis the aysmmetry of gait pattern with common single joint HDPs. A systematic methodology for optimizing the mechanism was developed and the combined measure evaluated the performance effectively.

# **DISCUSSION AND CONCLUSION**

The promotion of the designed of RCM HDP can be concluded as below: Increased the maximum flexion of HDP during swing phase More natural period of hip extension during stance phase Increased prosthetic knee flexion during stance/swing phase Reduction in the range of pelvic tilt especially in anterior side

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#### **ACKNOWLEDGEMENTS**

We are appreciated that Sun Youzhi provided suggestions for our research on hip disarticulated amputees' own experience about gait patterns.



# Design, Modelling and Simulation of Active Trans-femoral Prosthesis

<u>Izhar UI Haq</u><sup>1</sup>, Asim Shahzad<sup>1</sup>, Saqib Mehmood<sup>1</sup>, Muhammad Hamza<sup>1</sup>, Kamran Shah<sup>1</sup>, Muhammad Usman Qadir<sup>1</sup>, Nizar Akhtar<sup>2</sup>

<sup>1</sup>University of Engineering and Technology, Peshawar, Pakistan. <sup>2</sup>Pakistan Institute of Prosthetic and Orthotic Sciences, Peshawar, Pakistan

#### **BACKGROUND**

Extensive research in robotics and automation technologies have resulted in development of advance systems that can significantly improve our quality of life. Trans-femoral prosthesis is a complex electro-mechanical system in which mechanical structure is coupled with gait cycle of the amputee through electronics based intelligent system. The system can recognize lower-limb movements and execute corresponding control actions to replicate normal walking pattern. However, such intelligent prostheses are very costly and not affordable for most of the amputees throughout the world.

Figure 1 Computer Aided Design of Intelligent Knee.

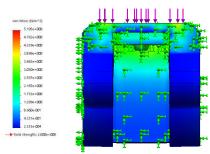
# **AIM**

The aim of this study is to design a hydraulic based active trans-femoral prosthesis available within a nominal cost and equipped with state-of-the-art technology to assist amputees in not only performing daily activities but also becoming active citizens of society.

#### **METHOD**

The concept of the proposed prosthesis is based on coupling of mechanical design with intelligent control system through sensory data for mimicking normal human gait cycle. The study comprises of the following major phases:

- Capturing end-user requirements
- 3D modelling of prosthesis
- Selection and controlling of sensors
- Manufacturing of mechanical design
- Integration of Electronics and Mechanical components
- Stance and Swing Control Design



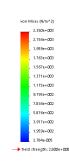


Figure 2 Results of static force analysis.

- Close loop Control System Design
- Trials on patient and testing

#### **RESULTS**

This research is recently initiated as a collaboration between Department of Mechatronics Engineering, University of Engineering & Technology, Peshawar and Pakistan Institute of Prosthetics and Orthotics. The mechanical design, analysis and 3D printing of prototype of Intelligent Knee has been completed successfully. The initial design of prosthesis is shown in Figure 1. The stress analysis of mechanical design is performed to ensure structure integrity upon application of full body load on structure. The results of application of static forces on various components of designed prosthesis is shown in figure 2. It is evident from figure 1 2 that mechanical strength of proposed design is enough to tolerate full body weight under various conditions.

### **DISCUSSION AND CONCLUSION**

The proposed active prosthetic lower limb apart from making amputees independent will improve mobility of amputee but also assist them in managing day-to-day activities. This research proposes a novel low cost intelligent transfemoral prosthetic limb to autonomously mimic the functionalities of healthy knee operations by characterizing it with amputee gait cycle. The next phase in this research is manufacturing of mechanical design and its integration with electronics.

### **ACKNOWLEDGEMENTS**

The authors are thankful to Pakistan Institute of Prosthetic & Orthotic Sciences (PIPOS) for their collaboration in this research.



# Necessity of Ambulatory Aids is Related to Balance Abilities in Elderly People with Transfemoral Amputation Undergoing Prosthetic Training

Yuji Azuma<sup>1,2</sup>, Mitsunori Toda<sup>1</sup>, Takaaki Chin<sup>1</sup>, Yasushi Miura<sup>2</sup>

Hyogo Rehabilitation Center, Kobe, Japan. <sup>2</sup>Kobe University Graduate School of Health Science, Kobe, Japan

## **BACKGROUND**

Previous study has been reported that the balance ability is different between the groups with and without ambulatory aids in community-dwelling people with lower limb amputation.[1] However, For elderly people with transfemoral amputation (TFA) undergoing prosthetic training, necessary balance abilities to walk depending on the kinds of ambulatory aids are not reported before.

#### AIN

To assess the necessary balance abilities for elderly people with TFA depending to the kinds of ambulatory aids required to walk with prosthesis.

## **METHOD**

Twenty people with TFA aged at least 60 years were included. Balance ability was evaluated by Berg Balance Scale (BBS). BBS sub scores were classified into three categories (Total score (T-BBS), Static BBS score (S-BBS) and Dynamic BBS score (D-BBS)) and calculated. The results of age and each BBS score was compared among the necessary ambulatory aids (Walker/Double canes, Single cane, and No aids). Receiver operating curves were used to compare the performance of each BBS score in predicting the necessary ambulatory aids and to determine their appropriate cut off point.

## **RESULTS**

Five subjects used walker/double canes, 9 used single cane and 8 did not use ambulatory aids during prosthetic walking. There were no significant differences in age among the three groups. The group with walker or double canes had significantly lower T-BBS, S-BBS and D-BBS scores than the group with single cane and no aids. Meanwhile, the group with single cane had significantly lower T-BBS and D-BBS scores than the group with no aids. T-BBS was the best predictor for walker/double canes or single cane (area under the curve 0.993 (0.975-1)) and the cut-off T-BBS score was 37. D-BBS was the best predictor for single cane or no aids (area under the curve 0.935 (0.828-1)) and the cut-off D-BBS score was 22.

# **DISCUSSION AND CONCLUSION**

The results suggests that the necessary balance ability of elderly people with TFA depending on the kinds of ambulatory aids can be predicted by T-BBS between walker/double canes or single cane, in contrast, by D-BBS between single cane and no aids. Improvement of balance ability evaluated with BBS could contribute to predict the reduction of necessary ambulatory aids. Further study should be conducted with more subjects.

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# Development and Evaluation of Total Surface Bearing (TSB) Prosthesis Using Reverse Engineering Tools and Procedures

Kamran Shah<sup>1</sup>, Mustafa Ur Rehman<sup>1</sup>, Izhar Ul Haq<sup>1</sup>, Nizar Akhtar<sup>2</sup>, Haider Ali<sup>1</sup>

<sup>1</sup>University of Engineering and Technology, Peshawar, Pakistan. <sup>2</sup>Pakistan Institute of Prosthetic and Orthotic Sciences, Peshawar, Pakistan

# **BACKGROUND**

The most critical component of transtibial prosthesis is socket, because it acts as a coupling between residual limb (stump) and artificial limb (prosthesis). The biomechanical properties particularly pressure and force-distribution of socket-stump contact, has significant influence on amputee satisfaction. Biomechanics and bioengineering of prosthesis can be better understand by using Finite Element (FE) modelling methods. FE modelling can accurately estimate stresses and strains in complex biomechanical systems and is considered as a useful tool to understand biomechanics in lower limb prosthesis.

#### AIM

The study aims to use numerical analysis techniques as a pre-evaluation tool for development of lower limb transtibial prosthesis. The FE analysis simulate the contact interface between stump and socket to evaluate the interface pressures and sliding friction in prosthesis

# **METHOD**

Male having weight of 52 Kg Computer Tomography (CT) images having scan interval of 6 mm

Numerical analysis using ANSYS Workbench 15.0 3D printed prosthetic socket Clinical measurements using FSR sensors

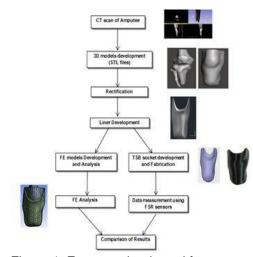


Figure 1: Framework adopted for development and evaluation of Total Surface Bearing (TSB) prosthesis.

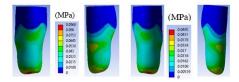


Figure 2: Anterior and lateral view of FE analysis pressure distribution map at (a) FBW and (b) HBW loadings.

# **RESULTS**

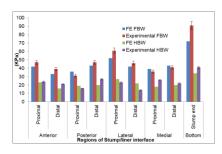


Figure No. 3: comparison of FE interface pressures and FSR

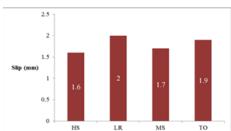


Figure No.4: Bone movement at stance phase of gait cycle

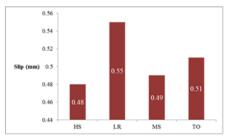


Figure No.5: Slip at stance phase of gait cycle

# **DISCUSSION AND CONCLUSION**

The most extensive bio-mechanical property used for evaluation of trans-tibial socket is interface pressures. This study presents validation of interface pressures by comparing FE simulation results with clinical measurements. The results from FE and clinical measurements presents that the interface pressures were distributed all over the residual limb. By keeping in consideration, the uncertainty in mechanical properties of tissues and placement of FSR sensors, the averaged interface pressures from experimental measurement and FE simulation were matched within an acceptable range.

# **ACKNOWLEDGEMENTS**

The authors present sincere gratitude to Mr. Mohsin for voluntarily participating in the study.



# Prosthesis and Rehabilitation Management with Nutrition Therapy for the Lower Extremities' Amputee Patients due to Peripheral Artery Disease

Naohisa Kikuchi, Atsushi Urata, Yumi Asano, Hajime Nakayama, Katsunori Yoshinaga Chiba Rehabilitation Center, Chiba, Japan

## **BACKGROUND**

It is difficult to make practical prosthesis for the lower extremities' amputee patients due to peripheral artery disease because of some medical complications or aging. Many articles reported that the successful rate of the practical prosthesis making for those patients was very low, especially in the transfemoral amputation. But we hypothesize that those kinds of patients have a chance to make the proper practical prosthesis to take care nutrition and enough muscle strengthening.

#### AIM

This study was pursued to prove the proper practical prosthesis making by nutrition therapy and enough muscle strengthening for the lower extremities' amputee patients due to peripheral artery disease.

# **METHOD**

Participants were 17 the lower extremities' amputee patients due to peripheral artery disease who admitted our hospital to make the prosthesis for the first time and rehabilitation therapy. Mean age was 68-year-old (47 to 83-year-old) There were 12 males and 5 females. Disease were 9 diabetes association, and 8 arteriosclerosis obliterans. There were 9 unilateral transfemoral amputation, 2 bilateral transtibial amputation, and 6 unilateral transtibial amputation. We investigated serum albumin, Body Mass Index (BMI), ambulatory ability at discharge, and disposition after discharge. We decided our nutrition program with our all medical staffs. We used Nutrition Supporting Team round as necessary.

# **RESULTS**

Serum albumin in admission was 3.29 (Standard Deviation; SD 2.87) for unilateral transfemoral amputation, 3.70 (SD 0.85) for bilateral transtibial amputation, and 3.65 (SD 0.36) for unilateral amputation. All of patients increased at discharge. BMI in admission was 21.1 (SD 3.04) for unilateral transfemoral amputation, 21.5 (SD 3.25) for bilateral transtibial amputation, and 19.8 (SD 2.87) for unilateral amputation. All of patients under 20 increased at discharge. As for ambulatory ability at discharge, 3 patients of unilateral transfemoral amputation and 3 patients of unilateral transtibial amputation could walk with minimal assistance, 3 patients of unilateral transfemoral amputation, and 3 patients of unilateral transtibial amputation could walk independently in the room, and 7 patients could walk independently outside. As for disposition after discharge, 13 patients discharged their home, and 4 patients of unilateral transfemoral amputation transferred to the nursing facilities.

# **DISCUSSION AND CONCLUSION**

We studied effectiveness of active rehabilitation approach and practical prosthesis making with nutrition therapy. Many of the lower extremities' amputee patients due to peripheral artery disease had malnutrition and sarcopenia. But if the patients have malnutrition or severe muscle weakness of lower extremities, we could achieve practical walking with prosthesis with proper nutrition support and muscle strengthening exercise.



# Task Effects and use of Insole Pressure Measurement System to Assess Weight Shifting in AK Amputation Gait Training – Single Case

Woo Sub Kim<sup>1</sup>, You Jin Choo<sup>2</sup>

1Korea University Guro Hospital, Seoul, Republic of Korea. 2ISPO Korea, Seoul, Republic of Korea

## **BACKGROUND**

During AK gait training, proper weight shifting to affected limb is an essential requirement for independent gait. However, amputee, therapist, and physiatrist frequently have difficulties in evaluation how well it is performed and what task is appropriate for current status. Although 3D gait analysis is gold standard, it has limitations in various task and environment. Therefore, we used insole pressure meter to assess weight shift and task effect.

#### AIM

We experienced that mode of crutch and cane has effect on lower limb loading, especially in affected side. To picture this effect, we used insole type foot pressure measurement system, which was clinically helpful.

#### **METHOD**

Case was male and 67 years old man. After TA, he had recurrent osteomyelitis and got operation; AK amputation in right femur. We trained him parallel bar, crutch and cane gait with various modes. We measured mode effects on lower limb loading by insole type foot pressure measuremen system.

## **RESULTS**

At POD 1 month, he was transferred to RM department for gait training. He did not have definite motor weakness in hip muscles. He had prosthesis with inschial containment socket, fluid vortex intelligent control knee, and dynamic foot.

At POD 37 days, insole pressure measurement was conducted. He walked crutch with 3 point partial weight bearing mode and 4 point mode. He was more familiar to modified 3 point mode than 4 point mode. Maximum load on prosthesis foot was 2.3 N/cm2 in 3 point mode and 4.8 N/cm2 in 4 point mode.

At POD 72 days, test was repeated with cane. He walked cane in ipsilateral and contralateral side. He was familiar to cane gait with contralateral side to amputation. Maximum load on prosthesis foot was 6.1 N/cm2 in contralateral mode and 9.7 N/cm2 in ipsilateral mode.

# **DISCUSSION AND CONCLUSION**

insole pressure measurement system can provide information for weight shifting in AK amputation. 4 point mode is more relevant for increasing weight shift than modified 3 point mode. Ipsilateral cane mode is more relevant for increasing weight shift than contralateral cane mode in AK amputation.



# Prediction of Transfemoral Stump Deformation During Donning Process in Bipedal Stances Using Finite Element Method

Mohd Syahmi Jamaludin<sup>1</sup>, Akihiko Hanafusa<sup>1</sup>, Yamamoto Shin-Ichirou<sup>1</sup>, Yukio Agarie<sup>2</sup>, Hiroshi Otsuka<sup>3</sup>, Kengo Ohnishi<sup>4</sup>

<sup>1</sup>Shibaura Institute of Technology, Saitama, Japan. <sup>2</sup>Niigata University of Health and Welfare, Niigata, Japan. <sup>3</sup>University of Human Arts and Science, Saitama, Japan. <sup>4</sup>Tokyo Denki University, Saitama, Japan

# **BACKGROUND**

Transfemoral amputee depending on their prosthetic socket to gain confident and enabling to walk normally. The stability and comfortableness socket depending on the accuracy of fitting level between the stump and the socket. Recent technology suggests utilization of 3D printer in manufacturing the socket and a simulation with subject-specified models can confirm the accuracy of the socket and predict the comfortableness of subject during socket fitting by measuring the interface pressure which reflected to composition of stump's soft tissue.

# **AIM**

This study proposed a method to predict the soft tissue deformation during donning process using finite element analysis. A simulation will be conduct in bipedal stances condition and the result of the analysis will be compared with image processing data.

# **METHOD**

Data Acquisition. Magnitude Resonant Image (MRI) of few subjects used in this research. The stump and the socket of every subject created with CAD software by following the procedures, i.e. pre-segmentation, segmentation, 3D model and material selection. Boundary condition for the simulation will follow the bipedal stances where 50% of body weight will be implemented in the top of the stump model. In the simulation, the socket constrained vertically, and the stump move toward the socket with horizontal direction constrained. After simulation completed, every 5mm layer of simulation image will be taken and analysed by image processing function in MATLAB.

# **RESULTS**

Comparison of fat volume before and after the donning process has been conducted where all 3D models (FEA) achieved high correlation (p>0.9) when compared with image processing (IP) models. The result shows high quantity of fat volume increased after donning in distal area (1<sup>st</sup>-15<sup>th</sup> layers) where for subject A the fat increase 18.11% while the increment of 17.41% and 11.77% for subject B and C respectively can be observed. In the other hand, in proximal area (16<sup>th</sup> layer above) showed the decrements of a fat volume for subject A and C where the volume decreased 9.02% and 10.62% respectively. However, for subject B the fat volume increases to 6.78% in proximal area. The graph in fig.1 showed the length of stump increased when it completely donned.

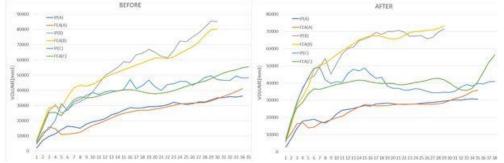


Fig.1 Comparison of fat volume for subject A, B and C in pre-post donning.

# **DISCUSSION AND CONCLUSION**

The high correlation between IP and FEA model can justify the boundary condition used in the simulation for mimicking the bipedal stances condition. The unique shape of muscle as in subject B case where the high ratio of muscle to fat leads to increment of fat volume in proximal area. As for the conclusion, the study has showed the quantitative analysis of transfemoral limb can be conducted with high accuracy before the socket 3D printing fabrication.

# **ACKNOWLEDGEMENTS**

The author appreciated the hardwork from Niigata University of Health and Welfare (NUHW) for providing the prosthetic socket data.



# Margin of Stability of Individuals Fitted with Transfemoral Bone-Anchored Prosthesis using Osseointegrated Fixation

Vincent Gibeaux<sup>1</sup>, Alexandre Naaim<sup>1</sup>, Thomas Robert<sup>1</sup>, Raphaël Dumas<sup>1</sup>, Rickard Brånemark<sup>2</sup>, <u>Laurent</u> Frossard<sup>3,4,5,6</sup>

Univ Lyon, Université Claude Bernard Lyon, Lyon, France. <sup>2</sup>Massachusetts Institute of Technology, Cambridge, USA. <sup>3</sup>Queensland University of Technology, Brisbane, Australia. <sup>4</sup>Griffith University, Gold Coast, Australia. <sup>5</sup>University of the Sunshine Coast, Maroochydore, Australia. <sup>6</sup>YourResearchProject Pty Ltd, Brisbane, Australia

# **BACKGROUND**

The concept of margin of stability in the medial-lateral direction introduced by Hof et al.[1] can characterize gait stability. Indeed, this margin has been presented for individuals with transtibial and transfemoral amputation fitted with socket-suspended prostheses [1]. Furthermore, margin of stability will be particularly relevant to further establish if direct skeletal attachment enabling osseoperception and overall better control on the prosthesis can improve balance during gait. However, this study is yet to be conducted.

#### ΔIM

This study aimed at presenting the margin of stability during gait of individuals fitted with transfemoral boneanchored prosthesis attached to osseointegrated fixation.

#### METHOD

Data extracted from a retrospective study included nine participants fitted with transfemoral screw-type osseointegrated fixation performing three gait trials at comfortable speed.[2] Kinematic and dynamic data were recorded simultaneously by a 6-camera 3D motion capture system and two force plates, respectively. The margin of stability corresponded to the difference in the medial-lateral direction between the centre of pressure and the extrapolated centre of mass at the time of the contralateral foot-off.[1] Furthermore, selected spatio-temporal gait characteristics (e.g., stride width, time of stance and double support, walking speed) were extracted and compared to the literature.[3]

# **RESULTS**

The margin of stability was 1.46 cm larger on the prosthetic side but 0.89 cm smaller on the contralateral side for the osseointegrated group compared to the socket group, respectively. Spatiotemporal gait

**Table 1.** Mean and standard deviation of margin of stability and selected spatio-temporal gait characteristics for participants fitted with transfermoral bone-anchored and socket-suspended prostheses.[3]

	•		suspended pro	tted with socket- osthesis (n 6) [3]
	Prosthetic	Contra-lateral	Prosthetic	Contra-lateral
Medio-lateral margin of stability (cm)	4.71 (1.52)	1.31 (0.97)	3.25 (0.88)	2.2 (0.92)
Stance duration (% of stride)	59.9 (5)	69.3 (3)	58.5 (2.9)	67.5 (1.5)
Double support duration (% of stride)	15.2 (3)	14.1 (4)	13.4 (2.6)	12.8 (1.3)
Stride width (cm)	14.18 (3.17)		14.7 (4.8)	
Walking speed (dimensionless)	0.375	5 (0.07)	0	0.40

characteristics were comparable (e.g., stride width and stance duration) or greater (e.g., duration of double support) for the osseointegrated group compared to the socket group.

The difference in margin of stability between the two groups might be confounded by study designs. The socket group walked on a treadmill while the osseointegrated group walked overground. The length of residuum or the prosthetic knee may also have an impact on the results although no effect was found within our study.

# **DISCUSSION AND CONCLUSION**

This study seems to indicate that individuals fitted with transfemoral bone-anchored prosthesis walked with larger margins of stability at least on prosthetic side potentially due to longer double support. However, stronger evidence is required to confirm these results.

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# **ACKNOWLEDGEMENTS**

Hubert Curien Partnership (French Ministry of Foreign Affairs), PHC FASIC # 39370PM.



# The Utility of Open Source Copyleft Software for Evaluating Lumbar Lordosis in the Transfemoral Prosthesis Wearers

<u>Jutima Rattanakoch</u>, Sawitree Srithamboon, Gary Guerra, Nova Cecilia, Charitha Prashad, Thanaphat Handechanon, Nurhaswanee Kolum, Junjira Pomsupa Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Siriraj Hospital, Bangkok, Thailand

## **BACKGROUND**

The reduced function of altered hamstring musculature results in an inability to control the pelvis, resulting in possible lumbar lordosis (LL) and lower back pain. This is evident by an increase in lumbar spine extension of transfemoral amputees as compared to able-bodied persons during walking.[1] Furthermore, Goujon-Pillet et al. discovered a greater degree of frontal and sagittal pelvic range of motion in transfemoral participants compared to able-bodied persons.

# **AIM**

There is little scholarship investigating pelvic motion, more specifically LL in transfemoral amputees. Insight into the effect common knee joints and sloped surfaces have on altering LL become an interesting phenomenon which we sought to objectively explore.

#### METHOD

Three male unilateral TF amputees ages 27, 44 and 51 participated in this study. Two-dimensional motion analysis while walking was performed for each participant while they walked on a treadmill using and high-speed digital camera and Kinovea software. As LL was the measure of interest, a single experienced investigator identified the spinous processes of L1, L3, L5, and S1 and adhered 75mm long rigid markers to these respective locations. All participants performed treadmill walking at a set speed of 0.36m/s and at treadmill grade 0°, 3° and 5°. Participants performed the same walking protocol after being fit with the alternative study knee.

## **RESULTS**

Participant data illustrating the effect of altered socket flexion on a degree of static lumbar lordosis, max lumbar lordosis at the terminal stance, and max pelvic forward tilt at terminal stance are presented in Table 1. Lumbar lordosis was induced by all treadmill grades in every participant wearing either of the knee units. A linear relationship between LL and increases in treadmill grade was observed for both knee units, with reduced LL observed in the 3R60 knee. Step length and cadence was altered but to a small degree. Participant two and three showed noticeable increases in step lengths as socket flexion was altered (Table 2 and 3).

Knee Flexion		Lur	Static nbar Lord	dosis	Terminal Stance Maximal Lumbar Lordosis			Terminal Stance Maximal Pelvic Forward Tilt		
		P1	P2	P3	P1	P2	P3	P1	P2	P3
3R60	Optimal	52.46	44.26	52.46	46.77	42.71	71.56	20.81	12.26	18.24
	-3°	44.71	47.29	58.07	44.73	43.17	72.93	20.23	12.50	18.47
	-6°	38.82	42.51	57.41	46.22	44.39	74.32	21.72	12.59	19.29
3R20	Optimal	37.34	45.38	68.87	47.55	52.96	68.72	18.24	14.17	16.30
	-3°	46.61	57.08	55.7	40.89	55.21	70.05	18.13	16.83	17.07
	-6°	47.78	49	55.73	42.14	55.64	71.65	18.40	18.07	17.54

**Table 1.** Average lumbar lordosis and pelvic tilt in three participants wearing two knee units at various magnitudes of socket flexion in static and terminal stance of treadmill walking. \*\*(P1-P3): Participants

Flexion	P	1		P2		P3
	3R60	3R20	3R60	3R20	3R60	3R20
Optimal	127 (2)	131(1)	51 (4)	58 (7)	69 (12)	68 (11)
-3°	124(1)	132 (6)	54 (6)	63 (17)	70 (13)	73 (16)
-6°	130(2)	133 (1)	54 (7)	64 (18)	71 (14)	71 (16)

Table 2. Step length averages in (cm) during treadmill walking for participants with two knee units at various magnitudes of socket flexion while wearing 3R60 and 3R20 knee units.

\*(P1-P3): Participants

Flexion	F	P1		2	P3	
	3R60	3R20	3R60	3R20	3R60	3R20
Optimal	88 (0)	84(1)	95 (0)	99 (1)	89 (0)	87 (3)
-3°	86 (2)	86 (1)	100(0)	96(1)	89 (2)	89 (0)
-6°	85 (0)	86 (0)	101(1)	97(0)	87 (2)	91(1)

Table 3. Average cadence (step/min) during treadmill walking for participants with two knee units at various magnitudes of socket flexion while wearing 3R60 and 3R20 knee units.

\*(P1-P3): Participants

# **DISCUSSION AND CONCLUSION**

Open source methods might have potential utility as an affordable tool for estimation and determination of LL in TF amputees. As the knee joint plays a critical role on the real world gait and energetics of the TF amputee, it is crucial to have an affordable and meaningful method to aide them in knee unit selection. Our report is one example of how the Kinovea software combined with the proper equipment and parameter of interest can provide clinical outcome metrics.

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# **ACKNOWLEDGEMENTS**

We also would like to thanks to all participants who were contributed a lot to this study.



# Effects of Walking Speeds on Loading Rate in Unilateral Transfemoral Amputees

Ryo Amma<sup>1,2</sup>, Hiroyuki Sakata<sup>1,2</sup>, Genki Hisano<sup>2,3</sup>, Satoru Hashizume<sup>2</sup>, Fumio Usui<sup>4</sup>, Hiroshi Takemura<sup>1</sup>, Hiroaki Hobara<sup>2</sup>

<sup>1</sup>Tokyo University of Science, Chiba, Japan. <sup>2</sup> National Institute of Advanced Industrial Science and Technology (AIST), Tokyo, Japan. <sup>3</sup>Tokyo Institute of Technology, Tokyo, Japan. <sup>4</sup>Tetsudo Kosaikai Foundation, Tokyo, Japan

# **BACKGROUND**

Unilateral transfemoral amputees are generally suffering from chronic pain, such as stump ulcer,[1] knee osteoarthritis,[2] and back pain [3] as a consequence of abnormal gait strategy. These injuries are mainly be attributed to the load accumulation during stance phase.[1,2,4]. Despite the fact that the loading rate is one of the indicators to estimate these chronic pains, little is known about the loading rate of the affected and unaffected limb in unilateral transfemoral amputees at various walking speeds.

## AIM

To evaluate loading rate in unilateral transfemoral amputees across a range of walking speeds.

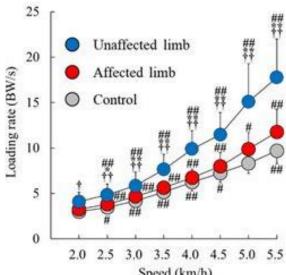
#### METHOD

Ten individuals with unilateral transferoral amputation and 10 non-amputees walked on a split-belt force-instrumented treadmill at 8 walking speeds (2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, and 5.5 km/h). Loading rate was

defined as the magnitude of the first peak of vertical ground reaction force divided by the time between heel strike and the first peak. A two-way ANOVA (speed x limb) with Bonferroni correction assessed statistical significance.

# **RESULTS**

Figure 1 shows the loading rate of all limbs at each walking speed. There was a significant speed by limb interaction effect on the loading rate (p < 0.01). Loading rate of the unaffected limb increased by 334% between 2.0 and 5.5 km/h, while loading rate of the affected and control limb increased by 262% and 222%, respectively. Loading rate of the unaffected limb was significantly greater than the affected (2.5-5.5 km/h, p < 0.05) and control limb (2.0-5.5 km/h, p < 0.05). There was no significant difference in the loading rate between the affected and the control limb.



# **DISCUSSION AND CONCLUSION**

A previous study also reported that the loading rate of the unaffected limb for unilateral transfemoral amputees and control limb increased with increasing walking speeds, but there was no significant interaction.[2] The discrepancy might be due to that our tested walking speeds (2.0-5.5 km/h) was wider than those of previous study (3.4-5.2 km/h). Our results suggest that the unaffected limb may be exposed to a higher risk for secondary conditions than other limbs in a wide range of walking speeds.

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# Kinematic Analysis of Transfemoral Prostheses with Northwestern University Flexible Subschial Vacuum Socket and other sockets

Ryoichiro Hayashi, Toshiya Nosaka, Yuuji Tanaka, Takeshi Tsuruga Hokkaido University of Science, sapporo, Japan

# **BACKGROUND**

In recent years, a socket such as the Northwestern University Flexible Subschial Vacuum Socket (NU - FlexSIV Socket) was developed as a femoral prosthesis socket. However, in Japan, subjective evaluation is many and objective evaluation is poor at present.

#### AIM

In this research, we aim to clarify the features of NU - FlexSIV Socket by objective comparison of NU - FlexSIV Socket and other sockets.

# **METHOD**

In this study, walking measurement using VICON and static measurement of the joint by ROM test were performed. The socket used for measurement is NU - FlexSIV Socket, quadrilateral socket, IRC socket and MAS socket. In walking measurement, hip joint angles (flexion, extension, abduction, adduction) and trunk side flexion angle in a single walking cycle were measured. In the static ROM test, the hip joint angle (flexion, extension, abduction, adduction) was measured when wearing each socket and without wearing them.

## **RESULTS**

In this measurement, the hip joint angle of a single walking cycle resulted in similar to each socket. In the ROM test, the quadrilateral socket had the smallest range of motion. NU - FlexSIV Socket resulted in the largest ROM, followed by MAS socket, IRC socket and Quadrilateral socket.

# **DISCUSSION AND CONCLUSION**

It is suggested that NU - FlexSIV Socket is able to acquire a wide ROM because its upper edge is lower than other sockets. In the gait analysis, we obtained data of joint angles similar to each sockets. However, in this study we measured only walking on a flat ground, but in the future it is necessary to measure gait in other conditions, such as slopes and stairs.



# Shape Measurement of Transfemoral Residual Limb on Standing Magnetic Resonance Imaging: A Preliminary Study with a Single Subject

<u>Takayuki Maruyama</u><sup>1</sup>, Takashi Nakamura<sup>2</sup>, Atsuko Mitsumoto<sup>2</sup>, Masato Maeno<sup>3</sup>, Tosiaki Miyati<sup>4</sup>, Naoki Ohno<sup>4</sup>, Yoshiko Tobimatsu<sup>2</sup>

<sup>1</sup>College, National Rehabilitation Center for Persons with Disabilities, Tokorozawa, Japan. <sup>2</sup>Research Institute, National Rehabilitation Center for Persons with disabilities, Tokorozawa, Japan. <sup>3</sup>Hospital, Rehabilitation Center for Persons with Disabilities, Tokorozawa, Japan. <sup>4</sup>Kanazawa University, Kanazawa, Japan

# **BACKGROUND**

The shape of a prosthetic socket is determined empirically. Conventional methods including shape measurement by magnetic resonance imaging (MRI) and finite element modeling have been used to establish a quantitative determination method of socket shape.[1,2] However, on supine MRI, the transfemoral residual limb appears deformed since it is difficult to apply the same load as in the standing position in the socket donning state.

## AIM

Here, we aimed to clarify the difference in the residual limb shape obtained by standing versus conventional supine MRI during donning and doffing of the transfemoral prosthetic socket.

# **METHOD**

The subject was one unilateral transfemoral amputee without residual limb complaints. For the standing and supine positions, 0.4-T multiposture MRI (Hitachi Healthcare) and conventional MRI (3T; Siemens) of an ischial ramus containment socket were used, respectively. On supine MRI, the socket was suspended by a belt to simulate the standing load. On standing MRI, a plastic pylon was attached to simulate weight-bearing. From each obtained MRI image, a cross-sectional image was constructed at equal intervals along the longitudinal thigh axis and used to calculate and compare the circumference, length, and tissue thicknesses to those of the residual limb.

# **RESULTS**

The doffing circumference was smaller in the supine position, while the donning circumference was smaller in the standing position. In the standing position, the stump length was the same during donning and doffing. However, in the supine position, it was shorter during doffing and longer during donning. The soft-tissue thickness during donning was increased in the supine position compared to that in the standing position, especially on the posterior side (from the posterolateral side to the posteromedial side), but was decreased on the anterior side. This tendency was particularly pronounced in the muscle tissue. During doffing, artefacts due to involuntary movements were observed in the standing position.

# **DISCUSSION AND CONCLUSION**

In conventional MRI measurements, due to tissue deformation in the supine position, the shape of the residual limb differed from that in the standing position. Using standing MRI, it was possible to measure the shape of the residual limb that is closer to the actual use condition.

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# **ACKNOWLEDGEMENTS**

This work was supported by JSPS KAKENHI Grant Number JP2635069.



# Effect of Hip Joint Center Estimation Method on Pistoning in an Above-Knee Amputated Subject

Julien Leboucher, Firooz Salami, Daniel Heitzmann, Sebastian Wolf, <u>Merkur Alimusaj</u> University of Heidelberg, Department of Orthopedic Surgery, Motion Analysis Laboratory, Heidelberg, Germany

#### **BACKGROUND**

True motion recording of the femur and the residual limb in transfemoral amputees (TFAs) is a challenging task and only few research groups focused on that topic.[1,2] Because of this issue, researchers rely on conventional motion analysis using skin markers to measure TFA patients' gait and consequently have to rely on biomechanical models, e.g. hip and knee joint center (HJC and KJC) estimation, and to suffer from soft tissue artifacts (STA).

## AIM

The goal of this preliminary study was to shed light on the influence on pistoning of STA and joint center estimation.

# **METHOD**

Pistoning was investigated by measuring the variation of the HJC-KJC distance. The HJCs considered were computed using Bell *et al.* [3], Harrington *et al.* [4] single regression, and Hunt *et al.* [5] methods. The KJC was defined as the midpoint between femoral epicondyle markers and on the knee hinge of the prosthesis. Pistoning was also computed on the non-involved side to evaluate STA and indirectly assess the accuracy of joint centers. One patient was investigated (female, 53 years old, 55 kg, 1.65m) while performing 36 steps. Kinematic data were collected using a Vicon 12 cameras system and processed using custom code on Matlab R2010a.

## **RESULTS**

Pistoning for the three HJC models investigated are presented on Figure 1 with solid lines representing the amputated side. Foot off instants for both sides are represented accordingly by vertical bars. From this graph, it can be seen that the distance between joint centres shows similar amplitude for both sides with a noticeable larger range for Bell's method.[3] This former method would suggest an elongation of the thigh segment for almost all of the stance phase followed by a steep shortening in the swing phase. The two other methods [4,5] show a decrease in pseudo-segment length until mid-stance

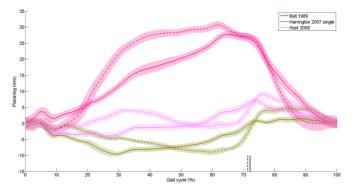


Figure 1. Pistoning (±1SD) measured in the amputated (solid lines) and the non-amputated side (dashed lines). Foot off instants are shown as vertical bars accordingly.

followed by a lengthening until foot off. Measurement using Harrington's method [4] also yields almost no pistoning during the swing phase.

# **DISCUSSION AND CONCLUSION**

The methods considered here to estimate the HJC location yielded qualitatively different results. About Bell's method [3], the amplitude of pistoning on both sides suggests that not only STA is involved but also HJC determination. On the contrary, the other methods [4,5] showed a rather similar pattern with a change at midstance also reported by Tang *et al.* [6] This study should be performed in addition with a gold standard for the location of joint centres to discriminate between methods.

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# **ACKNOWLEDGEMENTS**

This study is supported by the German Research Foundation (grant WO-1624/5-1).



# Innovative Prosthetic Socket System for Improving Adaptive Socket Behavior for Knee-Disarticulated Users

Tim Baumeister<sup>1</sup>, Olaf Gawron<sup>2</sup>, Michael Schäfer<sup>1</sup>
<sup>1</sup>Pohlig GmbH, Traunstein, Germany. <sup>2</sup>Pohlig GmbH, Heidelberg, Germany

# **BACKGROUND**

Users with disarticulation in the knee joint represent a rather small group compared to transtibial and transfemural amputated users. The focus is on the biomechanical components of the complete end bearing, the extremely long lever and the good muscular situation of the stump. The functionally good conditions take their toll in the cosmetic design, due to the resulting dysbalance when using microprocessor-controlled knee joints.

#### AIM

The aim of the presented socket system is a maximum adaptation to different everyday situations with consideration of the muscular actuators. Thanks to the carbon-silicone chuck technology with partially elastic quide zones made of silicone.

# **METHOD**

The basis is an individual liner interface. The ability to influence individual liners in terms of strength, texture and functionality offers tremendous benefits. The supporting parts of the final epoxy frame are reduced to a minimum in this system. To keep the weight down, sandwich materials are used. The realization of the adaptive socket zones is done by an individual HTV-Silkon-Inlay technology which is fixed connected to the carbon frame. The adhesive principle is realized by a seal between the proximal liner portion and the HTV socket. The distal valve creates a cushion system without further sealing aids such an additional sealing lip or sleeve.

# **RESULTS**

The treatment of users with knee disarticulation requires a differentiated approach, which differs significantly from the - often used for comparison - care of amputees. The problems in fitting, less affect load-force transmission in the prosthesis socket. Rather, one works at the knee disarticulation at several limits: limited heights limiting cosmetic designs, limited shifts of the socket, etc. In order to ask the supply cosmetic everything, every millimeter thickness, length, width and thickness must be roofed and justified.

# **DISCUSSION AND CONCLUSION**

Functionally speaking, the knee disarticulation stump is much better than any transfemural amputation. Hardly any user of transfemural prosthetic can move with that less compensation mechanisms as a knee-disarticulated user. Adaptive socket systems are not a luxury, but the result of the best possible adaptation to the various everyday situations. They serve and thus promote immediate disability compensation. Sitting, feeling, feedback - Exteroception and interoception give the users a clear plus in everyday life with prosthesis.

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# This Osseo Life - Bilateral Transfemoral Amputee Case Study

Marta Geada

APC Prosthetics, Sydney, Australia

#### **BACKGROUND**

We present a case study of a young Australian who suffer a motor vehicle accident and as a result, underwent bilateral above knee amputations and sustained left arm paralysis.

#### AIM

The aim of this case study is to share the journey of this patient and show the pathway followed to improve his mobility, independence and quality of life.

# **METHOD**

A 26-year-old patient who was wheelchair bound for the last 2 years had osseointegration. Initially unilaterally, he managed with one socket and one osseointegration. We fitted the patient with a knee disarticulation socket on the left and osseointegration connection on the right side. After 5 months the patient chose to have osseointegration on the contralateral side. We used the patient's existing knee units and feet. He was able to rehabilitate his general fitness condition, walk with a standing frame and progress to a higher level of independence.

# **RESULTS**

The result of this procedure and the rehabilitation programme was a significant increase in mobility, independence and quality of life.

# **DISCUSSION AND CONCLUSION**

Would be interesting to continue to look at this group of patients and collect some data to identify the benefits on a bigger scale.

This particular case is only one where osseointegration can make a difference when a 'socket prosthesis' is a challenging option. Osseointegration might not be appropriate for every amputee but it can be a limitless option for a specific group of patients.

# **ACKNOWLEDGEMENTS**

Thank you to my team who makes this work and transformation possible.



# Free Paper – Poster Presentation Prosthetics: Lower Limb Transtibial

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# Comparative Study of 3D Printed TSB and Manually Fabricated PTB Socket Designs

Nizar Akhtar<sup>1,2</sup>, Nimra Saqib<sup>1</sup>

<sup>1</sup>Pakistan Institute of Prosthetics and Orthotics, Peshawar, Pakistan. <sup>2</sup>Department of Mechatronics University of Engineering and Technology, Peshawar, Pakistan

# **BACKGROUND**

Comfort is the determinant of distribution of interface forces between socket and stump of a below knee amputee. One of the essential reasons behind discomfort of trans-tibial socket is improper socket fit; mostly as a result of manual fabrication. Although PTB socket has shown satisfactory results for trans-tibial amputees, it also needs a lot of labor in conjunction with high skills from prosthetist. 3D printed TSB socket is an appropriate option to enhance comfort of trans-tibial amputees.

# **AIM**

To compare the comfort PTB and 3D printed TSB socket designs.

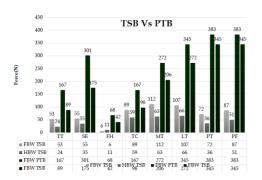
To determine the cost effectiveness of both socket designs.

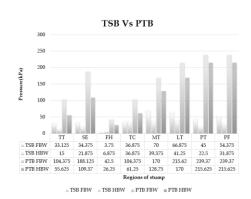
## **METHOD**

This study has been conducted in Pakistan Institute of Prosthetic and Orthotic Sciences (PIPOS), and Department of Mechatronics Engineering UET, Peshawar. A unilateral trans-tibial amputee of 21-year-old male having right side transtibial amputation was selected. The data was collected at Biomechanics Gait Lab through L.A.S.A.R Otto Bock Posture Alignment Apparatus, with both full body weight and half body weight through the Force Resistive Sensors (FSR). The data from FSR sensors were serial monitor through Hardware Arduino mega 2560. The material used for fabrication of 3D socket was PLA (Polylactic acid) filament, with 1.75 mm thickness, while for the manually fabricated socket were POP bandages, POP powder, EVA (9mm) and Polypropylene (5mm).

# **RESULTS**

The forces between stump and inliner with full body weight and half body weight of pressure sensitive areas and pressure tolerant areas of TSB socket and PTB socket were taken experimentally. All these measurements show that more forces and interface stresses acted on PTB





socket as compared to TSB socket. This also indicate that patient feel more comfort in TSB socket as compared to PTB socket.

# **DISCUSSION AND CONCLUSION**

This study used the philosophy of reverse engineering that assist a prosthetist to fabricate a good quality socket and measure the static values of interface forces in PTB and TSB sockets. Stephan found that PTB socket has greater comfort level than HCTSB socket. Our study supports the statements of Ryan Schmidt et.al who suggested that 3D-printed sockets were more comfortable in terms of distribution of interface forces and less expensive than manually fabricated PTB design.

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# **ACKNOWLEDGEMENTS**

The authors appreciate PIPOS and Department of Mechatronics, Peshawar for provision of software and 3D printer as rapid prototyping machine.



# Preliminary Effects of the Xtend Foot on Walking Patterns in Amputees Compared to their Regular Prosthetic Foot

Roland Zugner, Henrik Malchau, Maziar Mohaddes, Roy Tranberg
Department of Orthopaedics, Institute of Clinical Sciences Sahlgrenska Academy University of Gothenburg, Sahlgrenska University Hospital, Gothenburg, Sweden

## **BACKGROUND**

There is a projected increase in number of amputees in the United States. During the next three decades there will be a two-fold increase in number with limb amputation secondary to a vascular disease. According to the Swedish registrar (SwedAmp) there are about 3000 amputations every year in Sweden in lower extremities and 80 % is due to diabetes or vascular disease. Rates of prosthesis use in patients with lower limb amputation vary from 49% to 95%.

#### ΔIM

The purpose of the study was to compare the walking ability in amputees supplied with Xtend Foot compared to a regular foot prostheses.

## **METHOD**

Three trans-tibial and three trans-femoral amputated patients were included. Patients were asked to walk both with their current prosthesis and the new Xtend Foot. Primary outcomes were kinematics in trunk and arms and lower extremities together with kinetics in lower extremities. Secondary outcomes were balance, 6 minute walk, Time up and go (TUG) and PROM (Plus-M).

## **RESULTS**

Preliminary results from our pilot study showed that patients walking with the Xtend Foot used fewer steps in 10 meters walking distance, 15 vs 16 steps. They also walked a longer distance during "6 minutes walking test", 412 vs 377 meters. Furthermore, the patients also performed faster Tug-test, 10.4 vs 11.1 seconds.

Patients personal reflections Walking with the Xtend Foot patients personal reflections such as "possible to walk faster and with more energy, better balance, movement and joint load" has to verified in future randomized studies patient reported outcome mensurers (Plus-M).

# **DISCUSSION AND CONCLUSION**

In this small series the Xtend Foot improved walking ability in patients with trans-tibial and trans-femoral amputees together with patients reflexions. Larger randomized studies including patient reported outcome mensurers are needed to validate our findings in further studies.

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# Target of Physiological Gait: Realization of Speed Adaptive Control for a Prosthetic Knee during Swing Flexion

# Yu Hongliu

University of Shanghai for Science and Technology, Shanghai, China

#### **BACKGROUND**

Prosthetic knee is the most important component of lower limb prosthesis. Speed adaptive for prosthetic knee during swing flexion is the key method to realize physiological gait.

#### AIM

This study aims to discuss the target of physiological gait, propose a speed adaptive control method during swing flexion and research the damping adjustment law of intelligent hydraulic prosthetic knee.

#### **METHOD**

According to the physiological gait trials of healthy people, the control target during swing flexion is defined. A new prosthetic knee with fuzzy logical control during swing flexion is designed to realize the damping adjustment automatically. The function simulation and evaluation system of intelligent knee prosthesis is provided. Speed adaptive control test of the intelligent prosthetic knee in different velocities are researched.

## **RESULTS**

The maximum swing flexion of the knee angle is set between sixty degree and seventy degree as the target of physiological gait. Preliminary experimental results demonstrate that the prosthetic knee with fuzzy logical control is able to realize physiological gait under different speeds. The faster the walking, the bigger the valve closure percentage of the hydraulic prosthetic knee.

# **DISCUSSION AND CONCLUSION**

The proposed fuzzy logical control strategy and intelligent hydraulic prosthetic knee are effective for the amputee to achieve physiological gait.

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## **ACKNOWLEDGEMENTS**

The work reported in this paper is supported by National Natural Science Foundation of China, number: 61473193.



# Design and Mechanical Verification by FEA of a Pylon Prototype for Lower Limb Prosthesis Applications, Fabricated by Additive Manufactured Composites

Ignacio López-Gómez<sup>1</sup>, Miguel Araya-Calvo<sup>2,1</sup>, Nicolette Chamberlain-Simon<sup>3</sup>, Jose-Luis León-Salazar<sup>4</sup>, Teodolito Guillén-Giron<sup>4</sup>, Bruno Chiné<sup>4</sup>, Maria-Jose Rojas-Ugalde<sup>1</sup>, Olga Sánchez-Brenes<sup>1</sup>

<sup>1</sup>Instituto Tecnológico de Costa Rica, Laboratorio de Ergonomía Aplicada, Cartago, Costa Rica. <sup>2</sup>Instituto Tecnológico de Costa Rica, Escuela de Ingeniería en Diseño Industrial, Cartago, Costa Rica. <sup>3</sup>Rice University, Wagoner Fellowship, Center for Civic Leadership, Houston, USA. <sup>4</sup>Instituto Tecnológico de Costa Rica, Escuela de Ciencia e Ingeniería de los Materiales, Cartago, Costa Rica

# **BACKGROUND**

Additive manufacturing (AM) technologies have allowed the fabrication of personalized designs, mainly for prototyping. However, carbon fiber reinforced polymer parts fabricated by AM technologies allow the fabrication of composite parts with the required strength for end-use parts.

## AIM

The aim of this study is the development of a 3D printed prosthetic pylon, and the FEA evaluation of its mechanical performance under critical loads produced by the gait cycle.

# **METHOD**

A FEA model was developed in order to evaluate the structural performance of a prosthetic pylon prototype, following ISO 10328-2016 standard. A design methodology was used to develop an additive manufactured prosthetic pylon. Compressive and flexural mechanical properties of a 3D printed carbon fiber reinforced material have been determined in a previous study to establish the elastic constants for the FEA model. Different CAD prototypes were studied under gait cycle loads, in order to select the prototype with the best performance. The simulation considered critical loads of the gait cycle, specifically at the heel strike (4130 N) and toe off (3623 N) walking phases according to P4 level of standard.

# **RESULTS**

The FEA study showed that the joining mechanism of nut attachments has a higher risk of failure than the plate mechanism, because stress concentrations on the nut system are higher than the yield stress of the material. The final prototype evaluated under heel strike and toe off walking phases has lower maximum stress than the proportional limit of the material.

## **DISCUSSION AND CONCLUSION**

Structural FEA of the pylon prototype demonstrated that the design has the potential to resists loads of K3 level (80 kg) patients under the most critical loads of the walking cycle.

# **REFERENCES**

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# **ACKNOWLEDGEMENTS**

The authors would like to acknowledge the support from the Research and Extension Vice-rectory of Costa Rica Institute of Technology.



# A Case Study of Child with unilateral Congenital Lower Limb Deformity

Ayman Amer<sup>1</sup>, Rana El-Helaly<sup>2</sup>

<sup>1</sup>National institute of Neuro-motor System, Giza-Cairo, Egypt. <sup>2</sup>Ain Shams university, Giza-Cairo, Egypt

#### **BACKGROUND**

Congenital deformities in children are seen more often these days in Egypt. The challenge we usually face is how we can provide these children with a device that will help them practice a normal healthy upbringing without having to resort to surgery. Especially the parents refuse this type of surgery.

#### ΔIM

The aim of this study is to create prosthesis for an 8year old child with right lower limb congenital deformities to enable him to walk and Performance of proper functioning prosthesis for right lower limbs, to improve the gait pattern.

# **METHOD**

the foot behind end of tibia, fibula. diameter of middle part it was larger around middle tibia fibula. Manufacturing: techniques necessary for a total contact socket .soft socket was performed on the previous cast taken using polyform, taking the distorted shape of stump internally, with a minor attempt for correction shape of stump, conical shape on outside (soft socket its first layer 2 mm, Extra Poron was placed on the outer surface to fill any irregularities.second layer 4mm polyform). Hard socket, soft sockets, reaching patella, use PT bearing. In finally will catting hard socket from behind like U shape. Put strap from behind.soft socket cut from behind like I shape.

## **RESULTS**

The 8 year old boy was at first able to stand unsupported using a prosthesis, but now efficient gait pattern without crutches with the new modified prosthesis, with controlled knee motion eliminating the genu valgus. he is now after using prosthesis for two months is able to walk freely unsupported.

# **DISCUSSION AND CONCLUSION**

Our challenge. The diameter increase around calcaneus, end tibia, fibula and contact them from behind, made it difficult to be able to our normal hard socket inside, so came the idea of using principle of a soft total contact socket first that will closely take the shape of limp. The casting method and performance of a total contact correcting hard and soft socket helped improve the stump distortion.

Conclusion: no rules for different patients, each patient should be taken individually.



# The Effect of Wii Fit Board Games Training for Transtibial Amputees Balance Ability

Chen Hsin-Yu, Chang Chih-Kang

Rehabilitation and Technical Aid Center/Taipei Veterans General Hospital, Taipei, Taiwan

## **BACKGROUND**

It's an important issue that how to prevent falls and improve position stability on amputees. Balance improvement, one of the goals of amputee rehabilitation, can make a normal gait pattern. It has been shown that balance ability could be improved by using Wii Fit balance board games training. However, research by using Wii Fit balance board game training intervention is still rare for prosthetic users.

#### AIM

The purpose of this study was to describe the effects of a balance training program utilizing the Nintendo Wii Fit balance board and fear of falling for transtibil amputees.

## **METHOD**

We assessed center of pressure (COP) parameters in 2 patients with unilateral trans-tibial amputees. Participant A, a 65 year-old female 20 years post transtibial amputation, reported fear of falling and restrictions in community activity. Participant B, a 23 year-old male 5 years post traumatic transtibial amputation, reported limited energy and balance deficits during advanced gait activities. Participants receive Nintendo Wii Fit balance board gaming for 4-weeks, 3 sessions per week.

# **RESULTS**

Measures included center of pressure (COP) parameters, ABC Scale, and Berg Balance Scale. participants demonstrated improvement in dynamic balance, balance confidence, economy of movement. Participant A reduced the need for an assistive device during community ambulation. Participant B improved his ability during ambulation.





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d)	Participant A		Participant B-			
P	Before	After	Before-	After-		
Balance index-	4.1±1.3=	3.2±0.90	1.8±0.5=	0.9±0.2-		
Balance index(A-P)	3.2±2.1=	2.5±1.6	1.4±0.6-	0.8±0.2=		
Balance index(M-L)	2.7±1.8-	2.2±1.1≠	1.2±0.5₽	0.5±0.1		

# **DISCUSSION AND CONCLUSION**

This case study illustrated that the use of Nintendo Wii Fit training was effective intervention to achieve functional goals for improving balance confidence, reducing use of assistive devices when ambulating with a transtibial prosthesis. This is helpful in choosing treatment options and managing the unilateral trans-tibial amputees particularly when using Nintendo Wii Fit training.

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# **ACKNOWLEDGEMENTS**

Funding was provided from Taipei Veterans General Hospital Research. We would like to thank the subjects for their voluntary participation.



# Variation of Ground Reaction Force Measurements Across different Prosthesis-integrated Load Cells

Krista Kutina, <u>Goeran Fiedler</u> University of Pittsburgh, Pittsburgh, USA

## **BACKGROUND**

With miniaturized electronic components becoming more readily available, their integration into artificial limbs has become increasingly common. Load cells can help clinicians and researchers obtain a comprehensive picture of the effects of prosthetic alignment changes and other interventions.[1, 2] In recent years, a number of dedicated load cells for such purposes has been developed and marketed, making it conceivable that their data is interpreted equivalently across devices.

## AIM

The aim of this study was to quantify any differences in force data put out concurrently by two different commercially available prosthesis-integrated load cells.

# **METHOD**

Two load-cells for integration into lower limb prostheses (ipecs, RTC electronics, Dexter, MI,[3] and Europa, Orthocare Innovations, Tahoma, WA [4]) were installed into the same knee-bent prosthesis simulator (Figure 1, left). Both streamed force data at 100 Hz during a 10-meter walk test, including a sharp turn. In post-processing, the collected vertical ground reaction force data was time-synchronized by aligning the first peaks of both plots with each other. A bivariate correlation analysis was conducted across a sample of 1000 data points (i.e., 10

seconds of gait data). Likewise, root mean squared error (RMSE) was computed across the same sample.

# **RESULTS**

Visual inspection confirmed the generally good correlation between force data from both devices (Figure 1, right). The correlation efficient was 0.819 (p<0.001), and the RMSE was 164 N.

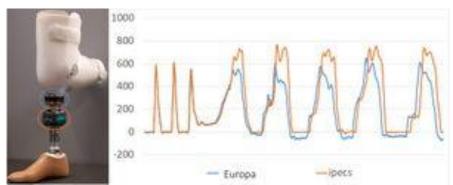


Figure 1: (Left) Data collection setup. Europa (proximal) and ipecs (distal) are part of the load bearing structure. (Right): Visualization of ground reaction force data

# DISCUSSION AND CONCLUSION

Our findings illustrate the inevitable differences in equipment when measuring the same variable, in this case vertical ground reaction force. Without a gold standard, it cannot be determined which of the devices was more accurate, but the deviation between two instruments that may commonly be assumed to deliver identical data was quantifiable. For a cursory gait assessment in the clinic, this deviation may be negligible. In research, limited external validity can be of greater consequence.

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# **ACKNOWLEDGEMENTS**

This work is supported by a University of Pittsburgh Innovation Challenge Grant and a PM&R Association Milbank Grant.



# Investigating Spatio-Temporal Gait Parameters and Ground Reaction Forces in Socket-Bearing and Osseointegrated Transtibial Prosthetic Users: A Case Comparison

Alexander Bek1, Mark Taylor1, Sally Cavenett2,3

<sup>1</sup>College of Science and Engineering, Flinders University, Adelaide, Australia. <sup>2</sup>College of Medicine and Public Health, Flinders University, Adelaide, Australia. <sup>3</sup>Southern Adelaide Local Health Network, SA Health, Adelaide, Australia

## **BACKGROUND**

Weight transfer for people utilizing a transtibial prosthesis is typically conducted with an external prosthetic socket. Recent advances in surgical technology include direct skeletal attachment of the prosthesis via an implant to the bone of the residuum, osseointegration. To date, there is little quantitative comparison between the two prosthetic mechanisms for people with transtibial amputation.[1]

# **AIM**

To investigate spatio-temporal gait characteristics and ground reaction forces (GRF) of two persons with transtibial amputation; one prosthetic socket user with specific surface bearing design utilizing silicon liner and distal pin suspension (SSB); and one with osseointegrated prosthetic fixation (OI).

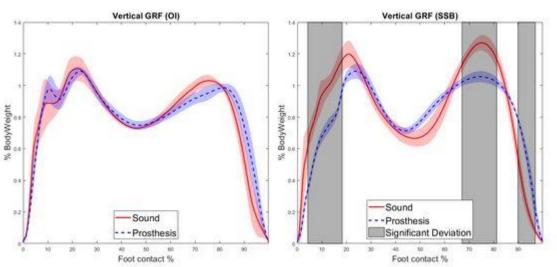
# **METHOD**

Two participants, matched for age and activity, were recruited in this prospective case comparison. Participants were instrumented with motion trackers using the Newington-Helen-Hayes model, with capture done by Vicon Nexus 2. GRF where captured using four AMTI OR67 force plates. Participants were instructed to perform 10 walking trials at self-selected pace. Data was exported and processed in MATLAB. Statistical Parametric Mapping (SPM) was used to determine significant differences between the sound limb and the prosthesis for each

participant.

# **RESULTS**

Both SSB and OI participants showed little asymmetry in spatio-temporal characteristics, with minor asymmetry in stance time in the OI subject (sound = 63.8%, prosthesis = 57.68%). OI



participant demonstrated greater symmetry in vertical ground reaction force (VGRF), with no statistically significant deviation, while SSB had three areas of significant deviation (p>0.001). The SSB participant had a higher VGRF2 (1.27 BW%) than VGRF1 (1.199 BW%).

# **DISCUSSION AND CONCLUSION**

Higher VGRF symmetry in the OI participant may indicate greater comfort in residuum loading over the SSB participant, resulting in unloading of sound limb. Although similar in age, the participants differed in prosthetic mobility experience with SSB utilizing a prosthesis for 60 years compared with OI participant having five years of prosthetic usage with an SSB prior to OI implantation. OI prosthetic usage was 20 months. Research to transtibial weight-bearing characteristics requires further investigation.

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# Developing a Framework for Automatic Prosthetic Socket Adjustment Control using FEAbased Tissue Damage Risk Estimation

<u>Florence Mbithi</u>, Andrew Chipperfield, Joshua Steer, Alexander Dickinson University of Southampton, Southampton, United Kingdom

# **BACKGROUND**

Ill-fitting lower limb prosthetic sockets can cause discomfort and pain. Internal stresses and strains generated in the residuum tissues under load, especially contiguous to bony prominences, can cause tissue injury when above threshold levels.[1] Current sockets designs still present unmet challenges that may affect comfort and extent of prosthesis usage. The conventional socket is far stiffer than the soft tissues, and commonly the fit cannot be adjusted automatically over time.[2]

# **AIM**

We present the development of an active prosthetic socket system applying predictive control to manage prosthetic interface loading, using finite element analysis (FEA) tissue damage risk estimates as cost functions.

#### METHOD

The concept (Fig. 1A-E) entails evaluation of expected internal tissue deformation within established damage risk thresholds,[3] under gait loading-(A). A 3D-FEA model of a transtibial residuum with a TSB socket [4] (B) was used to estimate deformation of soft tissues and corresponding interface stresses for several prosthetic loading cases.[5,6] A discrete-time predictive controller-(C) using a cost function performance index for minimising residuum tissue injury risk regulates actuation of translational spring-damper-based interface components located at three key residuum locations. The controller was optimised to meet design goals of no overshoot, fast rise-time and minimisation of overall actuation power. Output constraints were applied for maintaining prosthesis suspension during the swing phase.

# **RESULTS**

A full factorial FEA design study varying prosthetic liner stiffness across the three limb regions showed minimal cross-talk, therefore allowing for an independent control structure for the actuators. Throughout the stance phase, variations in interface pressure and compressive tissue strain estimates with load were observed to be consistent across the different applied loading cases. A linear relationship between interface pressure and tissue strain was observed at the posterior calf (R<sup>2</sup>> 0.9), whereas distal tibia and patellar tendon regions showed more complex

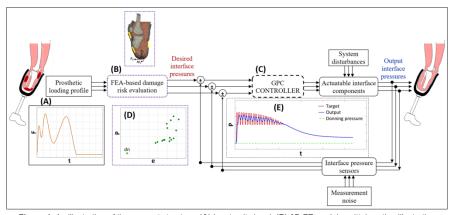


Figure 1. An illustration of the concept structure. (A) Input gait signal. (B) 3D FE model sagittal section illustrating loading configuration, boundary conditions and actuation locations. (C) Generalized predictive controller with feed-forward. (D) Interface pressure vs. tissue compression strain at patella tendon region. (E) Control output at posterior calf region. (F = GRF; t = time; P = interface pressure; "dn" = donned state prior to loading; e = tissue strain)

nonlinear relationships (D). Control output (E) achieved peak actuation rates of 5.6 and 5.0 kPas<sup>-1</sup> and amplitudes of 2.0 and 1.5 kPa at posterior calf and patella tendon regions respectively, and a distal tibia actuator rise-time of 12s.

# **DISCUSSION AND CONCLUSION**

Smoother and smaller interface actuations represented favourable control action for this application to minimise power-cost and potential discomfort. Limitations include use of several quasi-static loads cases rather than a full dynamic analysis, and a small set of training loading instances. The study demonstrates the architecture for an active prosthetic socket designed for minimizing tissue damage risk with predictive control for interface actuation, and the concept of utilizing FEA to provide biomechanical rationale for control targets.

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# **ACKNOWLEDGEMENTS**

Ethics: ERGO 29927, 41476. Funders: CSCUK (CA-16-28) and RAEng (RF130).



# **Outcome of Treatment Process Changes in Trans-Tibial Amputation**

<u>Jan Drakander</u>, Alen Cavka TeamOlmed Torsplan, Stockholm, Sweden

# **BACKGROUND**

The surgical methods for lower limb amputations above the ankle (LLA), the following postoperative treatment and the rehabilitation have not changed considerably over the years and there is no consensus on the best alternative. Irrespective of reason of the amputation, oedema is one of the major factors and diminishing it without risking an adequate perfusion is an act of balance. The high cost of hospitalization and often poor outcome requires new ideas and more efficient methods.

## AIM

To describe the settings and previous outcome of initial trans-tibial amputation (TT) at Capio St Görans Hospital (CStG) in Stockholm and to implement a new standardized method and evaluated the outcome.[1]

#### METHOD

Between January 1 and September 31, 2014, 26 consecutive patients, underwent initial unilateral LLA, because of peripheral vascular diseases (PVD) at CStG orthopedic department and enrolled into traditional treatment program. Changes in the treatment protocol where implemented during 2015, focusing on trans-tibial amputation's, consists of: surgery with sagittal flaps, -application of rigid dressing in the OR, -replaced a week later to compression treatment using silicone liners to diminish oedema and to shape and protect the residuum. The patients were thereafter fitted with definitive prosthesis. All prosthetic sockets were manufactured with direct lamination-technique (Direct-Socket™) to optimize the process. Bilateral amputations where excluded from this evaluation.

# N = 83 62 TT + 7 KD + 14 TF 62 TT 3 reamputations to TF 46 Prosthesis 16 No prosthesis

# **RESULTS**

In 2014, 26 initial amputations where performed. 10 where TT and 7 KD and 9 TF, 42% where men and the mean age was 83  $\,$ 

years. No data could be obtained regarding rate of prosthetic fitting. The follow up included an evaluation period of 32 months (2016-01-01, to 2017-08-31 and 2018). During that period, 83 initial LLA where performed, (62 TT, 7 KD and 14 TF), 65% men, mean age 81,5 years (fig1). Prosthetic fitting was obtained in 46 cases (74% of all TTA and 55% of all LLAs. Those who were fitted had a mean age of 77 years and 76% where men. The patients were fitted with definitive prosthesis after 39 days median (r = 22-180 days).

# **DISCUSSION AND CONCLUSION**

Introduction of a new strategy in treatment of amputees demonstrated improvements. TTs can be fitted with a prosthesis after a median time of 5 weeks. The outcome is highly related to the proportion of TTs to higher level amputations [2] specifically in elderly patients who have lost their anatomical knee joint.[3] Evaluation of a new strategy shows improvement in lowering the number of TF and KD amputations levels and increased number of prosthetic fitting.

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# Insight to Relevance of Ancillary Water-Activity Prosthesis for Individuals with Transtibial Amputation: Prospective Descriptive Study

Sally Cavenett<sup>1,2</sup>, Christopher J Barr<sup>3</sup>, Maayken E.L. van den Berg<sup>2,3</sup>
<sup>1</sup>Southern Adelaide Local Health Network, SA Health, Adelaide, Australia. <sup>2</sup>College of Medicine and Public Health, Flinders University, Adelaide, Australia. <sup>3</sup>College of Nursing and health Sciences, Flinders University, Adelaide, Australia

# **BACKGROUND**

In Australia there are 8000 lower limb amputations performed annually.[1] South Australian Government data (unpublished) indicates 1468 people with transtibial amputation (TTA) utilize a prosthesis, with 26% of those using a separate water-activity prosthesis (WAP). The WAP, prescribed for access to wet environments including bathrooms, rehabilitation and leisure activities, is designed to be worn without footwear. No studies have investigated the role of the WAP for people with TTA.

#### ΔIM

This study aimed to evaluate the experience and utilization of the water-activity prosthesis in people with unilateral TTA.

## **METHOD**

This exploratory descriptive study recruited participants with a unilateral TTA, who were able to walk independently with an everyday prosthesis and were utilising a water-activity prosthesis, from a South Australian prosthetic facility. To assess functional mobility level and use of the everyday prosthesis, participants completed the Modified Amputee Activity Questionnaire (MAAQ). An in-house developed WAP Survey relating to utility was completed to gain insight into participants' experience with the water-activity prosthesis, frequency, and purpose of use.

# **RESULTS**

Sixteen participants, 75% male, amputation aetiology 63% trauma, mean age 51.2±12, mobility level K3 or K4, were recruited and consented to take part in the study. Data from the MAAQ showed that the majority (62.5%) of the participants were their everyday leg between 11-14 hours a day. Eighty percent of the participants used the WAP at least twice a week, for shower, pool and beach and river activities. When asking participants how their life activities would change if they didn't have access to a WAP they revealed the following themes:

# Limiting independence

"I couldn't swim or shower", "It would make showering much more difficult", "It would limit activities during summer and would also limit showering", "It would be very different. I would not have the independence I have at present to have shower"

# Equal Rights and Quality of Life

"It would limit quality of life. I would be very unfair, I should have equal rights"

"Life would be more dependent on others; therefore, less independence and reduced quality of life"

# Access and Inclusion

"Showering would require a seat and modified shower. Travel would be affected, would need disabled accommodation", "It would be difficult to shower or go fishing", "It would limit my activities a lot. Being a parent of young boys we are weekly in a pool or beach environment"

# **DISCUSSION AND CONCLUSION**

Participants reported to use the WAP frequently, indoors as well as outdoors. This study supports the provision of a water specific prosthesis, as study participants reported that provision of a WAP was important in maintaining a higher quality of life.

# **REFERENCES**

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# Affordable EVA Roll-On (AERO) Liner for Low and Middle Income Countries: Case Study

<u>Yusuke Miyata</u>, Kazuhiko Sasaki, Gary Guerra, Jutima Rattanakoch, Sharmila Suntharalingam Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand

#### **BACKGROUND**

The prosthetic socket interface material is one of the most important factors associated with socket comfort and gait for the transtibial prosthesis wearer. It functions to provide shock absorption, distribute pressure and aid in suspension. Commonly used commercially available silicone, polyurethane and thermoplastic elastomer liners are costly for low and middle income countries. Therefore, we used a locally sourced EVA material for transtibial prosthesis user evaluation.

## AIM

The aim of this preliminary study was to compare and evaluate functional outcomes between AERO and a TPE liner in a suction suspended prosthesis user.

#### METHOD

Both 3mm and 6mm thick AERO liners with fabric outer were fabricated using conventional fabrication techniques. A 28 years old male K3 (MCFL level) transtibial prosthesis user was provided the liner as well as total surface bearing prosthesis with one-way expulsion valve and suction sleeve. In addition, he was provided an Otto Bock TPE liner for evaluation amongst liners. The patient performed a battery of outcome measures while wearing each liner in random order: 6-minute walk test (6MWT) at fast walking speed, Physiological cost index (PCI) with Polar heart rate monitor, and socket comfort score (SCS).

# **RESULTS**

Fast walking speed during 6MWT were 92.8m/min TPE liner, 89.1m/min for the 6mm and 85.3m/min for 3mm AERO liner (Fig1). The PCI during 6MWT was 0.56 for TPE liner, 0.74 for the 6mm liner and 0.64 for 3mm AERO liner (Fig 1). The Socket Comfort Scale (SCS) after 6MWT was10 points for TPE liner, 8.5 points for the AERO 6mm liner and 7.5 points for the AERO 3mm liner. Regarding the affordability for the AERO liner, an EVA sheet (2000mm x 1000mm x 3mm) was 200 Thai Baht (about 6 USD). It is estimated that an

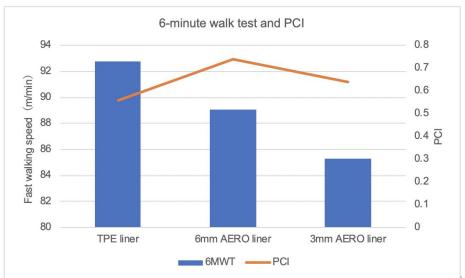


Figure 1. 6-minute walk test and Physical cost index

EVA sheet can fabricate at least 10 transtibial AERO liners.

# **DISCUSSION AND CONCLUSION**

The AERO 6mm liner provided effective shock absorption during walking according to feedback, yet effected walking speed and comfort. The AERO 3mm liner was less shock absorbent, but could still be reasonably considered for patients with good skin conditions at the residuum. Taking into consideration material costs and ease of fabrication, the AERO liner could be a reasonable alternative for use in low to middle income countries.

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# **ACKNOWLEDGEMENTS**

We'd like to extend our gratitude to our research participant, clinical and research help throughout the duration of this study.



# Assessment of Socket Pistoning and Prosthesis Satisfaction for the Magnetic-Lock Liner System

Youngkyu Chung, Jumsik Song, Shinki Kim, Yoonhee Chang, <u>Jongkwon Kim</u> Korea Orthopedics and Rehabilitation Engineering Center, Incheon, Republic of Korea

## **BACKGROUND**

The prosthetic suspension system is an important factor in determining the gait functionality and comfort of lower limb amputees. Excessive translation, rotation and vertical movements between residual limb and socket should be prevented through the suspension system.[1] We have developed a locking device of magnetic type to minimize movement between the socket and liner.

#### AIM

The purpose of this study was to compare the difference between magnetic- and pin-lock liner through analyse the characteristics of socket pistoning and prosthesis satisfaction.

# **METHOD**

3 male transtibial amputees(mean age  $57.7 \pm 11.6$  years, height  $170.1 \pm 7.0$  cm, body weight  $71.8 \pm 9.6$  kg) participated in this study and measured by 3D motion analysis system(Motion Analysis corp.) and treadmill. A transparent socket was used to measure the vertical movement of the inner liner and the reflective marker (RM) settings are as follows. RM 1(lateral side of the knee joint line) and RM2 (5 cm below the RM1) were attached

directly to the silicon liner, and RM3 (lateral proximal socket) and RM4 (lateral distal socket) were attached to the outer surface of the socket.[2] Subjective satisfaction was measured using the PEQ (Prosthesis Evaluation Questionnaire).

# **RESULTS**

At treadmill walking at 3km/h, vertical movement of proximal part of the magnetic-lock liner was 3.7mm, which was 95% less than that of pin-lock. Vertical and medio-lateral movements of the middle part of the magnetic-lock was 3mm and 5.6mm,respectively, which was 323% and 39% less than that of pin-lock. In the PEQ, the total score of the pin-lock and magnetic-lock liner was 75 and 93, respectively, and the

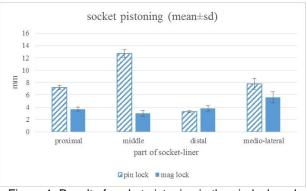


Figure 1. Result of socket pistoning in the pin-lock and magnetic-lock liner.

satisfaction of magnetic-lock was about 24% higher. Especially, it was found that the satisfaction of the magnetic-lock was very high in the items related to wearing on/off the prosthesis.

# **DISCUSSION AND CONCLUSION**

Our study is to verify the effect of the magnetic-lock liner system developed by KOREC through assessment of the socket pistoning and prosthesis satisfaction. In the magnetic-lock liner, it was confirmed that less pistoning of the vertical and medio-lateral movement of the proximal and middle part of the socket-liner, and a high prosthesis satisfaction. This will provide a clinical basic data for supply and improvement of the product.

# REFERENCES

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# **ACKNOWLEDGEMENTS**

This research was supported by the Bio & Medical Technology Development Program of the National Research Foundation (NRF-2017m3a9e2063255).



# A Coursework for Prosthetic Alignment using Socket Reaction Moment at Prosthetics and Orthotics Schools in Japan

Hiroshi Hashimoto<sup>1</sup>, Tomohiko Sasakawa<sup>2</sup>, Shigehiro Sakuma<sup>3</sup>, Shin Sasaki<sup>3</sup>
<sup>1</sup>Pacific supply Co.,Ltd., Osaka, Japan. <sup>2</sup>Kumamoto Collage of Medical Care & Rehabilitation,, Kumamoto, Japan. <sup>3</sup>Kobe College of Medical Welfare, Sanda Campus, Sanda, Japan

# **BACKGROUND**

Teaching prosthetic alignment at Prosthetics and Orthotics (P&O) schools is important. Though knowledge of biomechanics is necessary to understand prosthetic alignment, it is a difficult subject for many students. Socket reaction moment (SRM) is reported to be effective in evaluating prosthetic alignment by visualization [1], and may be beneficial for education at schools. However, there are no studies that show the effect of visualization in educational settings.

#### AIM

The aim of this study was to investigate the educational effect of the visualization of prosthetic alignment using SRM at P&O schools in Japan.

# **METHOD**

A short course for prosthetic alignment was designed consisting of two classes: Class 1 focused on understanding prosthetic alignment combined with basic biomechanics, and understanding graphs of SRM using interactive methods, such as peer instructions. Class 2 included practice and demonstration in which prosthetic users demonstrated their gait under several alignment conditions. Students were asked to interpret graphs of SRM and evaluate the alignment through discussion. Tests were performed before and after the course to assess its effectiveness. A Wilcoxon signed-rank test was performed for comparison (P<0.05). Comments for this course were also collected from the students.

# **RESULTS**

The study was performed at two schools and 42 students participated. The rate of correct answers on the test referring to the basic knowledge of alignment and moment of force was significantly higher after the course than beforehand (78% vs 39%, P<0.01, Fig (A)). The rate of correct answers on posttests including basic knowledge, relationship between gait cycle and ground reaction forces in the sagittal and coronal plane was 81.0% (standard deviation: 18.4, Fig (B)).

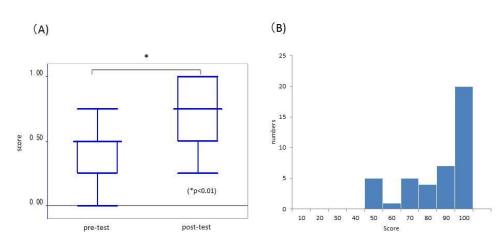


Figure (A): Comparison between pre- and post-test, (B): Result of post-test

Comments showed both positive and negative feedback.

# **DISCUSSION AND CONCLUSION**

Most students appeared to have understood the relationship between prosthetic alignment and kinetic parameters. They also found it interesting to evaluate prosthetic alignment using SRM and to

# **REFERENCES**

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# **ACKNOWLEDGEMENTS**

We are grateful to the late Mr Mitsuhiko Uchida of Kobe College of Medical Welfare, Sanda Campus for course designing.



# Trial Production of a Quick Change Connector for Transtibial Amputee to Use Carbon Blade

<u>Yusuke Ohno</u>, Yoshiki Aoyagi, Fumio Usui Tetsudo Kosaikai Prosthetics and Orthotics Support Center, Tokyo, Japan

#### **BACKGROUND**

Users of transtibial prostheses, especially with long stumps, are required to prepare dedicated sockets with carbon blades connectors on the back of the socket at their own expense. There is a situation that it is difficult to test carbon blades. Currently, some products such as Flex-Run (Ossur) are on sale as design to connect directly under the socket, but the prosthesis length becomes longer compared to the intact side.

## AIM

In order to solve above problems, we report here that a dedicated connector capable of trying on carbon blades with a daily prosthetic foot has manufactured.

# **METHOD**

As a preliminary survey, for 40 transtibial prosthetic users, we examined the prosthesis used routinely on (1) the total prosthesis length, (2) the maximum AP diameter (outline) of the socket abdomen, (3) the type of connector used as the lower part of the socket (male · female pyramid etc.), (4) the length from the connector at the bottom of the socket to foot bottom. From the results obtained, it turned out that there are a certain number of prosthetic users, mainly females, which can not be used with existing carbon blades

connecting directly below socket.

# **RESULTS**

The connector was designed to incorporate the following five adjustment mechanisms so that the test run can be carried out more comfortably.

- 1. Setting of carbon blade length
- 2. Inset and outset of carbon blade position
- 3. Flexion / extension and adduction / abduction
- 4. Alignment of the horizontal plane
- 5. Front-rear position of socket and the carbon blade

The connector was made of aluminum alloy, and the strength simulation with stress analysis and prediction of deflection amount was carried out, and the load carrying weight was designed at 120 kg. When we tried running with the cooperation of two prosthetic users, we got a good response as we got the feeling of leaping with a carbon blade as the socket of the daily prosthesis, very fun.

# **DISCUSSION AND CONCLUSION**

I tried to make a carbon blade connector to contribute to the creation of an environment that can respond to the desire "I want to run with a carbon blade" for prosthetic users who were away from feeling of running, bouncing feeling. Even

though there are issues such as verification of safety, weight saving, the price reduction, in the future, I believe they can familiarize themselves with sports.



# Measurement of the Consistency of Patella-Tendon-Bearing Modification using CAD

Marie O'Byrne<sup>1</sup>, Angus McFadyen<sup>2</sup>, Anthony McGarry<sup>1</sup>, <u>Dominic Hannett</u><sup>3</sup>
<sup>1</sup>Department of Biomedical Engineering, University of Strathclyde, Glasgow, United Kingdom. <sup>2</sup>AKM Statistics, Glasgow, United Kingdom. <sup>3</sup>Ability Matters, Abingdon, United Kingdom

# **BACKGROUND**

Computer aided design (CAD) is now commonly used in prosthetic clinical practice [1] and current scanners have been shown to have a high level of accuracy during the shape capture process [2]. To create a patella tendon bearing (PTB) socket, further modification of the transtibial shape is required. This may lead to less consistency as more personal judgement and human error is involved.

#### $\Delta IM$

To investigate the consistency of transtibial shape modification for a PTB socket design using CAD.

# **METHOD**

13 transtibial models with marked anatomical landmarks were made, each linked to a fictitious patient history. Three clinicians were asked to complete modification for a PTB socket with suspension sleeve at weekly intervals over the course of three weeks. Measurements were recorded at landmarks and compared for intra and inter reliability.

# **RESULTS**

Clinicians showed high intra and inter ICC values with narrow conference intervals for the tibial tubercle, medial and lateral flares and distal end of the tibia. One clinician demonstrated moderate intra rater reliability for modification over the patella tendon. All other ICC values for the patella tendon and fibula head modification were low. Inter rater reliability was not calculated for fibula head and patella tendon as intra ICC values should be above 0.6.

# **DISCUSSION AND CONCLUSION**

All clinicians showed good consistency at tibial tubercle, distal tibia, medial and lateral flares. Patella tendon and fibula head showed poorer consistency and require improvement.

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# **ACKNOWLEDGEMENTS**

We wish to thank clinicians who participated in this study, and Ms Sally Bell for assistance with the literature review.



# **Quantification Analysis of a Technique for Manufacturing a Transtibial Prosthetic Socket using a Three-Dimensional Scanner**

<u>Takahiro Go</u>, Hironori Suda, Yu Maeda, Yukio Agarie Niigata Univ. of Health and Welfare, Niigata, Japan

# **BACKGROUND**

In recent years, three-dimensional (3-D) scanners and printers have been used in the prosthetic and orthotic industries. In order to develop further these equipment, it is necessary to precisely digitize and record the techniques for experience of Prosthetist and Orthotist (PO). For this purpose, the shape change during casting of the stump and model modification must be determined.

#### ΔIM

Aim of this study were to quantify the stump casting technique and the method for modifying a positive model in the conventional method for making transibial prosthetic sockets.

#### METHOD

The PO cast the stump and modified model by using the conventional method (TSB type socket), and in that process, we scanned the (1)Stump,(2)Pre-modified positive model and (3)Modified positive model with a 3-D scanner. As the socket adaptation was good in the provisional adjustment, the modified model data were set as the data of the "adapted socket shape."We aligned the 3-D data of the (1) stump and (3) modified model, and analyzed the shape variation of the modified model as compared with the stump. The stump was separated into three parts, namely the anterolateral, anteromedial, and posterior surfaces and compared each areas.

# **RESULTS**

In comparison with the shape of the stump with the modified model, the cross-sectional area of the positive model was smaller than that of the stump around 80% proximal area in the stump length. The cross-sectional areas of the stump were separated into three parts, namely the anterolateral, anteromedial, and posterior surfaces, and were compared. The posterior surface area was the most reduced among the three parts, while no changes were observed in the anterolateral and anteromedial surfaces. Furthermore, the modified model length was extended by 3 mm.

# **DISCUSSION AND CONCLUSION**

We conducted a quantification of the stump casting technique and considered the method for modifying a positive model for making transtibial prosthetic sockets. The cross-sectional area of the positive model (after adaptation) was smaller than that of the stump by approximately 80% of the proximal area of the stump length. The shape of the posterior surface was greatly changed, but no changes were observed in the anterolateral and anteromedial surfaces of the stump.



# Free Paper – Poster Presentation Prosthetics: Lower Limb Ankle & Foot

## 5.061

# Major Lower Limb Amputation for Vascular disease: Does Diabetes Mellitus Influence Prosthetic Fitting?

Gorki Carmona<sup>1</sup>, Alain Lacraz<sup>1</sup>, Hala Kutaish<sup>2</sup>, Mathieu Assal<sup>2</sup>, Christophe Graf<sup>1</sup>
<sup>1</sup>University Hospitals of Geneva, Geneva, Switzerland. <sup>2</sup>Clinic La Colline, Geneva, Switzerland

# **BACKGROUND**

Peripheral arterial disease (sPAD) is one of the main causes of major atraumatic lower extremity amputations (MLEA). Diabetes Mellitus (DM) is a frequent concomitant condition in MLEA. However, the influence of DM on the rate of successful prosthetic fitting in MLEA is unknown.

#### $\Delta IM$

Evaluation of DM effect on the rate of successful prosthetic fitting in MLEA, when stratified by age, sex and level of amputation.

## **METHOD**

Retrospective survey of systematic data collection including all MLEA, the latter defined as any level of amputation proximal to the foot. The cohort included all patients requiring MLEA for sPAD, with or without DM, between 1993 and 2017 at Geneva University Hospitals. The rate of successful prosthetic fitting in both groups, corrected for age, sex, and level of MLEA was analyzed via logistic regression. Successful prosthetic fitting is defined as any patient with MLEA fitted with definitive ambulation prosthesis at 6 months postoperatively, Unsuccessful is any patient not fit for definitive prosthesis at 6 months because of cognitive and/or functional inability to securely use a prosthesis.

# **RESULTS**

Seven hundred sixty-three MLEA were performed from 1993 to 2017. Baseline characteristics showed a male predominance (67%; n=509). Diabetic patients (n=459; 60%) were significantly younger for amputation than non-diabetic patients ( $70.4 \pm 11$  vs  $74.1 \pm 12$  years p<0.001).

The majority of amputations (57.7 %) were performed below the knee (BKA). The probability of having a BKA was significantly lower in non-diabetic patients as compared to those with DM (OR 0.36 (CI95% 0.27-0.50), p<0.001).

The rate of successful prosthetic fitting was 65.3 %. The probability of successful prosthetic fitting was significantly higher in patients with BKA than in those with above knee amputation (OR 4.93 (CI95% 3.39-7.16), p<0.001), and lower in patients older than 65 years (OR 0.52 (CI95% 0.37-0.72), p<0.001). Sex and presence of diabetes did not influence the prosthetic fitting.

# **DISCUSSION AND CONCLUSION**

DM patients with peripheral arterial disease were found to have a lower level of amputation and a younger age at the time of amputation when compared to non-DM patients. Despite these objective factors, DM patients showed no difference in terms of prosthetic use. Preservation of the knee joint, and age below 65 years had a positive effect on the rate of prosthetic fitting.



# A New Hydraulic Prosthetic Ankle to Improve Amputee Cost of Walking

Anna Pace<sup>1</sup>, James Gardiner<sup>2</sup>, Laurence Kenney<sup>1</sup>, David Howard<sup>1</sup>
<sup>1</sup>University of Salford, Salford, United Kingdom. <sup>2</sup>University of Liverpool, Liverpool, United Kingdom

# **BACKGROUND**

In an intact ankle, tendons crossing the joint store energy during the stance phase of walking, and release it during push-off [1] providing forward propulsion. Most energy storage and return (ESR) prosthetic feet cannot plantarflex beyond their neutral ankle angle - the 90° angle between the foot and the shank - at push-off producing a plantarflexion moment. Therefore, they fail to provide the required energy at push-off, resulting in a higher metabolic cost of walking and slower walking speeds for amputees.[2]

## AIM

To tackle this problem, a new prosthetic ankle based on miniature hydraulics is designed which: a) stores all of the work done during mid-stance prior to push-off; b) releases the stored energy during push-off.

#### METHOD

The concept design comprises a prosthetic ankle joint driving two cams, which in turn drive two miniaturised hydraulic rams. The stance cam-ram system captures the work done during mid-stance prior to push-off by pumping oil into an accumulator, while the push-off system returns energy to power push-off. The mathematical modelling of the system uses a combination of theoretical and empirical models, implemented in Matlab to obtain

a simulation model. Design parameters are optimised based on the results of multiple Matlab simulations to minimise energy losses. Finally, the model's performance is assessed to provide justification for physical prototyping

# **RESULTS**

Design optimisation was completed in Matlab for the two camram systems during their working phases (mid-stance and push-off respectively). Results showed that the power absorbed/generated at the ankle by the new device mimics the required one (Fig. 1) – from an able-bodied person - during the two working phases. The stance system, during mid-stance, stores approximately 17J out of the 18.9J of eccentric work at the ankle, with energy losses smaller than 5% of the aforementioned eccentric work. The push-off system releases 11.9J of concentric work at the ankle out of the 14.1J output from the accumulator during push-off, with energy losses smaller than 5% of the energy from the accumulator. In addition,

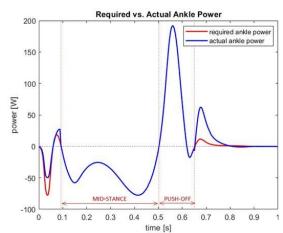


Figure 1. Ankle power curves comparison.

the main components of the system – cam, ram, and accumulator - would be physically realistic and could fit within a typical prosthetic ankle.

# **DISCUSSION AND CONCLUSION**

The performance of the final design still needs to be assessed over the full gait cycle. Nevertheless, given the promising results obtained in the two working phases in terms of energy storage and return, it seems that this new design based on simple miniature hydraulics may replicate adequately the energy-recycling behaviour of an intact ankle. It may eventually help many amputees by making their walking less tiring and faster.

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# Mechanical and Clinical Comparisons of Three Energy Storage and Return Feet: Pilot Study

<u>Thanyaporn Rakbangboon</u><sup>1</sup>, Prawina Sutdet<sup>1</sup>, Sarawanee Phaipool<sup>1</sup>, Pairat Tangpornprasert Tangpornprasert<sup>2</sup>, Chanyaphan Virulsri<sup>2</sup>

<sup>1</sup>Department of Prosthetics & Orthotics, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand, Bangkok, Thailand. <sup>2</sup>Department of Mechanical Engineering, Chulalongkron University, Bangkok, Thailand

## **BACKGROUND**

There are varieties of commercially available prosthetic feet in Thailand. The dynamic foot provides energy storage and release ability for the amputee. Nowadays dynamic feet are imported from abroad and costly. AM02 dynamic prosthetic foot was developed by Mechanical Engineering, Chulalongkorn University which was designed by using carbon fiber for low-priced, lightweight and giving ability of storing and releasing energy. Although, the foot has been tested by finite element but it hasn't been tested in both mechanically and clinically.

#### AIN

This study aim to mechanically test the AM02 dynamic prosthetic foot followed the ISO and verify the efficiency of foot regarding energy storage and release, velocity and cadence by comparing with other two commercial feet.

# **METHOD**

There are two phases, mechanical and clinical phase, in the study. Initially, the mechanical test includes static proof and cyclic test were tested by the universal machine testing referring to the ISO standard 10328. Clinically, there were three participants who were asked to walk with three prosthetic feet by random order. The AM02 dynamic, OttoBock® 1E56 Axtion, and OttoBock® 1S90 SACH. Values of ankle power, velocity and cadence were collected by Gait Motion Analysis system (Motion Analysis's Helen Heys full-body with head model) Wilcoxon Signed Rank test was used to compare dependent continuous variables from the data. Two-sided  $\alpha < 0.05$  are considered statistical significant as p-values.

# **RESULTS**

For mechanical testing; static test, the result was shown no failure in heel and forefoot parts when applying 2065N maximum load with rate 100 N/s. Cyclic test, the result was shown AM02 endure after 2 million cycles withapplying pressure at peaks of 1280N with frequency 1Hz. It has indicated acceptable performance of the design. Clinically, comparison result regarding energy storage, release, velocity, cadence exhibited that there were no statistically significant differences between the AM02 and Axtion® (p>0.05) as well the AM02 and SACH (p>0.05). However, in clinically result showed the energy storage of the AM02 was higher when compared with Axtion® and SACH. Energy release and cadence results were recorded in the same order as following, the AM02, Axtion®, SACH. Velocity result was sorted in descending order; AM02, SACH, Axtion®.

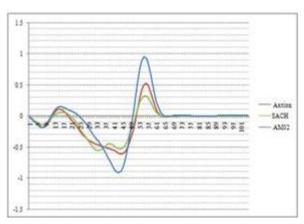


Figure 1: The Ankle power between three prosthetic feet during a gait cycle of the transtibial amputees

# **DISCUSSION AND CONCLUSION**

The difference in energy storage, release, velocity and cadence in three prosthetic feet showed no significant, this study can only explain in descriptive result from the whole of collected data. AM02 dynamic foot had tendency in higher energy storage and release which might come from the specific design. Further study was necessary to conduct more reliable research. Increasing more simple size should be considered. As much as the reliable research conduct to verify ability of AM02, more useful for amputees

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# **ACKNOWLEDGEMENTS**

We would like to thanks Sirindhorn School of Prosthetics and Orthotics, Thailand, for a facility, equipment and research funding.



# Gait Parameters, Safety and Energy Expenditure of Transtibial Prosthetic Users with Microprocessor Versus Non Microprocessor Ankles over Different Terrain

<u>Bethany Fieldsend</u>, Laura Murray, Anthony McGarry Department of Biomedical Engineering, University of Strathclyde, Glasgow, United Kingdom

## **BACKGROUND**

Amputation has been shown to result in decreased stability, increased energy expenditure, increased use of the contralateral limb, decreased quality of life, decreased self-selected walking speed and asymmetrical gait in those with unilateral amputation.[1, 2] Prosthetic foot and ankle component selection has been shown to affect prosthetic users' stability.[3] Microprocessor controlled ankles have been developed in the last 10 years, with reports of patient preference, improved safety and a more normalised gait.

# AIM

To assess the current level of evidence of the use of microprocessor ankles and feet.

# **METHOD**

A literature search was carried out for peer reviewed journal articles published in English between January 2000 and February 2018.

## **RESULTS**

Initial screening generated 20 relevant papers. Methodological quality was assessed using Credibility, Accuracy. Reasonableness, Support. Overall quality was rated as moderate.

# **DISCUSSION AND CONCLUSION**

Results have shown a patient preference, improved safety and more normalised physiological gait. Authors reported on trends of improvement but did not demonstrate significant results. Standardised outcome measures to facilitate testing of all componentry would allow for improved comparison between components and cross comparison between studies, increasing the evidence base.

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# Free Paper – Poster Presentation Prosthetics: Upper Limb

# 5.065

# Hours of Wearing a Prosthesis and its Efficacy in Activities of Daily Living in Children with Congenital Upper Limb Deficiency

Hiroshi Mano<sup>1,2</sup>, Satoko Noguchi<sup>1</sup>, Sayaka Fujiwara<sup>1</sup>, Nobuhiko Haga<sup>1</sup>
The University of Tokyo Hospital, Tokyo, Japan. <sup>2</sup>Shizuoka Children's Hospita, Shizuoka, Japan

# **BACKGROUND**

Congenital limb deficiency is a rare and intractable disease, which impairs function and appearance of the limbs.[1] Although upper limb prostheses can help in activities of daily living, some patients might develop a dislike for the prosthesis, or reject a prosthesis. As an approach to minimize the chances of prostheses rejection, it is recommended that children should start wearing them from an early age.[2] The effectiveness of the prostheses might be related to getting accustomed to wear them.

#### ΔIM

The aim of this study was to investigate the relationship between hours of wearing a prosthesis and its efficacy in activities of daily living, in children with congenital upper limb deficiency.

#### METHOD

The participants were 11 children with congenital transradial or transcarpal upper limb deficiencies, and their caregivers. We asked the caregivers to fill-in a questionnaire about their child's activities of daily living and hours of wearing the prosthesis. For each of the 20 listed activities, the caregivers selected the most appropriate response from the following options: (i) can do better without the prosthesis, (ii) does equally well with or without the prosthesis, (iii) does better with the prosthesis. The demographic and clinical information about the children was examined from their medical charts. We investigated the factors influencing the hours of wearing prosthesis by correlation analyses using the Spearman rank test.

# **RESULTS**

The hours of wearing a prosthesis was positively correlated with the number of activities that the children performed better with the prosthesis. Zipping and unzipping a jacket, unscrewing a bottle, removing a pencil from a pencil case, holding a piece of paper and writing, putting up a clothes peg were the activities that were significantly correlated with hours of wearing the prosthesis.

# **DISCUSSION AND CONCLUSION**

The more effective the prostheses were for performing the activities of daily living, longer the children with congenital limb deficiencies were them. To get children with congenital upper limb deficiencies accustomed to wearing their prostheses and to minimize the chances of rejection, the prostheses should have appropriate functions and be effective for activities of daily living. Appropriately functional prostheses should be prescribed and the children should be provided with appropriate and adequately frequent occupational therapy.

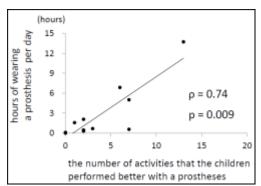


Figure 1. The relationship between hours of wearing a prosthesis and the number of activities that the children performed better with the prosthesis.

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# Improved Prosthetic Functionality Through Advanced Hydraulic Design

Bjorn Olav Bakka, Christian Fredrik Stray, Jos Pointers, <u>Ole Lerstol-Olsen</u> Hy5Pro AS, Raufoss Industripark, NO-2830 Raufoss, Norway

## **BACKGROUND**

Advancements in technology can result in overly complex designs leading to underutilized features. Advanced prosthetic devices are no different. Current prosthetic technology provides limited options for hand amputees: patients are provided with either standard utilitarian myoelectric grippers with limited functionality, or advanced and expensive bionic-like hand prostheses. There is a need for innovation to provide users with a hand prosthesis that are reliable, usable and with low cost.

#### ΔIM

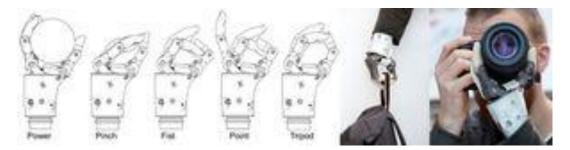
Hy5 had a research objective of designing a reliable, but optimal hand prosthesis to fill the gap between standard myoelectric grippers and premium, bionic-like hand prostheses.

#### METHOD

Hy5s approach applied state-of-the-art hydraulic actuator technology as "muscles" with core functionality embedded in advanced 3D printing structures composed of titanium and plastics. The opening and closing of the hand are myo-electrically controlled and compatible with industry standards. The prosthesis uses a single pump to control interconnected hydraulic actuators. The hydraulic actuators enable an adaptive and independent pressure build-up on the fingers as they grasp an object. The digits are closed by wires being actuated by the palm cylinders. The digit mechanism is a force balancing mechanism enabling the digits to close on objects regardless of their shape.

# **RESULTS**

The Hy5 design mimicks realistic hand gripping without requiring one motor per finger as in bionic-like prosthesis. Testing concluded that the Hy5 prosthetic hand manages all grips (pinch, power, fist, tripod and point) as intended and works as a substitute for a missing hand. Users also responded very favorably to the innovative emergency release button, an added safety feature. The users were attracted by the simplicity and sturdiness of Hy5, which promises a reliable product with low life-cycle cost. The Hy5 device design specifications demonstrate its impressive performance: a maximum power grip of 120N, maximum tripod grip of 60N, maximum static load of 40kg, the maximum time to close is 1.2 seconds and weight is 580g.



# **DISCUSSION AND CONCLUSION**

Analysis shows that the Hy5 prosthesis allow recovery of up to 30% of total gripping functionality compared to standard grippers. Further analysis showed that user functionality achieved with the Hy5 prosthesis is comparable to that of most advanced bionic-like prosthesis users. Functionality in the advanced bionic-like hand requires significant training, cognitive attention and risk of faulty functionality. Access to Hy5 gripping patterns is intuitive with less training and cognitive attention.

# **ACKNOWLEDGEMENTS**

This work was supported by Norwegian and EU grants.



# The Influence of Unilateral Hand Task and Bilateral Hands Task on Myoelectric Hand Prosthesis Performance -Verification by Simulated Myoelectric Hand

<u>Jumpei Oba</u><sup>1</sup>, Isamu Kajitani<sup>2</sup>, Kengo Ohnishi<sup>3</sup>, Sumiko Yamamoto<sup>4</sup>

<sup>1</sup>Kobegakuin University, Kobe, Japan. <sup>2</sup>National Institute of Advanced Industrial Science and Technology, Tsukuba, Japan. <sup>3</sup>Tokyo Denki University, Tokyo, Japan. <sup>4</sup>International University of Health and Welfare, Tokyo, Japan

#### **BACKGROUND**

The influence of myoelectric hand prosthesis training on the ability to operate a prosthetic hand has not been fully verified. In this study, the influences of single- and dual-hand myoelectric hand operation training on the ability to use a prosthetic hand were investigated.

#### ΔIM

In this project, we examined the effect of unilateral hand task and bilateral hands task on the manipulability of the myoelectric hand prosthesis using the simulated myoelectric prosthesis for the myoelectric hand prosthesis training.

#### **METHOD**

Subject were 20 able-body persons. The position of the electrode was determined using the myoelectric potential control device Myoboy by Ottobock Co. for the forearm of subjects' dominant hand. After the fitting, as a training before installation, it was confirmed that Myoelectric potential control for opening and closing Myoelectric hands were possible by executing for 20 minutes per day for 3 days. The simulated myoelectric prosthesis for the forearm is shown in next figure. We divided tasks into unilateral hand task group and bilateral hands task group and carried out Evaluation test of five days. Unilateral hand task was block / wood disk movement, and bilateral hands task executed activities of Macramé. It was examined with the BBT and SHAP for myoelectric hand ability assessment.

#### **RESULTS**

The BBT results of the comparison between the two groups of differences between the unilateral -handed task group and the two-handed task group before and after the BBT were  $1.7 \pm 2.9$  differences in the unilateral -handed task group and  $2.7 \pm 2.8$  in the two-handed task group. There were no significant difference between the results. (p = 0.436).The SHAP results of the comparison between the two groups on the difference between the two groups before and after SHAP in the unilateral -handed task group and the bilateral hands task group showed that the subjects in the unilateral -handed task group had a difference of  $17.9 \pm 8.8$ , and the subjects in the two- A significant difference was observed at  $27.0 \pm 7.3$  points, and the change in the score of SHAP was large in the bilateral hands task group (p = 0.011).

## **DISCUSSION AND CONCLUSION**

It was suggested that the dual-hand operation training are more effective than the single-hand the manipulating ability of goods, especially in the operation of accurately manipulating the gripping target at the tip of the myoelectric hand. As a result, the bilateral hand task improves the object operation more than the unilateral hand task.

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#### **ACKNOWLEDGEMENTS**

This work was supported by JSPS KAKENHI Grant Number 18K12156.



# Pilot Testing of a Novel Passive Adjustable Prosthetic Hand Combining 3D Printing and Steel Grasp/Release Mechanism

<u>Lisa O'Brien</u><sup>1</sup>, Gerwin Smit<sup>2</sup>, Luuk Lommerse<sup>2</sup>, Rowan Page<sup>1</sup>, Elena Montesano<sup>3</sup>

Monash University, Melbourne, Australia. <sup>2</sup>Delft University of Technology, Delft, Netherlands. <sup>3</sup>Alfred Health, Caulfield, Australia

#### **BACKGROUND**

3D printing technology has the potential to provide infinitely customisable and affordable prosthetics, attracting positive media attention world-wide. Existing open-source 3D printed hand designs, however, rarely meet consumer expectations in terms of grip strength and natural movement patterns. The "Self Grasping Hand" (Delft University of Technology) seeks to address this by combining 3D printing with an intricate steel-fabricated grasp/release mechanism that mimics the natural tenodesis grip pattern. It is designed to be easily fitted to consumers' existing prosthetic socket.

#### AIM

We aimed to pilot test the Self Grasping Hand with 10 adult prosthesis users with trans-radial limb difference. Specifically, we aimed to measure device daily usage time and collect consumer feedback to inform future models.

#### **METHOD**

Participants were fitted with the device by a prosthetist and Biomedical engineer and underwent training with an occupational therapist. They were then asked to use the device as much as possible over two weeks then return to provide feedback. Patterns of wear and total wear time were recorded via upper limb activity monitors worn on both wrists. Satisfaction, function and prosthesis-related quality of life were measured using the Orthotics and Prosthetics Users' Survey and the Trinity Amputations and Prosthesis Experience Scale.

#### **RESULTS**

The Self Grasping Hand performed very well on laboratory testing in terms of strength and robustness of the grasp mechanism. The consumer trial is currently underway in Melbourne Australia and results were not available at the time of submission.

#### **DISCUSSION AND CONCLUSION**

The reullts of this pilot study will inform the methodology for a larger-scale international consumer test of the hand. Feedback from participants will be used to refine the design, and will also inform future designs of passive adjustable hand devices.

## **ACKNOWLEDGEMENTS**

This study is funded by The Promobilia Foundation (Sweden).



# A Simple Pediatric Myoelectric Wireless Toy Control System

## Steve Blazeski

Atlantic Clinic for Upper Limb Prosthetics, Institute of Biomedical Engineering, University of New Brunswick, Fredericton, Canada

#### **BACKGROUND**

The EMG evaluation of an upper limb deficient child can be challenging. To have a young child give a repeatable muscle signal the child must make the cause and effect connection. The Atlantic Clinic for Upper Limb Prosthetics in New Brunswick, Canada has developed tools over the years to keep the child engaged in EMG site selection process to facilitate the fitting of a pediatric myoelectric.

#### AIM

To develop an innovative, inexpensive and effective assessment tool that will allow a Clinician to quickly and easily assess a child's EMG signals and determine if they are cognitively ready to use a myoelectric arm.

#### **METHOD**

Past devices used in the clinic were reviewed and their benefits and shortcomings were evaluated. To ensure

simplicity, the Clinic chose to eliminate the option of a software-based system. Instead, a remote-controlled vehicle with a two-state controller was chosen. The vehicle maintains its original sequential system of activation. Each new "ON" signal transmission will result in the vehicle changing its function between moving forward and spinning on the spot. The clinic's engineer devised a system that would reproduce the "ON" signal when the electrode signal was above a desired threshold and an "OFF" signal when below. The solution proved simple and fulfilled the design goals.

### **RESULTS**

Clinical observation of a child and their control of the remote-controlled vehicle provides visual feedback to support the efficacy of fitting a myoelectric arm. When the vehicle is remotely activated by the child using a myoelectric signal, the toy cycles between moving forward or spinning on the spot. When the signal drops below a threshold, the vehicle discontinues that function until a time where a new "ON" signal is present above the preset threshold. Upon the reapplication of a signal, the vehicle changes its function until the signal drops below the threshold again. This changing



Figure 1: Modified remote-controlled vehicle.

function allows the Clinician to observe that a child can easily and reliably produce the muscle action required for a pediatric myoelectric arm.

## **DISCUSSION AND CONCLUSION**

The modified remote-controlled vehicle has been put into the assessment toolbox at the Clinic. Its first use proved favourable. A child being assessed demonstrated that they could manoeuvre the vehicle with very little direction. This quickly showed the Clinician that the child understood how to trigger and control their muscles and was therefore a candidate for a myoelectric arm. The repurposing of a modified remote-controlled vehicle made for an inexpensive and robust tool.

#### **ACKNOWLEDGEMENTS**

Thanks Greg Bush, Clinician, and Walter Young, Senior Technician, for allowing me to pick your brains and supporting my creativity.



# Current Status of Myoelectric Upper Limb Prosthesis for Children in Japan: 15 Years' Clinical Practice of Hyogo Rehabilitation Center

<u>Yaeko Shibata</u>, Mitsunori Toda, Futoshi Mizobe, Hibiki Takami, Miki Ohgushi, Takaaki Chin Hyogo Rehabilitation Center, Kobe, Japan

#### **BACKGROUND**

Myoelectric prosthesis is a useful tool for congenital upper limb deficiency children in terms of expanding their activity and participation. However, very few children use myoelectric prosthesis in Japan. Our center has introduced a framework in 2002 to allow children with upper limb deficiency to undergo training and fitting a myoelectric prosthesis at any time. Here, we report the results of 15 years' experience of myoelectric prosthesis training for children and elucidate the current problems.

#### AIM

To gain better insight into the state of myoelectric prosthesis training, state of usage and identify a ratio of rejection among children with upper limb deficiency in our center.

#### **METHOD**

Children with congenital or acquired unilateral below elbow deficiency, who have undergone myoelectric prosthesis training at our center from 2002 to 2016 were included in this study. Medical records of each participant were retrospectively reviewed. The data collected for analysis included the following: gender, age at first consultation, age at first prosthesis fitting, level of deficiency, follow-up period, and the continued usage of prosthesis or not. Participants were divided into two groups; those who have continued using prosthesis (user), and who discontinued using prosthesis (non-user). Student's t-test and fisher's exact test was used as statistical analysis. Statistical significance was set at p<0.05.

#### **RESULTS**

Seventy-four children (34 boys, 40 girls) have undergone myoelectric prosthesis training. Mean age at first consultation was 2.3 years old (range 0-16 years, median 0 year). Age at first prosthesis fitting was 3.2 years old (range 0-17 years, median 1 year). Follow-up period was 59.3 months (range 4-187 months, median 52 months). Age at final follow-up was 7.4 years old (range 1-19 years, median 6 years). Sixty-three participants continued using prosthesis,11 discontinued, and rate of rejection was 14.9%. Both age at first consultation and first prosthetic fitting were significantly younger (p<0.05) in users (1.5 and 2.3 years old) compared with non-users (7.3 and 9.1 years old). Gender and the level of deficiency (transradial, wrist, or transcarpal) had no influence on rejection.

#### **DISCUSSION AND CONCLUSION**

Our results suggest that the earlier a child is fitted for myoelectric prosthesis, the rejection rate is lower, which have been shown in several studies. However, children could skillfully use their prosthesis regardless of their age at first prosthesis fitting. It is important to provide adequate training for children who need prosthesis irrespective of their age. Children included in this study were relatively young at the latest follow-up, so further careful observation should be needed.



# Long Term Use of Prosthesis and Health Related Quality of Life in Individuals with Upper Limb Amputation

Futoshi Mizobe<sup>1</sup>, Mitsunori Toda<sup>1</sup>, Yaeko Shibata<sup>1</sup>, Junpei Oba<sup>2</sup>, Miki Ohgushi<sup>1</sup>, Takaaki Chin<sup>1</sup> Hyogo Rehabilitation Ceter, Kobe, Japan. <sup>2</sup>Kobe Gakuin University, Kobe, Japan

#### **BACKGROUND**

Prosthesis is a useful tool for individuals with upper limb amputation/deficiency. However, there are limited researches on long term usage of upper limb prosthesis, employment status, and rejection rate. Progress in prosthetic limb technology could enabled many amputees to lead a better life in their community. But there is no research on health-related quality of life (HR-QOL) in amputees in Japan.

#### AIN

To investigate the usage of prosthesis, frequency of use, employment status, rejection rate, and HR-QOL in upper limb amputees who underwent prosthetic rehabilitation in our center.

#### **METHOD**

We posted questionnaires to 131 upper limb amputees aged from 12 to 75 years old, who underwent prosthetic rehabilitation in our center. The questionnaires included participant demographics (age, gender, amputation level, and age at amputation), occupational status (full-time, part time, student, unemployed, or other), prosthesis use (current use, type of prosthesis; cosmetic, body-powered, or myoelectric, frequency of use of prosthesis in a week and hours a day, kinds of activities that they use prosthesis, and additional comments on prosthesis), and EQ-5D. ANOVA was used as statistical analysis. Statistical significance was set at p<0.05.

#### **RESULTS**

Eighty-two (62.6%) responded the questionnaire. Mean age at investigation was 52.1±14.9 years, 63 men and 19 women. Level of amputation was 28 above-elbow, 50 below-elbow, and 4 bilateral upper limb amputation. As for the job, 32 was full-time employment, 11 part-time, 3 student, 7 unemployed, 5 retired, and 29 including unemployed and retired received disability payment by social welfare. Seventy-two (87.8%) used prosthesis (40 myoelectric, 21 body-powered, 10 cosmetic, and 1 unknown), and 10 rejected their prosthesis. As for the frequency of use, 61 (84.7%) used prosthesis more than 5 days a week, and more than half of users wore more than 9 hours a day. Fifty-three users used prosthesis for leisure/outing, 45 job, 32 driving, 29 eating, 26 cooking and so on (multiple answers allowed). EQ-5D score was not statistically significant among groups.

#### **DISCUSSION AND CONCLUSION**

Our results suggest that appropriate prosthetic rehabilitation for upper limb amputees leads to long term use of their prosthesis for various activities. However, previous study has reported that about 90% of users used cosmetic prosthesis without providing prosthetic rehabilitation in Japan. It is necessary to improve provision of prosthetic training and information service, together with active involvement of clients in the selection of prostheses that satisfy their needs. The factors relating to HR-QOL needs further investigation.



# A Prosthetic Hand with Opposing Three Fingers Using a Hydraulic Actuator

Yuma Yamanaka, Masahiro Yoshikawa Osaka Institute of Technology, Osaka, Japan

#### **BACKGROUND**

Various electric prosthetic hands have been developed. However, they are heavy and not suitable for working near water because they use several electric actuators and a battery. In addition, since they generate driving noise, it is difficult to use in a quiet environment. Though five-fingered prosthetic hands using hydraulic actuators have been developed, there are problems on workability with five fingers and operability with a cable control system.

#### AIM

To solve these problems, we propose a prosthetic hand with opposing three fingers using a hydraulic actuator.

### **METHOD**

An opposing three fingers were controlled with a lever of an operating interface mounted on the upper arm on the affected side. A hydraulic actuator consists of two syringes with different diameters connected to each other with a tube. A large syringe was placed in the hand and a small syringe was placed in the operating interface. So, the force given by the operating interface was amplified based on Pascal's principle. Three fingers were opened by pushing the lever with the movement of the upper arm. When the force to the lever was released, the three fingers were closed by the restoring force of a spring in the hand.

#### **RESULTS**

Fig. 1 shows the appearance of the developed prosthetic hand. Total weight including socket was 303 g. We measured forces required for lever operation of the operating interface to open the three fingers by using a force gauge. The force required to begin opening three fingers was 9.8 N and the force required to open them maximally was 13.2 N. We measured the grasping force by using a force sensor. The grasping force during a fingertip grasp and a power grasp were 1.1 N and 2.8 N, respectively. To evaluate the effectiveness of the developed hand, we conducted an abstract task of SHAP test in which a left forearm amputee (male, 30s) participated. As a result, the participant was able to grasp and move all 12 objects in 100 seconds.

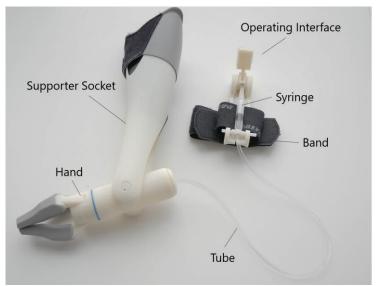


Fig. 1 Appearance of the developed hand

#### **DISCUSSION AND CONCLUSION**

The grasping force during a power grasp is 2.8 N. In the SHAP, the participant was able to grasp and move the heavy objects which are more than 500 g. Although the grasping force is not large, it is sufficient to perform the SHAP. The opposing three fingers and the operating interface allowed manipulation of various objects in the SHAP. Thus, the effectiveness of the developed hand was demonstrated.



## A Cosmetic Transhumeral Prosthesis with Electric Elbow Using a Clutch Mechanism

Yuma Tanogami, Masahiro Yoshikawa Osaka Institute of Technology, Osaka, Japan

#### **BACKGROUND**

Various transhumeral electric prostheses for amputees have been developed. However, most of them have a mechanical appearance. In addition, they are heavyweight because they use several high-power actuators and reduction gears for hand opening/closing and elbow flexion/extension to grasp objects. Conventional transhumeral prostheses have been developed to achieve grasping function, but approach from the viewpoint of achieving a natural appearance and motion are also necessary.

#### AIM

We report a cosmetic transhumeral prosthesis with electric elbow using a clutch mechanism to achieves a natural appearance, motion, and lightweight.

#### METHOD

The developed prosthesis was designed based on a skeleton of a commercially available cosmetic transhumeral prosthesis for an adult female. So, it had a natural appearance and could be covered with a cosmetic glove. The flexion/extension of an elbow joint was driven with an electric servo motor. A clutch mechanism which made the elbow joint free was incorporated in a gear train of a reduction gear to take natural postures according to gravity. A user could switch between a flexion/extension mode, a free mode, and a walking mode with a slide switch. The walking mode generated an upper limb motion during walking.

#### **RESULTS**

Fig. 1 shows the developed prosthesis. Its appearance was natural like a human's upper limb. The total weight was 391 g. The flexion speed of the elbow was 40 deg/s with a load of 250 g. The walking mode was evaluated by showing a movie that the healthy person wearing the developed prosthesis during walking to 21 participants. The participants compared the motion of the prosthesis with that of the healthy upper limb. As a result, the 14 subjects evaluated the motion of the prosthesis was similar to that of the healthy upper limb. In addition, the developed prosthesis was able to take a natural posture according to gravity at the free mode.

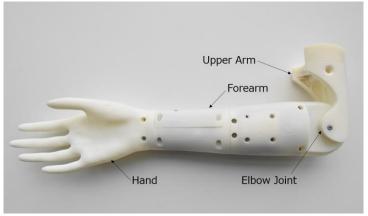


Fig. 1 Appearance of the transhumeral prosthesis

## **DISCUSSION AND CONCLUSION**

In the study, we developed a cosmetic transhumeral prosthesis with electric elbow using a clutch mechanism. It has a natural appearance like a human's upper limb. It allowed the natural walking motion and the posture according to gravity. We are planning to implement a function to recognize user's motions based on acceleration sensors and generate motions according to the situation.



# Compensatory Movement in Upper Limb Prosthesis Users during Activity Performance

Helen Lindner<sup>1</sup>, Nina Buer<sup>1</sup>, Liselotte Norling Hermansson<sup>2,3</sup>

<sup>1</sup>School of Health Sciences, Örebro University, Örebro, Sweden. <sup>2</sup>University Health Care Research Centre, Faculty of Medicine and Health, Örebro University, Örebro, Sweden. <sup>3</sup>Dept. of Prosthetics and Orthotics, Faculty of Medicine and Health, Örebro University, Örebro, Sweden

#### **BACKGROUND**

Low dexterity of conventional two-function (open, close) myoelectric hand prostheses with limited wrist movement often leads to compensatory shoulder and elbow movements, e.g. excess shoulder abduction and elbow flexion. Compensatory movements may lead to musculoskeletal pain [1] and it is thus important to identify prosthesis users with **compensatory movements** and to develop **preventive treatments for musculoskeletal pain**.

#### AIM

The study aim was to measure and compare compensatory movements during activity performance among upper limb prosthesis users with different levels of myoelectric control.

#### **METHOD**

Twenty-seven users of conventional myoelectric hand prosthesis performed the *Assessment of Capacity for Myoelectric Control* (ACMC) at the Örebro Limb Deficiency and Arm Prosthesis Centre. The performances were recorded and analyzed with *Dartfish motion capture video analysis software*. The software was used to track and measure the maximum angles for shoulder abduction and elbow flexion at the non-prosthetic and prosthetic sides during the activity performance. Two independent raters used Dartfish to analyze 10 videos and Intra-class Correlation Coefficient (ICC) was used to calculate inter-rater reliability. The ability to control a myoelectric prosthetic hand was assessed by the ACMC.

#### **RESULTS**

The within-individual differences for shoulder abduction ranged from 2° to 52° and for elbow flexion from 1° to

66°. When compared between prosthetic and non-prosthetic side, larger differences in shoulder abduction and elbow flexion were found among the users with ACMC ≤ 0 than users with ACMC > 0 (Fig.1a).

When comparing the within-individual side differences between prosthesis users with ACMC ≤0 and users with ACMC >0, a significant angle difference was found in the elbows (p=0.03) but not in the shoulders

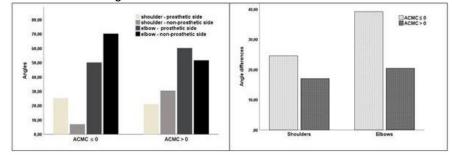


Fig.1a.Comparison of shoulder abduction and elbow flexion within users with ACMC ≤0 and users with

Fig. 1b. Comparison of side difference in shoulder abduction and elbow flexion between users with ACMC ≤0 and users with ACMC >0

(p=0.34) (Fig.1b). Inter-rater reliability between the two independent raters was excellent (ICC 0.91).

#### **DISCUSSION AND CONCLUSION**

Compensatory elbow movements during activity performance are higher in upper limb prosthesis users with low level of myoelectric control. Prevention for musculoskeletal pain should consist of both training for improved prosthetic control and improved prosthetic use in activity performance. Measurement of compensatory movements can help to identify amputees with frequent compensatory movements. Future studies are needed to investigate the effect of ability to control myoelectric prosthesis on musculoskeletal pain.

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#### **ACKNOWLEDGEMENTS**

This study was supported financially by the Norrbacka-Eugenia Foundation.



# Mechanism and Control of Powered Prosthetic Arm using Hydraulic Bilateral Servo Actuators

Higashihara Takanori<sup>1,2</sup>, Oshima Toru<sup>2</sup>, Tamamoto Takumi<sup>2</sup>, Kengo Ohnishi<sup>3</sup>, Saito Yukio<sup>4</sup>
<sup>1</sup>Takamatsu Prosthetic & Orthotic Mfg, Ltd, Ehime, Japan. <sup>2</sup>Toyama Prefectural University, Toyama, Japan. <sup>3</sup>Tokyo Denki University, Saitama, Japan. <sup>4</sup>Sibaura Institute of Technology, Saitama, Japan

#### **BACKGROUND**

In recent years, persons with bilateral shoulder disarticulation are challenging to wear multiple DOF high-tech computer controlled prosthetic arms. Research and development of those arms are focused on the operability using EMG or EEG with AI technologies. Those mechanism and control are based on the conventional industrial robot manipulators. Humanlike mechanism and control different from conventional robot manipulators are necessary to the prosthetic arm to improve the operability.

#### AIM

The aims and policies of this study are to design a unique mechanism and control of powered prosthetic arm using hydraulic bilateral servo actuators, and to change the idea of artificial arm.

#### **METHOD**

The powered prosthetic arm designed in this study consists of a wearable prosthetic arm and an external attachment to use it as desktop type. A linear type bi-articular hydraulic bilateral servo actuator is to use for shoulder and elbow flexion/extension. This actuator and its joint mechanism have many humanlike advantages, 1) bi-articular simultaneous smooth movement of the shoulder and elbow, 2) large force output, 3) antagonistic stability, 4) highly rigid bone and joint mechanisms. The other articular movements are performed by rotary type bi-articular hydraulic bilateral servo actuators. A new control role is proposed about the DOF and mechanisms of this powered prosthetic arm.

#### **RESULTS**

The advantages of the actuator and the mechanisms ware confirmed. And the control role was proposed under the concept of new DOF. This arm possesses the humanlike force output and movement compared with conventional robot manipulator. The concept of new DOF of this arm is built by the bi-articular actuator and complementation of the DOF by user of the arm. The role is based on the biomechanical force and movement control of the human musculoskeletal system. In addition, each digit on the 5-DOF hand is driven by electric servo motors. A new mechansism and control

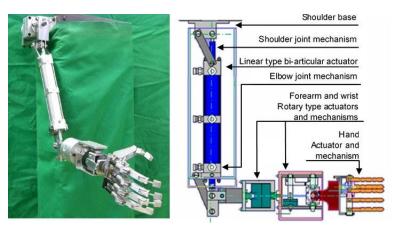


Figure 1. Powered prosthetic arm using hydraulic bilateral servo actuators.

of powered prosthetic arm using hydraulic bilateral servo actiators was proposed one of the future prosthetic arm.

# **DISCUSSION AND CONCLUSION**

It is difficult to use a powered prosthetic arm with multiple degrees of freedom for user with bilateral shoulders disarticulation. Not only user interface, but humanlike mechanism and control of the prosthetic arm are also a big element with the usability.

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# A Case Study on Myoelectric Prosthetic Hand Training for a Preschool Child

Reiko Watanabe<sup>1</sup>, Tomoyuki Ueno<sup>1</sup>, Yukiyo Shimizu<sup>1</sup>, Modar Hassan<sup>2</sup>, Yuji Idei<sup>3</sup>, Louis Ccorimanya<sup>4</sup>, Kimihisa Ishikawa<sup>1</sup>, Kenji Suzuki<sup>5</sup>, Yasushi Hada<sup>1</sup>

<sup>1</sup>Department of Rehabititation Medicine, University of Tsukuba Hospital, Tsukuba, Japan. <sup>2</sup> Faculty of Systems and Information Engineering, University of Tsukuba, Tsukuba, Japan. <sup>3</sup>Kowagishi, Tsukuba, Japan. <sup>4</sup>Faculty of Systems and Information Engineering, University of Tsukuba, Tsukuba, Japan. <sup>5</sup>Center for Cybernics Research, University of Tsukuba, Tsukuba, Japan

#### **BACKGROUND**

In recent years, the Japanese society has been exposed to myoelectric prosthetic hands for children through different media outlets, but their actual use in clinical practice is limited. In Japan, there are few environments that can produce satisfactory medical treatment and training for children to use prosthetic hands, and there is a wide disparity between regions in terms of the facilities and expertise required for such training. Improving this clinical infrastructure is a prerequisite to successful intervention.

#### ΔIM

We have had the experience of introducing and training a preschool child to a myoelectric prosthetic hand. Here we report on the progression and the after-thoughts and considerations on this case study.

#### METHOD

The subject was a 6-year-old girl with a congenital defect of the right forearm. We prescribed occupational therapy to the girl at 3 months of age as the parents expressed their desire for her to use a myoelectric prosthetic hand. We prescribed an artificial hand at the first stage, and then a myoelectric prosthetic hand (Ottobock, Electric Hand 2000). We followed the progression of the child's ability and motivation to use the prosthetic and adapted the content of training according to her interests and development stages.

#### **RESULTS**

She started using an artificial hand at 6 months and was introduced to a myoelectric prosthetic hand at 1 year 2 months. Training included visual trainings such as passively holding toys triggered by pushing a parental switch. However, at 2 years 2 months, she started to dislike the prosthesis and refused to use it for a while. We did not compel her to use the myoelectric hand; she had used only artificial hands. At 3 years 5 months, she started to notice the features and usability of the prosthetic, resumed using it, extended the wearing time, and started using it while playing and doing her activities of daily life. At the age of 5 years and 5 months she could smoothly operate the prosthetic hand with two electrodes and started using the hand at the kindergarten.

#### **DISCUSSION AND CONCLUSION**

According to previous reports, the parents' motivation, the start time of training, and the defective level are major factors for success in continuing to use myoelectric hands. In these lights, we started the prosthetic training at 1-year-old, we incorporated her parents' support, and continuously changed the content of training according to the child's development. We believe these considerations contributed to the outcome of this case. The experience presented could help guide attempting therapists to introduce myoelectric prosthetic hands to children.



# Bench-Top Assessment of Novel Designs of the 3D Printed Partial Hand Prostheses for Children

Timothy RD Scott<sup>1,2,3</sup>, Lucy Armitage<sup>1</sup>, Lauren Kark<sup>1</sup>, Gursel Alici<sup>4</sup>, Timothy Muling<sup>5</sup>
<sup>1</sup>Graduate School of Biomedical Engineering, University of NSW, Sydney, Australia. <sup>2</sup>School of Women's and Children's Health, University of NSW, Sydney, Australia. <sup>3</sup>Rehab2Kids, Sydney Children's Hospital, Sydney, Australia. <sup>4</sup>School of Mechanical, Materials, Mechatronic and Biomedical Engineering, University of Wollongong, Wollongong, Australia. <sup>5</sup>Orthotics, Sydney Children's Hospital, Sydney, Australia

#### **BACKGROUND**

Partial hand is the most common limb difference [1]. The advent of 3D printing technology has resulted in its use in our centre and elsewhere with a goal to improve upper limb function in children in a safe way. In order to determine if this goal is achieved, it is important to assess the outcomes of such innovations. We have investigated the body powered grasp and the impact on the residuum produced by novel 3D printed partial hand prostheses.

#### AIM

Our aim is to evaluate forces at the residuum and intrinsic to the grasp provided by the use of the novel partial hand prostheses with varying load.

#### **METHOD**

A bench top surrogate or imitation arm was created using a 3D printed skeletal forearm and partial hand. This was covered with simulated soft tissue. The hand residuum segment was replaceable and could be moved via motor drive to assess the variables of palmar size and position of the residuum as well as forces of wrist extension and flexion required for driving grasp. The surrogate arm and hand were instrumented using force sensors.

#### **RESULTS**

Evaluation of existing art and our novel designs were made. We compared (i) forces at the residuum produced by different distal loads. In addition, variables of (ii) palmar length and (iii) wrist position and force and their influence on prosthesis grasp force and function were assessed.

#### **DISCUSSION AND CONCLUSION**

Safety and positive impact on function are vital for the ongoing success of prosthesis interventions. We have devised a method of preliminary assessment of prosthesis interventions for the partial hand in both of these domains. Potential benefits will include minimisation of skin breakdown and optimising forearm loads in the residuum and producing useful force in the prosthesis grasp.

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## **ACKNOWLEDGEMENTS**

Financial: AMP Tomorrow Fund grant.

Clinical: Dr Adrienne Epps, Kathryn Asher, Leslie Wollin.

Engineering: Dr Nicole van der Laak.



# Development and ADL-Evaluation of the Novel Myoelectric Hand Prosthesis using Digital Fabrication Technology

Yuichiro Honda<sup>1</sup>, Hidemasa Nakamura<sup>1</sup>, Go Nakamura<sup>1</sup>, Hibiki Takami<sup>1</sup>, Mitsuru Irie<sup>2</sup>, Makoto Motoyama<sup>3</sup>, Seiji Yamasaki<sup>4</sup>, Hirokazu Takahashi<sup>5</sup>, Toru Amazutsumi<sup>6</sup>, Hiroyuki Kusai<sup>7</sup>, Nami Takenaka<sup>8</sup>, Futoshi Mizobe<sup>1</sup>, Yaeko Shibata<sup>1</sup>, Takaaki Chin<sup>1</sup>

<sup>1</sup>Robot Rehabilitation Center in the Hyogo Institute of Assistive Technology, Kobe, Japan. <sup>2</sup>Osaka Sangyo University, Daito, Japan. <sup>3</sup>Nippon Pulse Motor Co., Ltd., Osaka, Japan. <sup>4</sup>Sansei Rubber industry Inc., Kobe, Japan. <sup>5</sup>Almex Cosei Co., Ltd., Kyoto, Japan. <sup>6</sup>Amaz Techno-consultant. LLC, Sumoto, Japan. <sup>7</sup>Toyo Aluminium K.K, Osaka, Japan. <sup>8</sup>Prop Station, a social welfare nonprofit organization, Kobe, Japan

#### **BACKGROUND**

Recently digital fabrication technology (DFT), as like as 3D-Printer technology, is used with reasonable cost widely. One of appropriate target using this technology is a hand prosthesis. We have another approach with DFT to fabricate a hand prosthesis using a laser cutting machine, in order to include challenged people in this fabrication process. We grouped also various companies to realize a new concept of a myoelectric hand prosthesis from the Hyogo Rehabilitation Center/Hyogo Institute of Assistive Technology, Japan.

#### **AIM**

We aim to evaluate our novel myoelectric hand prosthesis under ADL-activities and to find improve points on the sight of the daily user of a myoelectric hand prosthesis.

#### **METHOD**

The novel myoelectric hand prosthesis has a semi-adaptive grip function. The hand structure was modified to grow up its pinch-grip force and to work quietly as compared with earlier model [1]. For the user-evaluation, the hand prosthesis was equipped by a linear-pulse-motor and test the semi-adaptive grip function with objects with ADL-activities. The objects were placed on a desk. The user holds and grips the objects in his way and evaluates the gripping-capability of the hand prosthesis. The evaluation was done by 3 classes for every object: 1) done, 2) possible with devises, 3) not done.

### **RESULTS**

The grip-force of the hand prosthesis is relatively weak, however antislipping surface of the silicon globe of the prosthesis covers the weakness of the gripping power. Most of the ADL-evaluation activities were done successfully with 1) done or 2) possible with devises. The prosthesis could not split a set of wooden disposable chopsticks.









Figure 1. Sample Scenes of ADL-evaluation: a) Suppling hot water, b) Covering with a plastic wrap, c) Wearing socks, d) Tying Shoelaces

#### **DISCUSSION AND CONCLUSION**

The user in this study is a very hard user of the myoelectric hand. He has many experiences of various myoelectric hand. We have followed his advice to improve our prosthesis. We mention also that requirements of another user may be not so high. At the same time, most user may not handle the prosthesis like himr. In order to tune the specification of this hand prosthesis, we need gather more voices of users of myoelectric hand prosthesis.

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# **Myoelectric Videogame Training Functional Outcomes**

<u>Carlos Martinez-Luna</u>, Todd Farrell, Benjamin McDonald, Nicholas Radda, Brianna Rozell Liberating Technologies, Inc., Holliston, USA

#### **BACKGROUND**

Myoelectric training is important for new patients learning prosthetic limb control.[1] Upper-limb prosthetic fittings are often not successful because the prosthesis does not provide functionality that the user expects. Myoelectric prosthetic users must develop control skills by exercising muscles. Without proper training, users cannot reliably provide suitable myoelectric signals and often fatigue quickly. A Myoelectric Gaming Interface (MEGI) system was developed to provide training by mapping myosignals to video game controls in order to improve muscle tone and coordination.

#### **AIM**

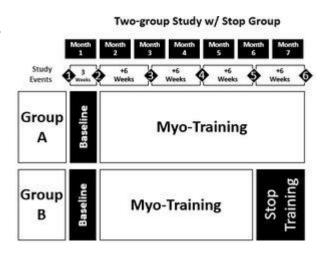
This study measured the functional effects of video game training on myoelectric control signal properties over time.

### **METHOD**

A training system was designed to leverage video-games to elicit muscle contractions typical for prosthesis control. Video-games were curated to focus on clinically-relevant contractions to train two-site skills: independent signals, amplitude range, proportional control, precision, sustainment, limb movement, contralateral coordination, switch events. Participants undergo baseline period of prosthesis recordings for comparison before training is introduced. Myo-training is introduced, and participants periodically train for periods of 15-60 minutes, multiple times a week. At interval study events, functional outcome tests evaluate prosthesis skill and functional perception. Subjects are separated into two groups; one group is tracked during a period of stopped training. The study spans up to six months of myoelectric training.

#### **RESULTS**

The study is in progress. A logging system records everyday prosthesis usage as baseline and during training. Initial baseline data from subjects was analyzed to summarize prosthesis wear time, prosthesis use time, number of actuation cycles for each device, and distribution of myoelectric signal amplitude. Prosthesis usage for a highly active myoelectric user was recorded for a week. The prosthesis use was logged in a 148-hour (6 day) window and measured powered-on 48% of the time (71 hours). During this time, electromyography was active for 1.43% of on-time. The myo signals were evaluated as percentage of full-scale span (%FFS) and demonstrated the user utilizing 67% FFS of the range of for both close and open signals.



## **DISCUSSION AND CONCLUSION**

The metrics analyzed in baseline and during training determine functional changes in prosthesis use over time. The stop period will evaluate any loss or carry-over functional effects of discontinued myoelectric training.

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#### **ACKNOWLEDGEMENTS**

Supported by USAMRMC contract W81XWH-18-C-0084. Views contained are the authors. Investigators adhered to policies regarding protection of human subjects.



# Design of the Forearm Socket at Different Stump Lengths

## Anton Kruglov

LLC Prosthetic and Orthopedic Center Scoliologic.ru, Saint-Petersburg, Russian Federation

#### **BACKGROUND**

Currently, most attention is paid to the shape of the sockets of various lower limb prosthesis. In this case, the shape of the upper limb prosthetic sockets are discussed less frequently. However, the implementation of the patient's rehabilitation potential often depends on the form of the socket. In the practice of prosthetists there is no consensus on the form of the most common truncation - the forearm.

#### AIM

Develop and test the design of the forearm socket taking into account the biomechanical features of the elbow joint and the forearm.

#### **METHOD**

A study group of 50 patients with different types of transradial amputations. Patient age from 7 to 67 years. The level of amputation from the disarticulation in the wrist joint to the short forearm stump is less than 5 cm. Patients are equipped with cosmetic and functional prostheses with sockets of maximum flexion amplitude at the elbow. We used HTV silicone with metal inserts as the attachment of the prosthesis. We used goniometry in measuring the amplitude of motion in the classical case and developed by us and also a subjective assessment of the patient.

#### **RESULTS**

As a result of this work, indications were determined for the appointment of various socket's design for upper limb prosthesis. It was used for individual sockets and for custom liners. We used X-ray analysis of changes in the functional length of the forearm stump at different flexion phases. As a result, we were able to achieve an increase in the amplitude of movement of short forearm stumps by 20–30%. With long stumps and disarticulations in the wrist joint, we managed to maintain normal pronation and supination. Subjectively, patients positively evaluated the new design of the socket. An increase in the amplitude of movement was noted against the Background of better fixation.

#### **DISCUSSION AND CONCLUSION**

Search and discussions about the introduction of new materials and design of prosthetic sockets of the upper extremities will make the most of the rehabilitation potential of users of prostheses. The introduction of soft and durable materials will increase the comfort of using the prosthesis. These materials should be implemented in parallel with the development of the design of the socket.



# **DEVISED the Harness Design for TRanshumeral Myoelectric Hand Prosthesis - A Case Study**

<u>Aya Masagaki</u><sup>1</sup>, Hiroshi Hashimoto<sup>2</sup>, Hono Morimitsu<sup>1</sup>, Miwa Suzuki<sup>1</sup>, Shouta Nishihara<sup>3</sup>, Sayaka Suzuki<sup>3</sup>, Yuji Honda<sup>3</sup>, Noriko Watanabe<sup>3</sup>, Naoshi Ogata<sup>3</sup>

<sup>1</sup>Kawamura Gishi Co. Ltd, Tokyo, Japan. <sup>2</sup>Pacific Supply Co. Ltd, Osaka, Japan. <sup>3</sup>Teikyo University, Tokyo, Japan

#### **BACKGROUND**

Transhumeral myoelectric prostheses have seen increasing popularity in Japan. Due to the weightiness of myoelectric terminal device, not only socket fitting but also suspension system design is very important. However, the design of effective socket suspension systems for transhumeral myoelectric upper limb prostheses has not been reported yet.

#### AIM

The aim of this study is to investigate the effectiveness of three types of suspension systems for transhumeral myoelectric hand prostheses.

#### METHOD

The case was of a 39 year-old male (Height: 165cm, Weight: 85.6kg). His occupation was sales. He suffered a transhumeral amputation due to a train accident. The length of residual limb was 8cm. Initial rehab was carried out including video image training. The following prostheses and suspension systems were fitted and evaluated:

Prosthesis #1: body-powered transhumeral, socket: suction, elbow: E-500, pulley: KP1-6, hand: V/O hand, suspension: figure 8 harness.

Prosthesis #2: myoelectric hand transhumeral, socket: suction, elbow: 12K44, hand: i-limb. Suspension #1: figure 8 harness. Suspension #2: shoulder supporter type. Suspension #3: soft harness.

#### **RESULTS**

Three types of socket suspension systems were designed, constructed and evaluated (Table 1).

	Figure 8	Shoulder Supporter	Soft harness
Cable control	Δ	×	×
Shoulder ROM	0	×	Δ
Socket suspension	Δ	0	0
Axilla comfort	×	0	0
Heat	0	×	0

○ : very effective ○ : effective △ : partly effective × : not effective
 Table 1. Comparison of three types of socket suspension systems

## **DISCUSSION AND CONCLUSION**

Figure 8 harnesses enable user to control the locking/unlocking of the elbow unit. However, if the socket becomes loose due to changes in stump volume, the lock released itself due to the heavy weight of myoelectric prosthesis. Shoulder supporters were very effective for suspension, but limited the ROM at the shoulder. Soft harnesses had superior socket suspension and comfort on the axilla. In conclusion, the soft harness was the best suspension system among the three suspension in this case.

### **ACKNOWLEDGEMENTS**

We thank Mr. K and all the people supporting our team.



## **Development of a Fabric-Based Functional Shoulder Disarticulation Prosthesis**

<u>Tullathorn Tulatharn</u>, Kazuhiko Sasaki, Gary Guerra Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Sirinaj Hospital, Mahidol University, Bangkok, Thailand

#### **BACKGROUND**

Shoulder disarticulation is an amputation level which is the removal of an individuals' limb through the shoulder joint or because of a congenital anomaly and is rare. Reports from a major prosthesis center in Thailand show only 1% amputation types. The conventional socket design is often met with problems such as poor perspiration, heavyweight, restricted limb motion, and overall bulkiness which can lead to the abandonment of device.

#### AIM

To develop a new shoulder disarticulation prosthesis design using fabric-based materials. To illustrate the use and experience of the use of the fabric socket in 1 shoulder disarticulation patient.

#### **METHOD**

One healthy shoulder disarticulation patient with who had experience using a shoulder disarticulation prosthesis at least 1 year was cast and fit with a designed fabric shoulder socket by one certified prosthetist. Outcomes measures administered were after an accommodation period; modified Box and Block Test (BBT), Socket comfort score and an informal unstructured patient interview were used to evaluate, socket design, user satisfaction, and device efficiency.

#### **RESULTS**

The fabric socket design (Figure 1) was composed of: Fabric based socket made from Ressel mesh fabric which a local affordable material. The Ressel mesh is breathable allowing some elongation which the patient saw as comfortable during use. The stability of socket and harness attachment area was achieved through use of a bar reinforcement system and fitting adjustment was done by tightening the fabric straps. A plastic frame socket was the connection fabric socket and prosthetic components. Outcome measures evidenced a transmission efficiency of 87%, BBT of 33.6 pieces and socket comfort score of 8.5 marks. The patient noted positive comfort, light-weight, breathability and effectiveness in use.

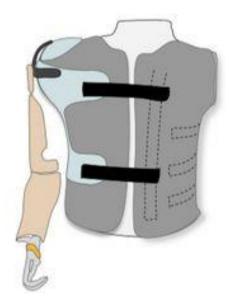


Figure 1. The fabric-based shoulder disarticulation prosthesis socket

## **DISCUSSION AND CONCLUSION**

Shoulder disarticulation is a rare amputation level seen in clinical practice. The complexity of shoulder prostheses is extremely high because technology availability and socket designs are challenging, requiring experience. The development of shoulder fabric-based socket has promise in reducing reduce the aforementioned problems by simplifying the design and fabrication procedures and reducing costs. The results of user satisfaction and performance were positive, however, this is an initial design iteration and continued design and evaluation are required.

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## **ACKNOWLEDGEMENTS**

The authors acknowledge the support and contribution of Sirindhorn School of Prosthetics and Orthotics (SSPO).



# Predicting Compensatory Movements of Upper Limb Prosthesis Users using Motion Capture Analysis and Virtual Modelling

<u>Chung Chua</u>, Ian Ashcroft, Ruth Goodridge University of Nottingham, Nottingham, United Kingdom

#### **BACKGROUND**

Current upper limb prostheses are generally unable to provide the functionality which amputees desire from their devices. A contributing factor to this is that there is a lack of effective evaluation methods to measure upper limb prostheses performance to aid their design. Current standards of using time-based tasks are inadequate as they do not take compensatory movements of the prosthesis user into account. An effective design feedback loop is therefore needed to improve upper limb prosthesis functionality.

#### AIM

This study aims to use motion capture analysis, mapped onto a kinematic model of the prosthesis user and their device, in order to predict their compensatory movements.

#### **METHOD**

The compensatory movements of prosthesis users performing the Southampton Hand Assessment Procedure (SHAP) are measured and characterised using a motion capture suit. The prostheses tested include but are not limited to: Split Hook, enAble Raptor Hand, and an in-house design. Design features of the terminal devices will influence the body to move in different ways. Able-bodied volunteers were tasked with completing the SHAP with each terminal device via a prosthesis simulator. A kinematic model was then constructed from the results of the motion capture analysis to understand and predict the effect that particular design features have on motor strategy.

#### **RESULTS**

It is expected that prostheses with Degrees of Freedom (DoF) that replicate forearm pronation/supination, wrist flexion/extension and thumb abduction will result in fewer compensatory movements. Due to the redundant DoF of the musculoskeletal system of the upper body, there are several motor strategies a prosthesis user can ultilise, typically involving excessive shoulder and trunk motions. Design features such as thumb abduction should allow the user to better position the prosthesis to grasp a wide range of shapes. The kinematics of a hand prosthesis can then be modelled based on its range of motion and influence, and linked to a set of induced movements as measured by the motion capture suit. The similarity of the mechanics of new terminal devices can then be compared to this kinematic model, and used to predict how similar the compensatory movements will be.

#### **DISCUSSION AND CONCLUSION**

This research aims to create a tool to allow engineers and clinicians to predict the compensatory movements which an upper limb prosthesis will induce. Providing the opportunity to design prostheses with optimised motor strategies; improving their functionality and ease of use.



# Comparison of the Dynamic Balance between in Individuals with Transradial, Transhumeral Amputation and Healthy Individuals

Elif Kirdi, Ali İmran Yalçin, <u>Özlem Ülger</u>, Gül Şener, Semra Topuz Hacettepe University, Ankara, Turkey

#### **BACKGROUND**

Individuals with upper extremity amputations have some postural asymmetries. The postural asymmetries are one of the factors affecting dynamic and static balance.

#### AIM

To compare of the dynamic balance between in individuals with transradial and transhumeral amputation and healthy individuals the aim of the study.

#### **METHOD**

13 with transradial, 11 with transhumeral amputation and 24 healthy individuals were the participants of the study. Dynamic balance was assessed by using star excursion balance test. This test requires the patient to balance on one leg while reaching with the other leg in eight different directions.

#### **RESULTS**

There were no difference in age, height and body weight between groups (p>0,05). When compared three groups, there was statistically difference only in medial direction while standing with amputated side (p<0,05). When post-hoc analysis applied, it was shown that there was difference between transradial amputees and healthy participants.

### **DISCUSSION AND CONCLUSION**

The study showed that in individuals with upper limb amputations have good dynamic balance without prosthesis. It may be caused that transradial amputees may have some compansations while doing the test procedure. It is recommended to evaluate dynamic balance with objective systems.



# Realtime Automatic Control Signal Adjustment Algorithm for Pediatric Myoelectric Prosthesis Controller

Kengo Ohnishi<sup>1</sup>, Kimihiro Hayashi<sup>1</sup>, Sayaka Fujiwara<sup>2</sup> <sup>1</sup>Tokyo Denki University, Hiki, Japan. <sup>2</sup>The University of Tokyo, Tokyo, Japan

#### **BACKGROUND**

Myoelectric prosthesis is effective to promote bimanual actions. However, myoelectric signals are weak and narrow banded communication make it more difficult to tune and train for the young children with upper limb deficiency. In addition, conventional myoelectric sensors for pediatric prosthesis operation is diverted from adult, and therefore relatively large for child's arm.

#### AIN

The object of this research is to develop a myoelectric prosthesis controller specialized for child to reduce the rejection ratio. The target is to develop an algorithm to compute myoelectric prosthesis operation signal with reduced manual gain adjustment.

#### **METHOD**

RT-method is applied to compute the pattern difference between myoelectric signal at resting stage and activation stage. The reference sample data collected is compared to the current sampled data of myoelectric signal, and similarity of their data dispersion and linearity pattern are computed to determine the output signal. IRB approved experiments were conducted to operate ottobock DMC hand. The RT-method myoelectric signal processing and full-wave rectification smoothed signal processing using two 10mm\*10mm size 2-pole electrode myoelectric sensors on the extensor and flexor muscle. The myoelectric prosthesis was operated by a 5-y.o. able-body subject after informed consent.

#### **RESULTS**

With the sensor mounted on the arm at the same site, the operation signal computed with the RT-method had average response time 1.01s for opening and 1.31s for closing, which was 30% of the time for traditional full-wave rectification smoothing process. The average of raw myoelectric signal's peak-to-peak using proposed and traditional signal processing were 383 and 352 for opening, 186 and 353 for closing, respectively. The average of raw myoelectric signal's level exceeding the threshold using proposed and traditional signal processing were 26 and 30 for opening, 10 and 24 for closing, respectively. The activation level is similar or smaller with RT-method compared with the traditional full-wave rectification smoothed signal.

# **DISCUSSION AND CONCLUSION**

With shorter response time and similar or lower muscle activation level for operating the hand opening/closing, the myoelectric prosthesis operation burden is lower with the proposed method. Child subject is 1 and not appropriate to draw scientific conclusion, yet, the signal processing includes adjustment to each individuals signal pattern. With the reference data updated while donned, the method has potential of reducing the barrier at the initial installation adjustment.

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## **ACKNOWLEDGEMENTS**

This research was supported by MEXT Private University Branding Project of Tokyo Denki University.



## Priority of Hand-shaped Prosthesis Design Based on Analysis of Daily Hand Activities

<u>Gai Higuchi</u><sup>1</sup>, Kengo Ohnishi<sup>1</sup>, Kohei Tsuda<sup>1</sup>, Hiroyuki Matsubara<sup>2</sup>, Isamu Kajitani<sup>3</sup>
<sup>1</sup>Tokyo Denki University, Hiki, Japan. <sup>2</sup>Hokkaido University of Science, Sapporo, Japan. <sup>3</sup>National Institute of Advanced Industrial Science and Technology, Tsukuba, Japan

#### **BACKGROUND**

Prosthetic hands with multiple degrees of freedom are aesthetically pleasing and capable of selecting prehensile forms, however, are not fully useful in daily living activities which is caused by the lack of design consideration of hand-arm coordination within tasks. A functional hand design priority should be based on evidence gained from observation and analysis on the coordination of reach and grasp motions of target objects.

#### AIM

In this research, we record daily hand activities and assess the terminal devices of hand-shaped from the results are analyzed to confirm the cadence of grasp used.

#### METHOD

The upper limb motions of daily-life desktop operation are recorded with body mounted video camera. The compensatable motion is combined, since the grasping directions are rotated by movement of shoulder joint and elbow joint. This calculation result is taken as the contribution rate to ADL. We define the grasping directions of hand-shape and compare the contribution rates is calculated. We compare hand-shaped with high degrees of freedom with the traditional prosthetic hands.

#### **RESULTS**

The hand with high degrees of freedom refers to bebionic hand. bebionic hand has the function to change lateral position by moving the thumb passively. The traditional prosthetic hand refers to MyoHand. The contribution rate of bebionic hand is 10.6% or 21.5% at opposition pinch, when rotate by wrist unit, the rate increases to 32.1%. At lateral pinch, the rate is 5.0% or 21.1%, when rotate, the rate increases to 26.5%. The contribution rate is increased by 5.6 points or 0.4 points due to changing the thumb position. Wrist rotation has a great effect on the contribution rate. The other hand, the contribution rate of MyoHand hand is 10.6% or 21.5%, when rotate, the rate is 32.1%. The traditional hand is only in the same grasping direction as rotation even if lateral pinch.

## **DISCUSSION AND CONCLUSION**

The bebionic hand can increase the grasping directions because it has a different direction at opposition from the traditional hand. However, if grasping at opposition is the same with the traditional hand, there is no difference between the hand-shaped with high degrees of freedom. Furthermore, it was found that addition of the wrist joint function to hands is given priority over changing the thumb position.



# Free Paper – Poster Presentation Seating & Wheelchair

#### 5.087

# Wheeled Chair Seating Approach for Pelvis Partial Removal Person

Toshihiro Kawai Saitama Rehab. Center, Ageo, Japan

#### **BACKGROUND**

There are few reports about hip disarticulation, pelvis cutting in half and pelvis partial removal. In particular, the report about a wheeled chair seating is very little more than an artificial leg. The case which raised assistance for 6 years will be reported.

#### AIM

Continuation support of movement to a pelvis partial removal person was experienced, so a problem of the support process will be reported.

#### **METHOD**

Artificial leg for hip disarticulation was supported about attachment after cutoff, but it isn't done to walk long time. Wheeled chair seating position maintenance equipment for new sockets was made. 6 years rise and trouble has formed once again. The weight increased 10 kilogram very, and wheeled chair seating position exclusive socket was nonconformity. When repairing it, the cushion was changed, so it was corrected.

#### **RESULTS**

A puncture of a cushion passed for 3 years since it was made by contact with an air room structure cushion and a sitting position exclusive socket, and frequented. Every time it was repaired, the kind of cushions was changed. We held a meeting publicly and manufactured special wheeled char seating position exclusive socket. The ready-made ordinariness type wheelchair with the load-proof was chosen.

### **DISCUSSION AND CONCLUSION**

After short distance movement by an artificial leg and an artificial leg are removed. A wheeled chair seating position exclusive socket, it's loaded, and, they were being used appropriately according to the wheelchair movement, the starting working and the living situation, but a problem occurred by badness of an exchange at the time of increase of body weight and repairing. It's a problem about increase of body weight, but solution method can't be found specifically.



# Free Paper – Poster Presentation Footwear

## 5.088

# The Association Between Osteoarthritis Stage and Response to the Lateral Wedge Insole to Medial Meniscus Extrusion in the Knee Joint

Yosuke Ishii<sup>1,2</sup>, Masakazu Ishikawa<sup>3</sup>, Hiroshi Kurumadani<sup>1</sup>, Toru Sunagawa<sup>1</sup>

<sup>1</sup>Health Sciences Major, Graduate School of Biomedical & Health Sciences, Hiroshima University, Hiroshima, Japan. <sup>2</sup>Department of rehabilitation, Shimura hospital, Hiroshima, Japan. <sup>3</sup>Department of Orthopedic Surgery, Graduate School of Biomedical & Health Sciences, Hiroshima University, Hiroshima, Japan

#### **BACKGROUND**

The difference of medial meniscus extrusion ( $\Delta$ MME) between non-weight- and weight-bearing conditions has been presented as a risk factor for the progression of knee osteoarthritis (KOA), especially in the early stage.[1] Therefore, minimizing  $\Delta$ MME during daily activity could be a critical approach to prevent KOA progression. However, the association between KOA stage and response to  $\Delta$ MME after application of LWI has not been elucidated

#### AIM

To investigate the effect of LWI on  $\Delta$ MME in the early and late stage KOA and reveal the correlation between KOA stage and  $\Delta$ MME after application of LWI.

#### **METHOD**

Twenty-three patients with KOA were recruited and divided into two groups according to the Kellgren-Lawrence (K/L) grade: the early KOA group (K/L = 2, n = 13) and the late KOA group (K/L > 2, n = 10). The MME was evaluated ultrasonographically with the patients in three positions: 1) non-weight-bearing (NWB), 2) weight-bearing (WB) without LWI and 3) WB with LWI. We evaluated two conditions of  $\Delta$ MME, *i.e.* obtained from NWB and WB without LWI conditions ( $\Delta$ MME  $^{LWI}$  (-)) and NWB and WB with LWI conditions ( $\Delta$ MME  $^{LWI}$  (-)). These measurements performed at two time points: initial office visit as the baseline and three months postintervention with LWI.

### **RESULTS**

The  $\Delta$ MME in the early KOA group was significantly greater than that in the late KOA group at baseline (p < 0.01). In the early KOA group,  $\Delta$ MME <sup>LWI (+)</sup> at baseline significantly decreased compared with  $\Delta$ MME <sup>LWI (-)</sup> at baseline (p < 0.01) ( $\Delta$ MME <sup>LWI (-)</sup>, 1.07 ± 0.49 mm;  $\Delta$ MME <sup>LWI (+)</sup>, 0.46 ± 0.44 mm; p < 0.01), and the  $\Delta$ MME <sup>LWI (+)</sup> at 3 months postintervention still presented a significant smaller value ( $\Delta$ MME <sup>LWI (+)</sup>3M, 0.31 ± 0.39 mm; p < 0.01). In contrast, in the late KOA group, there was no significant difference between  $\Delta$ MME at baseline and 3 months postintervention.

## **DISCUSSION AND CONCLUSION**

We confirmed that the early stage of KOA is more responsive to the LWI in reducing  $\Delta$ MME. A previous study on the response of LWI reported a correlation between the amount of decreasing MME with LWI and greater  $\Delta$ MME.[2] Then, the greater  $\Delta$ MME in the early KOA group might explain the response of the LWI. Our study suggests that interventions of LWI aimed at minimizing the  $\Delta$ MME might have a potential to delay OA progression in early stage of KOA.

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## Effects of Custom Carbon Fiber Foot Plate on Normal Gait: a Case Report

Yuparat Premprasopchok<sup>1</sup>, Wareerat Petmunee<sup>2</sup>
<sup>1</sup>Siriraj Hospital/SSPO, Bangkok, Thailand. <sup>2</sup>SSPO, Bangkok, Thailand

#### **BACKGROUND**

Nowadays CFFP already commercially available yet so **expensive in Thailand**, and there is lack of information related to the **designing of CFFP and different fiber orientation** that might have an **effect on speed during walking and energy consumption during jogging.** Therefore, it is worthwhile to find the ways to manufacture the CFFP locally and reflect the application before applying to real patient. We hypothesized the energy consumption would be reduced and walking speed would be increased on using of CFFP.

#### ΔIM

The aims of this study were to **establish the prototype of a carbon fiber foot plate** and to **examine the effect of CFFP** on **walking and jogging** in the healthy subject.

#### **METHOD**

CFFP fabrication in each design. Then clinical test and data analysis. During outcome measurement, in healthy subjects had performed **Twenty-meter walk test** and **metabolic cart test**. Participant begins with 5 minutes resting, then he had completed three 5 minutes trials without CFFP as the baseline and with each CFFP prototype with three different velocities (6.5, 8.5 and 10.5 km/h) on the treadmill level. We measured the average rate of O2 consumption and CO2 production during each trial and **calculated the rate of metabolic consumption over the average of last two minutes** in each trial using **Weir equation: 16.29 O2 + 4.57 CO2.** 

#### **RESULTS**

We had compared the metabolic cart test with the baseline to find out the energy cost improvement in a subject. we got a conclusion and the percentage reduction in each prototype, with different speed, shows that prototype A can **reduce energy** in every speed and maximum reduction at 44.26% at speed8.5 Km/h, B and C can **reduce energy expenditure** start at 8.5km/h. And Prototype A is the most helping to reduce energy expenditure.

The prototype considerably **increased the walking speed.** Notably, the range of speed is increased compared with his baseline (without a prototype) and shows prototype B was the most recommend one for using with able people because it can provide comfort and **improves speed** in **normal walking.** 

## **DISCUSSION AND CONCLUSION**

Footplate which has **rigidity features** in the whole part of the foot plate will be good for persons who need to jogging everyday .who secretly hates running since it gives a **reduction of energy expenditure**. Comparing with any other available foot plate, CFFP has a lower range of price, also it can **increase walking speed** yet **decrease energy expenditure** which is important to balance the metabolism of the body and make energy more efficient while perform **jogging**.

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# The Effect of Heel Height on Plantar Pressures with Dorsiflexion Limitation

<u>Yuri Kanaoka</u>, Akihiro Miyamoto, Shuhei Takayama, Taichi Sano, Katsuhiro Konishi Sawamura Prosthetics and Orthotics Service Co., Ltd., Kobe, Japan

#### **BACKGROUND**

Abnormal plantar pressure is common problem for diabetic patients, and it is presumed that abnormal plantar pressure is concerned with foot ulceration. Previous studies have reported that limited dorsiflexion of ankle joint increase peak planter pressures at forefoot.[1] In general, any footwear is prescribed for abnormal plantar pressure to improve. However not much is available on the effect of heel height on planter pressure with limited dorsiflexion of ankle joint.

#### AIM

The purpose of this study was to determine change of planter pressure with limitation in both ankle dorsiflexion by addiction heel height; instead of improvement in limited ankle dorsiflexion.

#### METHOD

Subjects: Three healthy people participated in this study. Dorsiflexion-limiting equipment set limitation angle at 0 degree, had been made by the thickness 4mm polypropylene and EVA sheet.

Footwear: Same three shoes with different heel height: standard heel height to metatarsal-phalangeal joint (5mm, approx. 1 degree), 10 degree heel height to metatarsal-phalangeal joint, and 10 degree wedge to tip of the shoe.

Apparatus: F-scan system.

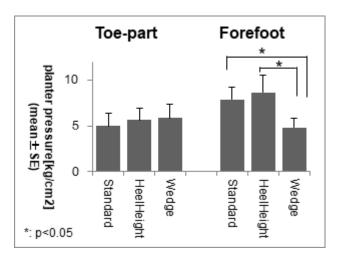
Procedures: Participants walked 10m with three previously footwear, we recorded average peak plantar pressure of six walking cycles without first and last walking cycles.

Data analysis: The data were examined using one-factor repeated measures analysis of variance and post-hoc comparisons.

### **RESULTS**

Figure 1. Planter pressure of toe-part and forefoot Average peak plantar pressure of toe-part and forefoot with three previously footwear illustrated in Figure 1.

- (1) Toe-part: There were no significant differences among three foot wears by one-factor repeated measures analysis of variance test.
- (2) Forefoot: There were significant differences among three foot wears by one-factor repeated measures analysis of variance test(p<0.01). As post-hoc comparisons, Shaffer's procedure was used to compare between each foot wears: Plantar pressure with standard heel height was significant higher than 10 degree wedge to tip of the shoe (p<0.05). Planter pressure with 10 degree heel height to MP joint was significant higher than 10 degree wedge to tip of the shoe(p<0.05). There was no significant difference between standard heel height and 10 degree heel height to MP joint.



# **DISCUSSION AND CONCLUSION**

Only 10 degree wedge for 0 degree limited dorsiflexion made forefoot plantar pressure decrease, it indicated effect of addiction mobility to dorsiflexion, and importance of maintenance of extension range of motion at MP joints while stance phase. However this study has any problem such as number of participants and only one-type wedge. In conclusion, this study suggests the effect of 10 degree wedge, however further studies are needed in order to clarify influence of it.

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# A Case Study; Comparison of Efficiency between CAD-CAM Method and Foam Impression Method of Foot Orthosis

Marisa Amattayakul, Kanyanut Kaewkiti, Phensuda Thaweephong, Saloottra Kla-arsa Sirindhorn School of Prosthetics and Orthotics, Bangkok, Thailand

#### **BACKGROUND**

The function of FO is redistributed plantar pressure of the foot deformity. In clinical practices, there are three methodologies to made FO (I) the plaster casting (II) the foam compression (III) computer-aided design and computer-aided manufacturing(CAD-CAM) method. The CAD-CAM system resolved problems such as casting error and time-consuming processes.[3] It provided a pressure distribute pattern similar to the foam impression method [2] but nowadays is still lack of information on the effectiveness of CAD-CAM foot orthosis.

### AIM

This study was to compare the effects of foot orthosis that made from CAD-CAM and Foam impression method.

#### **METHOD**

One participant with a diagnosis of flexible pes planus(grade 1) evaluation by the foot pressure graph, female age 57 years old, activity is walking and standing (7-8 hour/day). Used CAD-CAM method by the 3D scan of foot and loaded it to design in Delcam software program and carved out by the milling machine by the EVA foam block. And used foam impression box for casting, modification, fabrication by CPO. Compare the efficiency by 1) Foot sensor array (FSA), 2) Two-minute walking test, 3) berg balance scale test (BBS), 4) Visual Analogue Scale test (VAS).

#### **RESULTS**

The foot pressure that measure by the used force sensing array (FSA) shows the pressure distributions on the plantar area the FO orthosis that made from the method of foam impression was better to off-load weight from heel to other areas than FO from CAD-CAM method. There is no significant difference between both methods in the velocity of the 2-minute walking test. Both methods of FO are provided stability via the CAD-CAM FO is got 54 scores and foam impression FO is got 52 scores. The subject feels comfortable got 0 scales with foam impression FO show in visual analogue pain scales and CAD-CAM got 3 scores when walking for 6 minutes.

#### **DISCUSSION AND CONCLUSION**

The CAD-CAM method was easier when scanning the shape of the foot, faster and cleaner. The foam impression method has to use more hand skill experience for quality and accuracy than CAD-CAM method. However, there was a limitation of materials have to find the closest property for CAD-CAM FO while another method is able to choose material in different layer because hardness and softness were one of the factors to pain relieved.

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#### **ACKNOWLEDGEMENTS**

We would like to express the sincere to the director of SSPO and supervisors for all the support to reassure the knowledge.



# The Difference in Dynamic Balance with and without Ankle Brace during Single-Leg Lateral Drop Jump Landing

<u>Shogo Sakai</u>, Yukio Urabe, Junpei Sasadai, Shuhei Numano, Noriaki Maeda Hiroshima University, Hiroshima, Japan

#### **BACKGROUND**

The ankle brace is designed to limit the range of ankle joint during exercise. In addition, Maeda et al. reported that wearing the semi-rigid ankle brace improves dynamic balance compared to soft ankle brace during single-leg front jump.[1] However, people wearing ankle brace feel anxious for ankle eversion more than dorsiflexion. Therefore, it was necessary to investigate the effect of lateral jump landing.

#### AIN

This study aimed to investigate the difference in dynamic balance with and without ankle brace during single-leg lateral drop jump landing and help to choose appropriate ankle brace in sports activity.

#### METHOD

Eleven healthy men participated in this study. The subjects performed single-leg lateral drop jump landing from stand with a height of 20 cm to 20 cm lateral side on the non-dominant leg with and without wearing semi-rigid ankle brace (A-1, SIGMAX). Center of pressure (COP) path length divided foot length (% foot length) during 20 ms – 200 ms, 20 ms – 1000 ms after landing and peak mediolateral ground reaction force (mlGRF) divided body weight (N/kg) were measured using a force platform (TFP-4040A ver. 1.2.5.1, Technology Service, Ltd). Paired t-test was performed between conditions for statistical analysis.

#### **RESULTS**

As result of this study, COP length after landing 20 ms - 200 ms were 74.2  $\pm$  18.2 % with an ankle brace and 77.92  $\pm$  16.8 % without ankle brace, and there was no significant difference in each condition (p = 0.11). COP length after landing 200 ms - 1000 ms were 116.4  $\pm$  16.4 % with an ankle brace and 123.8  $\pm$  16.1 % without ankle brace, and there was a significant difference in each condition (p < 0.01). Peak mIGRF were 8.8  $\pm$  4.1 N/kg with an ankle brace and 11.7  $\pm$  5.1 N/kg without ankle brace, and there was a significant difference in each condition (p < 0.01).

### **DISCUSSION AND CONCLUSION**

Our results suggested that wearing ankle brace decrease COP length and peak mIGRF during a single-leg lateral drop jump landing. Decreased COP length would result from improving the sense of joint position by wearing ankle brace.[2] In addition, a biomechanical study has reported that ankle joint inversion velocity decreased by wearing an ankle brace.[3] It implied that ankle brace worked centrifugally during lateral drop jump landing.

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# Free Paper – Poster Presentation **Paediatrics**

## 5.093

# Clinical Trials of APPNA Orthopedic Rehabilitation Institute (A.O.R.I) Foot Abduction Brace and **Comparison with DENNIS Brown Splint**

Zeshan Zahid<sup>1</sup>, <u>Muhammad Imran</u><sup>2</sup>, Rehan Ali Malik<sup>3</sup> <sup>1</sup>SPORS, Rawalpindi, Pakistan. <sup>2</sup>Specialized Orthotics Prosthetics & Rehabilitation Center, Rawalpindi, Pakistan.

<sup>3</sup>AdvanceCare Medical Equipment, Abu Dhabi, UAE

#### **BACKGROUND**

Clubfoot is one of the commonest congenital deformities especially in developing world. More than 100,000 babies are born worldwide each year with congenital clubfoot. The main goal of treatment is to achieve a functional, pain-free, planti-grade foot with good mobility and without surgery. For the purpose, Ponseti method is a very successful followed by an effective orthotic intervention (brace). The Ponseti method is safe and effective treatment for congenital idiopathic clubfoot, and radically decreases the need for extensive corrective surgery.

#### AIM

To develop an effective, efficient and cost effective foot abduction brace for the maintenance of corrected clubfoot deformity mainly for developing countries.

#### **METHOD**

Non randomized interventional study. Study subjects were selected by convenient sampling method. It was Therapeutic intervention/ experimental study without strict protocol with sample size of 110 patients divided in study and control group. 30 patients using AORI FAB were included in study group where as data of 80 patients using DB Splint with information on variables under study was included in control group. Study was performed in Rawalpindi division at Benazir Bhutto Hospital Rawalpindi. It was 3 years study from 1<sup>st</sup> April 2011 to 30 March 2014.

#### **RESULTS**

Deformity relapsed in 15% of patients in control group but it was not relapsed in study group where P-value was <.05. Skin damage occurred in almost 50% of patients in control group but it was about 20% in study group with P-value = <.05. Residual adduction was reported in >50% of patients of patients in control group and it was about 0% in study group with P-value = <.001 which is highly significant. Fabrication Cost of AORI Foot Abduction Brace was >50% less than the DB Splint.

### **DISCUSSION AND CONCLUSION**

We found that Foot holding is much better in AORI FAB because its AFO type design that also keeps foot in desired dorsiflexed position. AORI FAB is light in weight and dynamically support Dorsi-flexion with its Polypropylene abduction bar as compared to D.B splint. We also observed that cycling is very easy with this brace. In conclusion we can say that AORI FAB could be a better substitute of DB Splint with more compliance in low income countries.

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## **ACKNOWLEDGEMENTS**

This study was done at APPNA Orthopeadic Rehabilitation Institute. Brace was designed by Orthotics Prosthetics student Zeshan Zahid in 2011.



# Free Paper – Poster Presentation Psychosocial Issues / Quality of Life

## 5.094

# Factors Associated with Patient Satisfaction in the UERMMMCI-Philippine School of Prosthetics and Orthotics, Teaching Clinic

<u>Maria Jobel Meñez</u>, Gene Kenneth Flores, Kishea Maglangit, Julienne Catherine Ramirez University of the East Ramon Magsaysay Memorial Medical Center Inc., Quezon City, Philippines

### **BACKGROUND**

Patient satisfaction surveys have been measured throughout the years to improve services of clinics and different institutions. In the Philippines, the UERMMMCI-PSPO offers prosthetic and orthotic services through its

Teaching Clinic. However, patient satisfaction data has not been established. Various literatures revealed that array of factors may influence the overall service of the clinic.

#### **AIM**

Determine the association between patient characteristics and satisfaction, and to determine the level of satisfaction of patients in the UERMMMCI-PSPO Teaching Clinic.

## **METHOD**

The researchers utilized a quantitative, and descriptive-inferential study design. A final sample size of 135 patients was gathered. Data were collected through recorded phone calls of assessors using a 16-item measurement tool to interview participants in a two-week period. The measurement tool was categorized into three sub-domains, namely, Device, Service and Facility Satisfaction in a 4-point Likert Scale. A scoring system was also established to identify satisfied and dissatisfied participants. Prevalence Rate Ratio was used to determine association and Chi-Square to determine significance. This study gained approval from UERMMMCI-Research Institute of Rehabilitation Sciences – Ethics Review Committee.

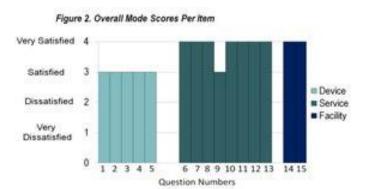


Table 1. Association and Significance per Domain of Demographic and Clinical Characteristics (Type of Device)

DOMAIN	PRR	P-VALUE
Device	1.05	0.64
Service	0.86***	0.01**
Facility	0.99	0.92

#### **RESULTS**

The teaching clinic received a high overall satisfaction rate of 93%, however, the device domain (questions 1-5) and the decision making of the P&O intern (question 9) were rated with a lower score ("3"). The device domain pertains on device comfort, visual appearance, device fit, ease of donning and doffing, and device weight. Prosthetic participants demonstrated a significant (p=0.01) and negative association (0.86). Prosthetic patients were less satisfied with the services than orthotic participants.

\*\*\* negative association

## **DISCUSSION AND CONCLUSION**

Patients are generally satisfied with the services of the teaching clinic however; improvements with device and service domain should be emphasized. Thorough student evaluation prior to internship should also be imposed to further develop knowledge, attitudes, and skills. Prosthetic users also reported dissatisfaction with the services which included complaints of undergoing gait training and waiting time for device fabrication. These problems should be taken into account for future clinic developments.

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#### **ACKNOWLEDGEMENTS**

The researchers would like to thank UERMMMCI- Research Institute for Health Sciences Ethics Review Board, the Nippon Foundation and Exceed.



# AAC Support, A Post Orthotic Treatment as Diseases Progress: A Case Study

Nami Tanaka, Hiroshi Ishihara, Hirokazu Sugiyama, Hiroki Tomiyama Hashimoto Artificial Limb Manufacture Co., Ltd, Okayama, Japan

#### **BACKGROUND**

Patients with ALS, Muscular Dystrophy, and other progressive diseases would go through phases and do face difficulties in their daily lives and representing themselves as diseases progress. Augmentative and Alternative Communication<sup>1</sup> (hereinafter referred to AAC) is one of the most effective solutions for the patients to express themselves and perform daily along with orthoses and other assistive technologies yet this field of technology requires different supports from different occupations.

#### ΔIM

To fill in needs from the patients in the assistive field through AAC point of view and to explore a necessity of roles in different occupations surrounding the patients.

#### METHOD

Two cases shown in RESULTS are well represented that how AAC delivers an interaction to the patients with the environment and different occupations have worked on to provide the support well. The interaction referred to here is performed, for example, by gestures, sign languages, facial expressions, or linguistic methods such as alphabets, symbols, or even computer based artificial voices through a spectrum of a simple letter board to a high-tech computer. Depending on the environment, progresses of the diseases, or the needs from the patients, all the AAC support vary, and of course a cooperation from the different occupations is necessary to achieve all the requirements from the patients.

#### **RESULTS**

Table 1 shows brief information about the patients with diseases and the process of AAC introductions with different occupations involved to provide the well fitted devices and settings for the cases. All the cases were thoughtfully considered like, an operation site on a body for an input device and the device itself were chosen according to an occupational therapist's opinion in case A, which lead a stable input operation eventually. In case B, an AAC device was placed on her wheelchair table and her BFO<sup>2</sup> was attached to the wheelchair arm support to operate an input device so that the production and the attachment of BFO was thoughtfully done and monitored by an orthotist.

	Diagnosis	sex	Age	AAC device	occupations invoved	Purpose
case A ALS		male	48	communication	occupational therapist	selection of operation site and input device
	ALS				nurse	placement of AAC device
	6				device provider	communication
case B	AL C	female			prosthetist & orthotist	BFO for input device usage
	ALS	temale	44	smart phone	occupational therapist	placement of AAC device
				8	device provider	communication

#### **DISCUSSION AND CONCLUSION**

Needs from the patients would change as these diseases progress and AAC is one of the solutions to provide more ease to their daily lives. Through the process of AAC introduction, many different occupations such as orthotists, physical/occupational therapists, nurses and family have involved deeply to explore the desired result for the patients and yet it is still something to seek for the way to involve and cooperate each other even smoother and more effectively.

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# Prosthesis Materials and Physical Activity: Key Research Directions in Lower Limb Prosthetics Informed by Patient and Public Involvement

Elena Seminati<sup>1,2</sup>, Dafne Zuelima Morgado Ramirez<sup>3,4</sup>, Matthew Young<sup>2</sup>, Martin Twiste<sup>5,6</sup>

<sup>1</sup>University of Bath, Department for Health, Bath, UK. <sup>2</sup>CAMERA Centre, University of Bath, Bath, UK. <sup>3</sup>Interaction Centre, Computer Science, University College London, London, UK. <sup>4</sup>Global Disability Innovation Hub, London, UK. <sup>5</sup>School of Health and Society, University of Salford, Salford, UK. <sup>6</sup>United National Institute for Prosthetics & Orthotics Development (UNIPOD), Salford, UK

#### **BACKGROUND**

Thermal homeostasis of the residuum when inside a prosthesis users's socket is key for long-term utilisation of prostheses. Over 53% of prosthesis users feel discomfort from excessive heat/sweating. Increased environmental temperature of few degrees and physical activity can trigger discomfort and make the prosthesis loose. Characterisation of residuum temperature and humidity related issues remains necessary to understand currently failing and well-working

solutions.[1] However, it is essential to understand the context from the user and prosthetist's perspective.

#### **AIM**

The aim was to identify the needs and challenges of lower limb prosthesis users and prosthetists when managing environmental temperature and choosing prosthesis material and physical activity to reduce the effect of temperature and humidity inside the socket.

Table 1. Patients Characteristics

Gender	Age (years)	Level	Cause	Years since Amputation
Female	55-60	Trans-tibial	Infection	27
Female	40-50	Trans-femoral	Trauma	31
Male	95	Trans-femoral	Trauma	75
Male	75	Knee disarticulation	Trauma	44
Male	<30	Trans-tibial	Neurological	3
Male	85	Trans-femoral	Vascular	<1

## **METHOD**

Informal scoping interviews were carried out to determine the research direction towards enabling the design of a prosthetic interface guided by determinants of wearing comfort (relevant to temperature and humidity). Informal discussions within a Public and Patient Involvement (PPI) framework with six unilateral amputee patients (Table 1) and two prosthetists (with over 20 years' experience) was organised at one of the UK's prosthetics service centres.

## **RESULTS**

The main causes of discomfort when wearing a liner, socket and prosthesis were shared by all amputee patients. Humidity caused the biggest discomfort while high environmental temperature did not appear to be an issue. Physical activity increases sweating, yet physical activity is dependent on participant age and the types of activities performed (e.g. sport) but independent from the cause of amputation. Trans-femoral amputees consider sweating a secondary issue to prosthesis fitting and risk of falling. It was agreed that no proper solution currently exists that prevents issues related to humidity. Some amputees regarded sockets made of metal and liners made of leather as forgotten past yet efficient materials used in prosthetics that were better at managing temperature and humidity. Current dynamic monitoring of the interface parameters is difficult due to a lack of appropriate measurement.

# **DISCUSSION AND CONCLUSION**

Findings provide essential information on the direction that research should take in the following ways: a) need to investigate how different materials distribute temperature and humidity in different environmental conditions and under different levels of physical activity; and b) influencing the direction of our study in terms of identifying the need to create a framework to instrument socket liners of different materials for the purpose of characterisation and to support the development of suitable future liners.

### REFERENCES

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## **ACKNOWLEDGEMENTS**

Thanks to the patients/prosthetists who took part in the discussion and to CHRERISH-DE UK Digital Economy Crucible (Swansea University).



# Improvement of Quality of Life (QOL) for Females with Amputation through the Establishment of a Support Community

Midori Ito<sup>1</sup>, Yukiko Matsui<sup>2</sup>

<sup>1</sup>Kawamura Gishi Co., Ltd., Daito-shi, Japan. <sup>2</sup>Pacific Supply Co., Ltd., Daito-shi, Japan

#### **BACKGROUND**

Annual prevalence of lower limb amputation is 1.6 persons [1] per 1 billion in Japan. Among our prostheses customers, male-to-female ratio is 74:26. Individuals with amputation seldom have opportunity to communicate with the other individuals with amputation after discharge from hospital. In recent years, some groups have been established for running with prostheses. However, there have been no communities established specifically for females with amputation.

#### AIM

The aim of this study is to examine the possibilities of improvement of QOL (quality of life) for females with amputation through the establishment of a support community.

#### **METHOD**

We established a community exclusively for female prosthetic users and held social gatherings two times. Our staff members for these gatherings, including the CPO, were also only females to facilitate a more comfortable atmosphere for the participants. The participants could share their experiences and knowledge, especially on female-specific issues. We also encouraged the participants to avoid casual dress [i.e. wearing heels or Zori (special shoes for Kimono) (Kimono are difficult to wear with prostheses on their own)], using feet with heel height adjustment features.

#### **RESULTS**

Four females participated in the first gathering and shared their experiences and a foot with a heel height adjustment feature was introduced to them. Five females participated in the second gathering to challenge wearing Zori and Kimono with the adjustable foot (figures 1 and 2). The satisfaction ratio for both gatherings was 100%. All participants answered that they wanted to meet the other females with prostheses as a reason for their participation. Another reason for the participation included "because the event was limited to females". As for the second gathering, 80% of the participants answered, "I have wanted to wear Kimono."



figure 1 figure 2

#### **DISCUSSION AND CONCLUSION**

According to the questionnaires, it became apparent that females with prostheses have a desire to communicate with others. Although it is exceptionally difficult for prosthetic users to walk with Zori and Kimono, it became apparent that they would like to challenge it if communal support were available. Through these results, it was clarified that connecting with associates through community would assist them to overcome limitations caused by prostheses and help them improve their QOL.

#### **REFERENCES**

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# Lower Limb Prosthetic Users, Activity Restrictions and Prosthesis Wear-time - Preliminary Results

Inger Marie Starholm<sup>1</sup>, Vegar Hjermundrud<sup>1</sup>, <u>Gitte Flindt Hilding</u><sup>2</sup>, Hege Lund<sup>2</sup>, Jette Schack<sup>1</sup>, Terje Gjøvaag<sup>1</sup> Oslo Metropolitan University, Oslo, Norway. <sup>2</sup>Unicare Bakke AS, Halden, Norway

#### **BACKGROUND**

The ability to do daily activities and recreate outdoors is an important determinant of health-related quality of life (HQoL) of persons with lower limb amputation.[1] The impact of a lower limb amputation on the HQoL of Norwegian prosthetic users, has, however, never been investigated. Thus, there is a lack of information on how Norwegian prosthetic users adapt to different restrictions imposed by a lower limb amputation

#### AIM

This study was designed to investigate the HQoL of Norwegian persons living with transtibial amputation (TTA) and specifically investigate how a TTA affect Activity Restrictions in this population.

#### METHOD

In an ongoing investigation, twenty-five persons (15 males, 10 females) with an unilateral transtibial amputation, mean (SD) age 59 (11) years, were enrolled as participants in this preliminary study. The participants' scores on different psycho-social and activity restriction domains were investigated using the Trinity Amputation and Prosthesis Experience Scale-Revised (TAPES R) questionnaire. Here we report only The TAPES-R scores for

the Activity restrictions domain (10 questions). The scores were summarised using descriptive statistics as appropriate. Associations between prosthetic wear-time and subscores for activity restrictions was investigated by one-way ANOVA (IBM SPSS statistics, v24)

#### **RESULTS**

The participants' prosthetic wear time was divided into three clusters; less than 8 h/day, between 8 and 12 h/day and more than 12 h/day. Mean (SD) Activity Restriction subscores for persons within

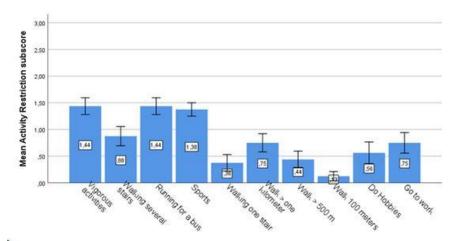


Figure 1. Mean (SE) scores on each of the 10 items in the Activity restrictions domain (Higher scores indicate larger restrictions)

each wear-time cluster were 1.34 (0.49), 0.85 (0.40) and 0.67 (0.35), respectively. Compared to persons using the prosthesis less than 8 h/day, the subscore was significantly lower for persons using the prosthesis more than 12 h/day (p < 0.017), i.e. these persons felt less restricted. Looking at the scores on each question within the Activity Restrictions domain (Fig 1), we observe that the greatest restrictions are associated with the more vigorous activities. The least affected activities are walking short distances and performing hobbies.

## DISCUSSION AND CONCLUSION

This is the first study investigating psychosocial adjustments to prosthetic use in Norwegian TTA. Our results suggest that Activity Restrictions are less pronounced for persons using their prosthesis most of their awake hours. Conclusion: The loss of a lower limb may have a substantial effect on the person's HQoL. Thus, the perceived restrictions on performing more demanding physical activities may in turn reduce the HQoL of this group of TTA.

## **REFERENCES**

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# Predicting Adherence to Prescribed Health Behaviours in Conditions Requiring Orthotic Management: A Meta-Analysis of Theory of Planned Behaviour Investigations

Christine McMonagle<sup>1</sup>, Susan Rasmussen<sup>2</sup>, Mark Elliott<sup>3</sup>

<sup>1</sup>NCPO, Department of Biomedical Engineering, University of Strathclyde, Glasgow, United Kingdom. <sup>2</sup>School of Psychological Sciences and Health, University of Strathclyde, Glasgow, United Kingdom. <sup>3</sup>School of Psychological Sciences and Health, University of Strathclyde, Glasgow, United Kingdom

#### **BACKGROUND**

Poor adherence to orthotic interventions is a significant concern. Therefore, it is important to understand the reasons why people may or may not adhere to recommendations regarding use of their orthoses. Psychological models of behaviour are potentially useful because they provide a framework for researchers to identify causes of behaviour that might constitute effective targets for interventions. The Theory of Planned Behaviour (TPB),[1] is one such theory which has been applied across a wide range of health behaviours.

#### **AIM**

The aim of this meta-analytic review was to integrate research, which investigates the utility of the Theory of Planned Behaviour in predicting or explaining adherence to prescribed health behaviours in health conditions, which may give rise to an orthotic intervention.

#### **METHOD**

An electronic literature search using key data-bases was conducted to identify relevant articles. A random effects meta-analysis was used to calculate correlations between the components of the TPB, using a weighted mean effect size, r. Calculations were made using Comprehensive Meta-Analysis (v.2) software [2]. Heterogeneity across studies was assessed using Q and I<sup>2</sup> statistics. The following moderating variables were investigated: (a) adherence behaviours; (b) health condition (c) study design (d) measurement of adherence; (e) compatibility of measures; (f) conceptualisation of perceived behavioural control (PBC). Finally, meta-analytic path analysis was carried out to simultaneously test theoretical predictions using the weighted average correlations from the meta-analysis.

### **RESULTS**

Twenty-three articles met the inclusion criteria. All of the weighted mean correlations were statistically significant. A large effect size for the PBC-intention correlation; a medium-large effect size for the attitude-intention and intention- behaviour correlations; and a medium effect size for the subjective norm-intention and PBC-behaviour correlations were seen. TPB relationships were moderated by compatibility of the TPB measures, and the conceptualisation of the PBC measure. However, different health behaviours or conditions did not moderate the strength of correlations between the TPB constructs. The path analysis showed that the TPB accounted for 28.3% of the variance in intentions and 14% of the variance in adherence behaviours. Attitudes and PBC were significant predictors of intention and intention was a significant predictor of behaviour. Intention was shown to mediate the effects of attitude and PBC on behaviour in line with TPB theory.

#### **DISCUSSION AND CONCLUSION**

This study demonstrates that the TPB is applicable across a range of different health conditions and in investigating different health adherence behaviours. This study therefore offers support for using the TPB as a theoretical framework for investigating adherence to orthotic devices. Identification of methodological moderators, will guide the design of a future investigation which aims to test the efficacy of the TPB in understanding adherence to use of AFOs in people with stroke.

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#### **ACKNOWLEDGEMENTS**

This study was supported by the Orthotics Education and Training Trust (OETT).



# Free Paper – Poster Presentation Outcome Measurements

#### 5.100

# Effect of Virtual Reality Training on Balance Outcomes in Traumatic Lower limb Amputees in Lebanon

<u>Didier Cooreman</u><sup>1</sup>, Rami Abbas<sup>2</sup>

<sup>1</sup>ICRC, Bogota, Colombia. <sup>2</sup>Beirut Arab University, Beirut, Lebanon

#### **BACKGROUND**

Lower limb amputations are frequent consequences of war wounds and traumatic accidents. For an effective prosthetic rehabilitation, Physiotherapy (PT) interventions are essential. Balance training and weight bearing exercises are usually part of the treatment plan to reduce the risk of falling. Recently, virtual reality (VR) training is being increasingly used in neurorehabilitation, since its effects in improving balance and walking abilities in patients with stroke have by now been acknowledged. However, the use of VR-based training is less documented.

#### **AIM**

The project is a part of a research study to assess the effects of adding VR training (by using Kinapsys® System) to the Traditional Prosthetic post Fitting training on balance outcomes for traumatic lower limb amputees in three participating centers.

#### **METHOD**

In a single blinded randomized control trial, 3 months after being fitted with their prosthesis, unilateral lower limb amputee will assign to the whole period of intervention either to an experimental group (VR with TPF) or to a control group (TPF) (3 sessions per week for 6 weeks). The VR training focused on specific tasks related to lower limb exercises in standing position with the prosthesis such as football, obstacles, multidirectional movement, avoidance exercise with movement, ....

#### **RESULTS**

Between April 2017 and June 2018, 22 were committed to the whole period of intervention. In total, 12 patients were allocated to VR with TPF and 10 to TPF. The preliminary results showed improvement in some outcome measures according to the descriptive analysis of the available results (The recruitment of participants is still open till end of November 2018 to allow more data collection). Inferential statistical analysis will be done by January 2019 to detect statistical significance of the collected data.

## **DISCUSSION AND CONCLUSION**

It could be concluded that adding VR training to the traditional post fitting rehabilitation is a promising area of intervention, also considering the very positive acceptance displayed by patients so far.

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### **ACKNOWLEDGEMENTS**

This study was approved by the IRB committee of Beirut Arab University under the following approval code: 2017H-0032-HS-R-0239.



# **Evaluation of Corrective Moment of Measuring Orthosis using CB Brace for Knee Osteoarthritis**

Yasuhiro Mine<sup>1</sup>, Tamotsu Sakima<sup>2</sup>

<sup>1</sup>Toyo University, Saitama, Japan. <sup>2</sup>Sakima Prosthetics & Orthotics Co., Ltd., Okinawa, Japan

#### **BACKGROUND**

we have previously performed gait analysis by placing eight markers on the primary positions of the CB brace and using the optical three-dimensional motion capture analysis system. Results showed that the arm of the brace at medialis cruris, one of the four arms of the CB brace, was found to be the involved in correction of the internal torsion of the knee.

#### AIM

In this study, we successfully developed such the measurement orthosis to measure the corrective force.

#### **METHOD**

We developed the measurement orthosis using the CB brace. The sensor fixture, which contains the load cell, can be attached to the arm joint of the CB brace at the medialis cruris. As mentioned earlier, the arm of the brace at the medialis cruris is involved in correcting the internal torsion of the knee, and the vertical force to the sagittal plane of the brace arms during walking can be measured by the load sensor. Three different arm lengths of the brace at the medialis cruris, "short", "normal", and "long", were used for the experiment. Synchronous measurement by this device was performed with the optical three-dimensional motion capture analysis system.

#### **RESULTS**

The results of synchronized measurements with the motion capture are shown in the Figure 1. The test subject was diagnosed with bilateral knee osteoarthritis with varus alignments. In comparison with the right leg, the left leg had a higher degree of varus (worse malalignment). One of the characteristics of the knee OA with alignment abnormality is the momentum sideways movement of the knee. sometimes called lateral thrust, which occurs suddenly in between the early stance phase of walking and the load response. It is caused by the floor reaction force and the varus torque moment. The developed device was feasible measuring





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Figure 1:The results of synchronized measurements with the motion capture

the lateral thrust, and this is the first device that facilitates the measurement of the lateral thrust during walking.

#### **DISCUSSION AND CONCLUSION**

The future possible development includes the use of Bluetooth and other devices to make the system wire-less and be able to monitor the condition of the knee during the walk through a portable terminal. Also, we are aiming to make selections of suitable knee bracing device specifically for each person, as well as supporting the conscious improvement of one's gait by monitoring the generation of lateral thrust, which exacerbates the knee OA.

# **REFERENCES**

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#### **ACKNOWLEDGEMENTS**

This study was supported financially by the Precise Measurement Technology Promotion Foundation.



# The Me-Amputee Study: Exploring Meaningful Outcomes of Recovery Following Lower Limb Amputation and Prosthetic Rehabilitation: The Patient's Perspective

<u>Chantel Ostler</u><sup>1,2</sup>, Alex Dickinson<sup>2</sup>, Cheryl Metcalf<sup>2</sup>, Maggie Donovan-Hall<sup>2</sup>

1 Portsmouth Hospitals NHS Trust, Portsmouth, United Kingdom. 2 University Of Southampton, Southampton, United Kingdom.

#### **BACKGROUND**

Defining and measuring a successful outcome following lower limb amputation is discussed extensively both within the current evidence base and UK clinical practice. A number of reviews have been published describing the different measures that have been developed for use with this population with over 35 measures included.[1-3] It is clear there is a lack of consensus around which outcome measures should be used and how to select them.

#### AIM

The aim of the study was to understand what people with lower limb loss feel are meaningful outcomes following prosthetic rehabilitation and how they should be measured.

#### **METHOD**

Despite a growing focus on the importance of the patients experience in healthcare today it is currently unknown how people with limb loss view recovery and success following amputation. This unique and critical viewpoint could offer interesting insights on the important factors that we as clinicians or researchers should be considering when we select outcome measures. The theme of patient involvement running through this study has also extended to the development and design of the research and people who have experienced limb loss have been involved in the study from the outset.

#### **RESULTS**

40 participants were recruited from limb fitting centres, social media and limb loss supporting organisations across the UK. Data were collected using focus groups and interviews with people who had undergone a lower limb amputation in the last five years and had completed prosthetic rehabilitation. Thematic analysis has been used to identify key themes from the data which describe the most meaningful aspects of recovery following lower limb amputation from the viewpoint of a person with limb loss. The themes also highlight potential areas of focus for outcome measurement within prosthetic rehabilitation and give us a unique perspective on what is 'success'.

#### **DISCUSSION AND CONCLUSION**

Understanding what recovery means to people following amputation can help to guide prosthetic rehabilitation and inform the selection of outcome measures to evaluate interventions. Identifying key measures will help to reduce measurement burden and inform the rehabilitation community of what outcomes are important to people with lower limb loss. We hope this will provide a unique patient led perspective for a consensus on the use of outcome measures which is grounded in the experience of amputees.

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#### **ACKNOWLEDGEMENTS**

Ethics: IRAS ID 248850.Funders BACPAR and EPSRC/NIHR (EP/R014213/1).



# Implementation of the Amputee Mobility Predictor as a Gold Standard in the Clinical Rehabilitation of Amputees in Israel

<u>Yael Dotan Marom</u><sup>1</sup>, Anat Kristal<sup>2</sup>, Rachel Tiktinsky<sup>1</sup>, Michal Nehama<sup>1</sup>, Hanania Sharon<sup>1</sup>, Oren Barzel<sup>1</sup>, Itzhak Siev-ner<sup>3</sup>

<sup>1</sup>Sheba Medical Center, Ramat Gan, Israel. <sup>2</sup>University of Miami, Miami, USA. <sup>3</sup>Ministry of Health, Jerusalem, Israel

#### **BACKGROUND**

In 2002 Professor Robert Gailey developed and published the "Amputee Mobility Predictor" (AMP).[1] This functional assessment was developed to predict the potential of using a prosthesis (AMPnoPRO), determine the functional level (K0-K4) and assist in assigning of the prosthetic prescription. In 2015 the AMP was translated to Hebrew by Mrs. Anat Kristal. The AMP translation was implemented in the working routine of the Orthopedic Rehabilitation Department at Sheba Medical Center, Israel.

#### AIM

To implement the AMP as gold standard in the clinical rehabilitation of amputees in Israel.

#### **METHOD**

First phase: "Forward translations" of the AMP to Hebrew by two Physical Therapists.

Second phase: Final evaluation of the translations was done by an experts' committee.

Third phase: "Back translation" of the AMP from Hebrew back to English by two other Physical Therapists.

Forth phase: The experts' committee evaluated both the English translations in comparison to the Hebrew version and approved the Hebrew final version. Finally, working with the Hebrew version of the AMP at our department. We evaluate each patient in the gait training and whenever there is doubt about the amputee's ability to complete the fitting of prosthesis.

#### AMP SCORE: Admission / Release 65 60 55 50 40 Admission 35 ■ Release 20 15 10 K4 K3 82 K1 KO

Figure 1. AMP admission and release scores

#### **RESULTS**

138 subjects were evaluated. Their admission and release scores are presented in figure 1. 8 didn't finish their gait training due to medical

problems. 81 improved their score (more than 3.4 points is considered an improvement beyond the Minimal Detectable Change.[2] 2 subjects with a score which indicated K0 mobility received a program to improve their skills, reassessed after 2 months and improved to K1. They received a prosthesis and finished successfully their gait training.

# **DISCUSSION AND CONCLUSION**

The translation was found efficient and easy to use and was integrated into functional evaluation of amputees in our department. It was found useful for clinicians to conduct an objective evaluation of the amputee's functional capacity and assists the physicians with prosthetic prescription. The AMPnoPRO assisted with the decision on admission for gait training. The AMP will provide an excellent tool for multi-center research and professional collaborations.

#### **REFERENCES**

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# Free Paper – Poster Presentation Developing Countries

#### 5.104

# A Community Rehabilitation Project for the Limb Deficient Children in Rural India

#### Tarit Datta

Taki Thuba Rehabilitation Welfare Society, Taki, India. National Institute for Locomotor Disabilities, Kolkata, India

#### **BACKGROUND**

Birth of a child with congenital anomalies is a traumatic event for the parents as well as the community. In Indian subcontinent the mother is a house wife and has to shoulder other responsibilities in the family and community which is lacking due to the larger involvement and engaged with the child and the parents becoming non supportive in the event of treatment.

#### AIM

There is no systemic treatment of the limb deficient child in the Indian subcontinent. This project was undertaken to develop a guideline to provide systematic support and to improve the functional abilities in the community for the limb deficient children.

#### **METHOD**

In this project we short listed ten severely limb deficient child from a particular remote and rural areas of east India bordering with Bangladesh and treated as an individual basis at home on a specially developed software support system which provides reminder in a periodical intervals to maintain the follow up and intervention. Among ten limb deficient children we prepared different assistive devices for ADL, some are severely four limb deficient children.

#### **RESULTS**

The simple applying of assistive technology for these children is not adequate. We struggled to improve quality of life and participation in a dignified way. We developed such environment at home and continuous monitoring, technical support and follow up by the professionals and same time the report card of functional development seen the significant improvement. The advantage of individual consideration in the rehab process through a scientific management tool will certainly support to collect the research data and information for the research and evidence based practice.

#### **DISCUSSION AND CONCLUSION**

An effort has been made to document a philosophy for management of the limb deficient child. Particular emphasis is placed on using all function in tactile areas and set up a suitable guideline for poor and developing countries. We identified ten different categories of limb deficient child under this method and observed significant outcome and improvement in access to rehabilitation as well as fulfilment of our goal that participation in all.

### **ACKNOWLEDGEMENTS**

All community worker, parents, local Municipality involved in this project.



# Situational Analysis of the Rehabilitation Workforce, Specialized in Assistive Devices, in Niger

<u>Lamine Oumarou</u><sup>1,2</sup>, Amadou Abdoulaye<sup>1,2</sup>, Amadou Bassirou<sup>1,2</sup>, Elia Bernabeu Mira<sup>3</sup>

<sup>1</sup>Hopital National de Niamey (HNN), Niamey, Niger. <sup>2</sup>Association Nigérienne des Professionnels de l'appareillage Orthopédique (ANPAO), Niamey, Niger. <sup>3</sup>Comité International de la Croix-Rouge (CICR), Niamey, Niger

#### **BACKGROUND**

People with disabilities face challenges accessing basic rehabilitation health care. Niger had ratified the United Nations Convention on the Rights of Persons with Disabilities (CRPD) that outlines the global necessity to meet the rehabilitation needs of people with disabilities, but this goal is often challenged by the undersupply and inequitable distribution of rehabilitation workers and structures

#### AIM

Analysis of the current situation of the rehabilitation workforce, specialized in assistive devices, in Niger and identify the gap linked with the estimated needs, aiming at steering further research and policies on developing the workforce

#### **METHOD**

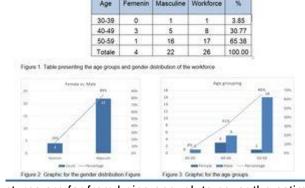
The study was organized in 2 phases:

- 1) A situational analysis has been conducted through a data analysis of the existent rehabilitation workforce working in the 4 orthopaedic workshops (organized by gender, age, location and profession)

  Selection criteria: all the persons working in the 4 P&O workshops of the country were included: 1 technical director, 1 administrative manager, 1 receptionist, 8 P&Os, 1 Physiotherapist, 6 P&O Assistants, 1 PT Assistant, 3 shoe makers, 2 cleaners.
- 2) An estimation of the Needs and triangulation with the existent capacity.

#### **RESULTS**

The rehabilitation workforce specialized in orthopedics in Niger is: 1) aging with most of its workers over 50 years old (17/26); 2) lacking gender equity (4/26) 3) very centralized in the cities (16/26 in Niamey) 4) and lacking on multidisciplinarity (only 1 PT, no social worker or occupational therapist)



The current workforce and structures are far from being enough to cover the estimated demand (0,5% of general population (ISPO)) in their areas of coverage (11% in Niamey, 1% in Zinder) and the remaining provinces are left without services.

#### **DISCUSSION AND CONCLUSION**

Results highlight the need of conducting planning on human resources in rehabilitation and increasing the resources and importance attributed to it. Not doing so will lead to the deterioration and even a further lack of services, which are already insufficient for the estimated demand. The lack of incorporation of other disciplines and overall gender unbalance suggests possible red flags on the quality and barriers to the access of woman and economically vulnerable persons to services.

#### **ACKNOWLEDGEMENTS**

To both the National Hospital of Niamey (HNN) and the International Committee of the Red Cross (ICRC).



# An Assessment of the Status of Orthotics and Prosthetic Services and Patient Health Needs in South Africa

Mariëtte Deist<sup>1,2,3</sup>, Courtney Marshall Snyman<sup>4,1</sup>

<sup>1</sup>ISPO, Pretoria, South Africa. <sup>2</sup>South Africa Orthotics and Prosthetics Ass, Pretoria, South Africa. <sup>3</sup>Health Professions Council of South Africa, Pretoria, South Africa, Pretoria, South Africa. <sup>4</sup>SAOPA, Pretoria, South Africa

#### **BACKGROUND**

During the 2006 United Nations convention on the rights of persons with disabilities, it was stated that optimal access to and use of high quality functional assistive devices and technologies at affordable rates are the responsibility of all relevant government institutions [1]. The government healthcare system in South Africa for Orthotics and Prosthetics have not been formally assessed to establish the needs of patients and work circumstances of practitioners. Our B-Tech study group is taking on this task.

#### ΔIM

This study aims to conduct an analysis of the public sector orthotics and prosthetics services including patients and the workforce

#### **METHOD**

A Mixed method are used. Data collection are at main prosthetic and orthotic centres in nine provinces in South Africa. Gauteng have four big centres and because of the population in this province, all four centres will be covered.

Four main areas:

Patient related

- 1. Quantitative: Epidemiology, types of assistive devices, budget allocation and waiting lists
- 2. Qualitative: A questionnaire to determine the satisfaction of service delivery and assistive device satisfaction related to quality of daily living

Practitioners

- 3. Quantitative: Determining demographics and employment status
- 4. Qualitative: Looking at the work environment and satisfaction around working conditions

### **RESULTS**

Statistics will mostly be descriptive. The productivity of each centre, the supply and demand of patients and practitioners per province and the satisfaction of both will be determined. We will also determine if there is a relationship between the supply deficit and size of the workforce, the number of patients served and disabled population.

### **DISCUSSION AND CONCLUSION**

Cross-sectional analysis and predictive studies of future prosthetic needs are vital in the planning and implementation of effective healthcare services and pragmatic allocation of resources [2, 3]. We hope to contribute to our country by providing the statistics around the needs identified in the study.

#### **REFERENCES**

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### **ACKNOWLEDGEMENTS**

To the Tshwane University Of Technology that provided the platform for the B-Tech students to do a B-Tech project.



# Successful Rate of Prosthetics and Orthotics Services in Siriraj Hospital Post ISO 9001:2008 Accreditation

Wichuda Siriphanyakamakul, <u>Chonthicha Chaemkhuntod</u>, Yasmin Nutchanlong, Nisarat Opartkiattikul Sirindhorn School of Prosthetics and Orthotics, Bangkok, Thailand

#### **BACKGROUND**

Thai Foundation for the Disabled aided by Thai Government and United Nation established the first prosthetics factory under Orthopaedic department at Siriraj hospital in 1960. In 2002 Siriraj Hospital, Mahidol University initiated the bachelor degree of prosthetics and orthotics where in graduates started to serve the country and continue the legacy to teach. Sirindhorn School of Prosthetics and Orthotics started to provide services to the patients since 2012 and got accredited by ISO 9001: 2008.

#### AIM

This research aims to study the successful rate of Prosthetics and Orthotics services in Siriraj Hospital post ISO 9001:2008 by exploring rates and patient satisfaction on devices and services.

#### **METHOD**

A retrospective descriptive study was performed by explored the qualitative data of follow up results to gather the usage rate of the devices and the occurrence of the relevant device problems to the patients who received prosthetics and orthotics services at Siriraj Hospital between the year of 2016-2018. The data of patient satisfaction on the device and service gathered during 2013-2017 was also included to analyze the success rate of services and satisfaction of the patient Post ISO 9001:2008 accreditation.

#### **RESULTS**

I. The result of 1,010 patients who received follow up during the year 2016-2018. The amount of 313 patients received prosthetics services and 697 received orthotics services. The average usage rate of prosthetics devices is 78% and orthotics is 83% while 6.1% of prosthetics users and 3.6% of orthotics users who are not using their devices. The three main problems of prosthetic device rejection which are loose fitting, uncomfortable socket fit and broken, and three main problems for orthotic device rejection which are painful, tight fitting and leaving pressure marks on the skin.

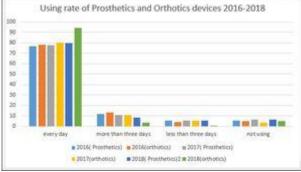


Figure 1. The usage rate of Prosthetics and Orthotics devices at Siriraj Hospital during 2016 -2018.

II. The result of device satisfaction and services during 2013-2017 is average 84 percent: 2013 is 71%, 2014 is 81.8%, 2015 is 86.5%, 2016 is 91.3% and 2017 is 89.6%.

# **DISCUSSION AND CONCLUSION**

Prosthetics and Orthotics services in Siriraj Hospital were established many decades ago to serve disabled people in Thailand by the trained PO technicians. In early 2006, the country started to produce Certified Prosthetist and Orthoptist to integrate into the services in order to improve the quality of services to the patients. The result device usage rate and patient satisfaction provide an increasing trend Post ISO 9001: 2008 accreditation. This study can use as a baseline for future related scientific study.



# Working Motivation between Prosthetists and Orthotists who are Working in Charity and Noncharity Clinic Setting Models in Cambodia

Odom Teap

Exceed Worldwide, Phnom Penh, Cambodia

#### **BACKGROUND**

In Cambodia, the prosthetic and orthotic services have been provided free of charge since 1989. For future sustainability in the field of prosthetics and orthotics, in the last three year, the Exceed Worldwide has established a private clinic for affordable patient and introduced a cost recovery system in one of the Exceed's charity clinic. Presenting new working model can impact to staff's performance positively and negatively.

#### AIN

This paper, presents a research project about the staff motivation performance comparison between charity and non-charity clinic setting.

To study staff's working motivation between the charity and non-charity clinic setting model in Cambodia.

#### **METHOD**

the questionnaire related to staff motivation's scale was developed and circulated to prosthetists and orthotists as well as bench worker whose experience working in the charity's clinic's and currently move to work in the private clinic. The data was collected and analyzed and some comments were listed down.

#### **RESULTS**

From the research outcome, staff working motivation is increasing dramatically when moving to work at the non-charity working clinic. Prosthetist and Orthotist feels more value acknowledge by clients when they come to work at the non-charity clinic. They are willing to take more responsibilities with their work. Several P&O mention "I feel my profession is not for free" They can see also client's responsible and involvement in the treatment rehabilitation are increasing. Bench worker are also willing to taking more responsibilities to their work for assembling, finishing and repairing the prosthetic and orthotic device. They feel their work are paid by client as other profession, not being paid by donors.

### **DISCUSSION AND CONCLUSION**

The level of staff's working motivation at the charity and non-charity setting are quite different. Most of the staff are motivated with their work when they feel their works are paid by client who they are working for, not being paid by donors.

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# Free Paper – Poster Presentation Education

#### 5.109

# Barriers in Implementing Evidence Based Practice in Physical Rehabilitation

Zia Ur Rehman<sup>1,2</sup>, Hufsa Shahzad<sup>3</sup>

<sup>1</sup>Pakistan Institute of Prosthetic & Orthotic Sciences (PIPOS), Peshawar, Pakistan. <sup>2</sup>ISPO Pakistan, Peshawar, Pakistan. <sup>3</sup>Rawalpindi Medical University (RMU), Rawalpindi, Pakistan

#### **BACKGROUND**

Health professionals value research as a means of improving clinical practice, but they face number of practical barriers in performing evidence based practice (EBP). This study provides empirical data about the underlying barriers relating to evidence-based practice. According to the study conducted by Stevens K. in 2013 on topic. The Impact of Evidence-Based Practice in Nursing and the Next Big Ideas and his result showed that the impact of EBP has echoed across

nursing practice, education, and science.

#### AIM

The aim of this study is to gather information from practitioners and highlighting the underlying barriers to the implementation of EBP in physical medicine and rehabilitation.

To determine the impact of EBP in improving the existing clinical practices.

#### **METHOD**

This study was conducted in Allied Hospitals of Rawalpindi Pakistan. In this descriptive cross sectional design study 50 healthcare professionals were

	Frequency	Percent
insufficient time	6	12.0
lack of research skills	2	4.0
lack of understanding statistical analysis	4	8.0
lack of Internet at workplace	7	14.0
lack of journals in hard copies at workplace	1	2.0
lack of seminars/conferences	12	24.0
the time on job is not sufficient to read research findings	9	18.0
there is resistance to make changes in the work setting by seniors	3	6.0
lack of interest	5	10.0
Total	50	100.0

included, who were working in the field of physical Medicines & rehabilitation (PM&R), like orthopedic doctors, physiotherapist, Orthotist and Prosthetist. The responses of the study participants were recorded on customized questionnaire. Participants were selected through convenient sampling technique. Both genders of Healthcare professionals were included in the study. Statistical package for social sciences (SPSS) version 21 was used to enter and analyze data. For all the catagorial variables like frequency and percentage was calculated by using on SPSS version 21.

## **RESULTS**

Fifty participants were included in the study. Out of 50 participants 26 were male and 24 were female. There were 17 orthopedic doctors, 18 orthotist prosthetist and 15 physiotherapists. Mean working experience were 2 years. All the participant agreed that evidence based practice improve the quality of patient care. Following barriers were identified by the study participants:

# **DISCUSSION AND CONCLUSION**

The survey results revealed ten primary factors affecting evidence-based practice. These include time constraints, workload and system demands, limited relevant evidence from research, and gaps in skills and knowledge required to perform evidence-based practice. The limitations of the study were small sample size, short duration of study & study location. Finding from this study showed that practitioners were positive towards evidence based practice, but they practiced it to a small extent, due to insufficient time at workplace and lack of seminars.

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# Blended Learning - A Novel Approach for Passing the P&O National Examination in Japan

### Kyoko Kamada

Kobe College of Medical Walfare, Sanda Campus, Sanda City, Japan

#### **BACKGROUND**

In Japan, a license is necessary to work as a prosthetist and orthotist and a national examination system is used to acquire the license. The examination began in 1987 and so far 5,323 prosthetists and orthotists across Japan have passed and received their P&O licenses. The P&O program in our school was established in 1997 and 636 students have gone onto pass the national examination.

#### AIM

Our aim was to establish a foundation of knowledge using information and communication technology (ICT) to increase students' exposure to exam questions with the goal of improving learning efficiency.

#### **METHOD**

We adopted the blended learning method by using e-learning for our national examination preparation class. Students can see exam questions from past exams in the e-learning platform and are able to do some questions individually that are selected by the teacher. After the practice exam, the students research and explain incorrect questions and then attend a review lecture to better their understanding. We checked the number of logins over a period of time for each student and compared that number to the exam results of each student. We found there is a proportional relationship with the exam results and the number of logins.

#### **RESULTS**

We were able to confirm the relationship between the number logins to the e-learning platform and the results of the students' grades. Students who had a higher number of logins saw their results improve. Several students who received a good score used a book of questions from past exams instead of the web service. Students who had a lower number of logins to the e-learning platform or students who did not login at all saw their score drop or remain the same. We confirmed that these students did not use a book of questions from past exams. However, even though some students used the web service, they still received bad scores. In these cases, the students logged into the e-learning platform only a short time before the practice exam.

#### **DISCUSSION AND CONCLUSION**

We identified a correlation between the number of logins to the e-learning platform and the results of practice exams. By doing this, we helped students with poor grades use our e-learning platform to prepare effectively and increase their scores. Providing an online environment to study for the National exam on their own gave the students the ability to study anytime and anywhere.



# The Survey for Researching the Difference in what the Students Prescribe between in Thailand and Japan

#### Masato Mukae

Kobe College of Medical Welfare, Sanda Campus, Prosthetist and Orthotist Department 4-Year Program, Sanda, Japan

#### **BACKGROUND**

I went to Thailand to study a lot of knowledge and techniques for P&O as an international student. However, only a few P&O students in Japan have been able to get a chance to go abroad for studying yet although it is becoming increasingly common for other university students in Japan to do it. So, I thought Japanese students had better have more opportunities to know about overseas P&O affairs.

#### AIM

I wanted to clarify whether there were some differences in way of thinking between Thai and Japanese students even if they thought about the same clinical cases.

#### **METHOD**

I conducted a survey by questionnaire about an acute stroke patient to a total of 10 people (5 Thai and 5 Japanese students). I picked out the final grade college students who had already studied like this case in Thailand or Japan as the participants. I gave them the questionnaire sheet with the same condition of a clinical case and had them reply to the questions freely.

#### **RESULTS**

These questionnaires are currently being added up, so I have not got all the answers from them yet. I heard the answers from Thai students seemed to be basically the same as Japanese because of following the ISPO educational guidelines. However, there were some differences in way of thinking in detail between the two countries. It was depended on the condition surrounding P&O clinicians in each country, for example, the economic or natural ones, and labor style as P&O. The financial reason for patients was the most influential with the differences above all the others. Some people get low income in Thailand, so they are not able to choose freely a prosthesis or an orthosis from a wide variety of options. It makes Thai clinicians think out a way of describing.

#### **DISCUSSION AND CONCLUSION**

I had a questionnaire to the only 10 students this time. So, it may not be enough at all to decide if there're differences of how to prescribe for the same case. However, it was so meaningful to listen to various views, regardless of nationality. I should find this information helpful at my own work because it can enable me to see things from various viewpoints from always. Even if people cannot have real experience, it'll help them.



# Selection Criteria for Train of Trainers Program and Strategy for P&O in Iraq to Ensure Better Practice

Abdullah Fatlawi

International Committe of Red Cross, Baghdad, Iraq

#### **BACKGROUND**

International Committee of Red Cross (ICRC) has been providing technical support to the Physical Rehabilitation Centers (PRCs) in Iraq through training courses, and on-site training since 1993. Responsibility for providing ongoing training had not been taken on by Iraqi Prosthetic and Orthotic (P&O) technicians. Therefore, a programme was developed to target a group of motivated technicians. who upon selection would be trained on specific subject areas and subsequently ICRC could transfer training responsibility to national technicians

#### AIM

The aim of the program is to establish a specialized groups of P&O technical trainers that can sustain training delivery within Iraqi physical rehabilitation services to ensure better quality practice and become mentors to new graduates on clinical placement.

#### **METHOD**

A targeted approach using stringent selection criteria was developed to ensure the right candidates were accepted to P&O device specific 'Training of Trainer' programmes. Selection criteria included - years of experience (>5yrs), demonstrate a live case presentation (from assessment through to delivery with a pass/fail scoring) during which they were assessed on each aspect of the process, presentation technique, ability to accept constructive criticism and motivation to learn how to become trainers. Following each ToT course the trainers are supported by ICRC staff when they deliver training in their own workplace.

#### **RESULTS**

For a successful training programme, the correct choice of participants is the key to positively change the learning and working environment. Many participants are fully capable of accomplishing the required tasks however, being a trainer is based on the willingness to share knowledge with colleagues and the motivation to continue to seek learning and development themselves. 13 trainers out of 25 who attended ICRC ToT have been selected to join a Teaching Methodology course at the National Centre for Human Resources Development (Ministry of Health) in order to give recognition and legitimacy to their ICRC certification

#### **DISCUSSION AND CONCLUSION**

The recognition will fit very well in the overall strategy of the ICRC training programme, as well trained clinicians with teaching skills are much needed to support and mentor new graduates and students on clinical placement. Therefore, correct selection remains one important component to ensure sustainability for future training. This strategy can be applied in any country of similar circumstances to Iraq.

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## **ACKNOWLEDGEMENTS**

This work is dedicated for the ICRC-PRP team in Iraq BGD for making the TOT program such a success.



# Effects of Amputee Education Counselling to the Knowledge of Using and Taking Care the Prosthetics

Burlian Mugnnie, Galuh Nurul Annisa

Polythecnic of Health Science Jakarta 1, Jakarta School of Prosthetics and Orthotics, Jakarta, Indonesia

#### **BACKGROUND**

Disability number in Indonesia is 9,046 million people from 237 million in total population based on Susenas (2012). Prothesis is a device to replace the missing body part. The used of prosthesis itself might be interfered by the knowledge of the patient on how to use and take care the prosthesis. It is very important for the patient to have good knowledge in that aspect as it could improve their quality of life and daily activities.

#### AIM

Know the knowledge level of amputee in using and taking care the prosthesis with its influences before and after counselling and its correlation with age, education level, and economic status.

#### METHOD

This research is pseudo experimental research (quasi experiment). The variable consist of amputee whom using lower limb prostheses and knowledge (education level, economic status, experiences, and information) in using and taking care the prosthesis. the research was focus to the lower limb prosthetics user. The participants were gathered to fill in the pre-test questioner to know the knowledge level in using and taking care the prosthesis while assessing the factors that might influences the knowledge level. They were then given an educational counselling with the topic of treating the stump and prosthesis. The post-test questioner was then be given after.

#### **RESULTS**

The pre-test shows that the level of knowledge good is 0%, fair is 33,3%, and poor is 66,7%. The post-test shows that the level of knowledge good is 0%, fair is 33,3%, and poor is 66,7%. meaning that there is an improvement of knowledge in a good direction from the statistics calculation. Base on Mann Whitney calculation the p value is 0,001 which p value < 0,05 meaning that there is a significant influence in before and after counselling on the patients in using and taking care the prosthesis. There is no correlation between the education level, age, economic status, and experiences in using and taking care the prosthesis with the p value >0,005.

## **DISCUSSION AND CONCLUSION**

There is an increasing of patients knowlede before and after the counselling in using and taking care the prosthesis. There is no correlation in using and taking care the prosthesis with education level, age, economic status, and experiences. Thus educational counselling is essential to give the patients understanding of using and taking care the prosthesis.



# Understanding the Relationship between EDUCATION, RESEARCH and CLINICAL SERVICE in Health Professions Program

<u>Sasithon Sukthomya</u>, Sirintip Kaewtip, Prawina Sutdet, Nisarat Opartkiattikul Sirindhorn School of Prosthetics and Orthotics, Bangkok, Thailand

#### **BACKGROUND**

While the theoretical knowledge remains the critical foundation. Literature suggested that experience or 'touching the realities' was recognized the most important in competence development.

Aiming to be a prosthetic and orthotic school toward international excellence, the Sirindhorn School of Prosthetics and Orthotics focuses on three missions which are education, clinical service and research. Although a number of researches studied on the effect of each component on the professional development. The relationship of the three missions have not been explored yet

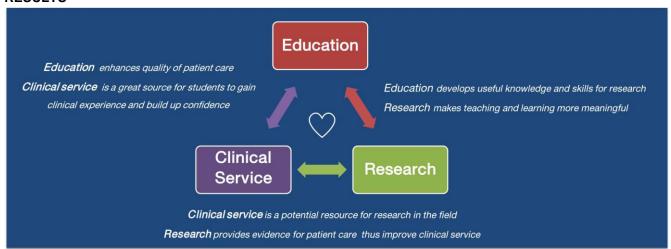
#### AIM

To explore the perceived relationship between education, clinical service and research.

#### **METHOD**

A purposive sample of twelve lecturers of SSPO were recruited. Data collection was by open-ended questionnaire. The answers were analysed according to the qualitative methodology of content analysis. A computer software, NVivo, had been used in coding process

#### **RESULTS**



SSPO Strategic Model

### **DISCUSSION AND CONCLUSION**

Relationships of each pair of components were identified from the data. The findings suggest that research, education and clinical service has considerable effect on each other. An understanding of these relationship may influence the faculties to develop their skills or the program leader to modify the strategy, thus advancing not only education of students, research skills of researchers or clinical competence of the clinicians but also the profession.

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#### **ACKNOWLEDGEMENTS**

Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Sirinaj Hospital, Mahidol University.



# The Prevalence of Psychosocial Problems in Physically Disabled Person in Pakistan Institute of Prosthetic & Orthotic Sciences (PIPOS) Peshawar.

Zia Ur Rehman<sup>1,2</sup>, ZARNOOB SAFRI<sup>1</sup>

<sup>1</sup>Pakistan Institute of Prosthetic & Orthotic Sciences (PIPOS), Peshawar, Pakistan. <sup>2</sup>ISPO Pakistan, Peshawar, Pakistan

#### **BACKGROUND**

Disability is defined as "a physical, mental, or psychological condition that limits a person's activities". Physical disability is the limitation of a person's physical functioning, mobility, dexterity or stamina. Disability ranged from 3.6 to 66% and low quality of life and psychosocial problems resulting from disability ranged from 1.8 to 26%.

#### AIM

To determine the prevalence of psychosocial problems regarding physically-disabled at Pakistan Institute of Prosthetic-Orthotic Sciences Peshawar Pakistan.

#### **METHOD**

A cross-sectional research survey was conducted by using the authentic "Beck Anxiety Inventory" procedure through the comprehensive questionnaire prepared for this purpose. There were total 50 participants as respondents were interviewed and selected regarding the physical disability at the Rehabilitation Centre by using the convenient sampling method. The raw data in this regard was analyzed and tabulated by using the Statistical Package for the Social Sciences (SPSS) version 23. These differences were statistically significant (p <. 05) by level of injury, those with quadriplegia were significantly (p <. 05) more handicapped (i-e, they had lower CHART scores) while people with neurologically incomplete injuries were the least handicapped.

#### **RESULTS**

44 males and 6 female's participants were selected as target population in the present study. Present study results revealed that 1 patients have low anxiety, 32 patients have moderate and 17 patients have severe anxiety. This shows that physically disabled persons have psychosocial problems in which majority of the patients have moderate to severe anxiety respectively. These types of subjects require special attention and treatment to become productive people of our society.

### **DISCUSSION AND CONCLUSION**

There is considerable prevalence of psychosocial problems in physically disabled persons Peshawar district, in this regard, it should be suggested that public and private partnership conducted the joint venture program so as to ensure to rehabilitate them at proper manner.



# Free Paper – Poster Presentation Rehabilitation Medicine & Surgery

#### 5.116

# Treatment and Management of Chronic Lateral Epicondylitis: A Survey of Current Clinical Practice in Khyber Pakhtunkhwa, Pakistan

Nizar Akhtar, Jehanzeb Afridi

Pakistan Institute of Prosthetic and Orthotic Sciences, Peshawar, Pakistan

#### **BACKGROUND**

Lateral Epicondylitis (LA) orTennis Elbow is a chronic, painful and one of the most prevalent disorder of the arm. It causes lateral elbow pain, which occurs when tendons in elbow are overloaded, usually by repetitive motions of the wrist and arm that may results in functional impairment and affects the ability to work; therefore, needs special treatment and management.

#### **AIM**

The aim of this study is to explore and understand the current clinical practice in Khyber Pakhtunkhwa (KPK) Pakistan for managing patients suffering from chronic tennis elbow and to identify the best and effective treatment modalities.

#### **METHOD**

A cross sectional survey was conducted using comprehensive survey questionnaire adapted by Bateman et al.[1] It was modified according to the scope of this study, which contained 17 questions with the selection options of best and or free-text responses. The questionnaire was selected and modified in consultation with experts in the relevant field. Then the final questionnaire was generated online through Google Forms and distributed through different online platforms, social media and through personal emails to the target group of professionals involving Orthotists, Physiotherapists and Orthopedic Surgeons in the region.

#### **RESULTS**

In total, 74 responses satisfied the inclusion criteria. The respondents were comprised of 17 physiotherapists, 35 orthopedic surgeons, and 22 orthotists. The preferred first line treatment for chronic tennis elbow (≥6 months) was steroid injection (40.5%), exercise based physiotherapy (29.7%) and orthotics (20.3%). The preferred second line treatment option is surgery (25.7%), exercise based physiotherapy (24.3%), orthotics (16.2%), PRP Injection (13.5%) and steroid injection (12.2%).

### **DISCUSSION AND CONCLUSION**

The recommendation of steroid injection (40.5%) as a first line treatment is a concern given the evidence of poor practice and potential for long-term harm and that surgeons negate the beneficial effects of conservative treatment. Surgery as a second line treatment is also a concern since it is not supported by the results in the literature. Surgery may be advised after 6-12 months of failure of conservative care. There is still a need for evidence-based guidelines in this domain in Pakistan

#### REFERENCES

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#### **ACKNOWLEDGEMENTS**

We extend our appreciation to Dr. Marcus Bateman, Orthopaedic Outpatient Department, Royal Derby Hospital, Derby, UK, for the survey questionnaire.



# Transfemoral Amputation: Assessment Before and After a New Distal Weight-Bearing Implant

<u>Gorki Carmona</u><sup>1</sup>, Alain Lacraz<sup>1</sup>, Axel Gamulin<sup>1</sup>, Hala Kutaish<sup>2</sup>, Alice Bonnefoy<sup>1,3</sup>, Stéphane Armand<sup>1,3</sup>, Mathieu Assal<sup>2</sup>

<sup>1</sup>University Hospitals of Geneva, Geneva, Switzerland. <sup>2</sup>Clinic La Colline, Geneva, Switzerland. <sup>3</sup>Geneva University, Geneva, Switzerland

#### **BACKGROUND**

Individuals with a transfemoral amputation may experience limitations in activities of daily living due to reduced mobility and prosthesis-related problems with several hard socket designs. In this context, we proposed a new internal femoral implant that allows for distal weight-bearing. This implant, named MAKAN<sup>®</sup>, was developed at the University Hospitals of Geneva with improvement of the gait and the use of the prosthetics satisfaction as goals.

#### **AIM**

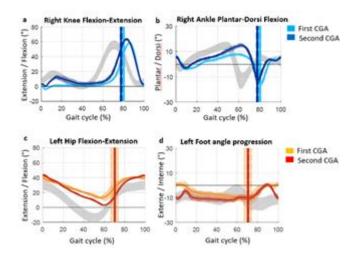
To assess change in gait quality, mobility, physical function, pain and satisfaction with use in daily life before-and-after MAKAN<sup>®</sup> implantation using validated outcome measurement tools.

#### METHOD

A 64-year-old man with a left traumatic transfemoral amputation underwent clinical gait analysis (CGA) with a traditional hard socket prosthesis including the ischial tuberosity, and 6 months after MAKAN<sup>®</sup> implantation. The CGA was performed with shoes and crutches at different walking speeds. Spatio-temporal parameters, including kinematics of the hip, knee and ankle were calculated and compared. In addition, the patient underwent tests, including 6-minutes walk test (6-WT), TUG, Tinetti, and Short Physical Performance Battery (SPPB). Patient satisfaction with use of the prosthesis (Satpro) and the level of pain (AVS) were evaluated at each session.

#### **RESULTS**

At the second evaluation, CGA was higher on the MAKAN® side  $(0.64 \pm 0.03 \text{ m/s} \text{ vs. } 0.56 \pm 0.04 \text{ m/s})$ . We observed also a better ankle and knee kinematic for the sound side (Figure a and b). For the left side, we observed a better angle foot progression and hip kinematic (Figure c and d). The step width was lower at second CGA  $(0.13 \pm 0.01 \text{m vs. } 0.21 \pm 0.01 \text{m})$  and the Tinetti test evolved from 22 to 25 points, reflecting a better equilibrium. The 6-WT improved by 45.5 % (165 to 240 m). The SPPB was 2 points improved (7 to 9). TUG was realized in 18 seconds instead of 23 with traditional hard socket. AVS went from 4 to 2: There was no difference with Satpro.



# **DISCUSSION AND CONCLUSION**

The use of the MAKAN<sup>®</sup> prosthesis produced improvements for the patient in terms of gait quality, speed and distance of walking, equilibrium, physical function and level of pain. We did not observe any difference concerning patient satisfaction with use of the MAKAN<sup>®</sup>.



# Effects of Ischial Weight-Bearing Brace for a Patient with a Femoral Fracture on the Paralyzed Side: A Case Report

Takumi Hirabayashi<sup>1,2</sup>, Moe Matsuba<sup>1</sup>, Naoki Tamada<sup>1</sup>, Badur un Nisa<sup>2</sup>, Norihisa Nose<sup>1</sup>
<sup>1</sup>Nose Hospital, Kobe, Japan. <sup>2</sup>Department of Rehabilitation Science, Graduate School of Health Sciences, Kobe University, Kobe, Japan

#### **BACKGROUND**

Ischial weight-bearing brace (IWBB) is prescribed when a patient with femoral fracture needs a long-term weight bearing restriction, as IWBB allows standing and gait training from the early stage with Weight bearing restriction at the fracture site. However, when using the IWBB, relatively high body function is required, and it is difficult to adapt in cases with paralysis, leg length difference, and deformation.

#### **AIM**

To assess the effects of Ischial weight-bearing brace for a patient with a femoral fracture on the paralyzed side.

#### METHOD

This case report describes rehabilitation of a man in his 50s, who presented with right femoral supracondylar fracture and right lower limb Post-polio paralysis. He underwent open reduction and internal fixation. In the right lower limb, Gluteus maximus muscle was normal, Quadriceps muscle was completely paralyzed and other muscles indicated paresis. We fit the IWBB after surgery for gait training at an early stage. In addition, we prescribed Lofstrand crutch. Resistance training activities carried out gluteus maximus muscle mainly. The number of days to gain walking, Duration of hospitalization, duration to return to work, muscle strength and activity level was used as the index of effects of the IWBB.

#### **RESULTS**

After the brace fitting, the number of days to achieve indoor walking and outdoor walking was 7 and 16 days, respectively. The duration of hospitalization after brace completion was 24 days and the return to work was achieved after 4 days of discharge. There was little difference in muscle strength before bracing and at the time of discharge. The activity level after bracing upon discharge, during the first and second month recovered to about 70% and 90%, respectively, as compared with the activity level before the injury.

#### **DISCUSSION AND CONCLUSION**

Proactive resistance training to prevent muscle atrophy of the gluteus maximus muscle provided adequate support in the stance phase on the brace side. Furthermore, using Lofstrand crutch on the brace side supported the swing phase and contributed to the gait stability. Therefore, when the strength of the gluteus maximus muscle is maintained, it is expected to obtain practical activity level earlier by using IWBB even for cases with paralysis or deformity.



# Relationship between Kinematic Factor and Lower Limb Muscle Activity during Assistance Walking in Severe Stroke Patients

<u>Naomichi Mizuta</u>, Yasutaka Higa, Ayaka Matsunaga, Masako Tsutsumi, Junji Taguchi, Tomoki Nakatani Medical Corporation Syowakai, Takarazuka Rehabilitation Hospital, Hyogo, Japan

#### **BACKGROUND**

To improve the lower limbs function in severe stroke patients, assistance walking training using the knee ankle foot orthosis (KAFO) is performed for therapeutic purposes. Although assistance walking using KAFO can increase activity of lower limb muscle, the magnitude of muscle activity is different for each case. We consider that this difference is influenced by kinematic factors during assistance walking.

#### AIM

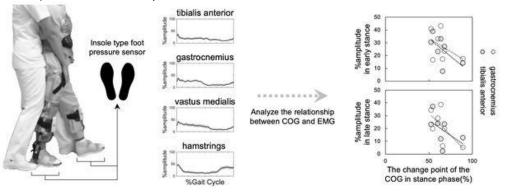
In this study, we examined the relationship between kinematic factors and lower limb muscle activity in paralyzed side during assisted walking using KAFO.

#### **METHOD**

Seven participants with subacute stroke (age,  $77.0 \pm 7.1$  years; stroke onset,  $102.0 \pm 42.9$  days) and participants performing a backward assistance walking training using patient's KAFO (ankle joint: oil damper, knee joint: ring lock) were enrolled. In the measurement protocol, the physical therapist walked assistance from backward the participants and recorded the location of the center of gravity (COG) and the activity of lower limb muscle of paralyzed side during assistance walking. Participants used KAFO. The relationship between the location of the COG and the magnitude of the muscle activity was examined using spearman's correlation analysis.

#### **RESULTS**

The mean value of each variable was  $65.1 \pm 12.2\%$  at the change point of the COG in stance phase, the average amplitude of the muscle activity in stance phase was  $22.0 \pm 10.5\%$  at the tibialis anterior, the medial gastrocnemius was  $24.5 \pm 12.0\%$ , the vastus medialis was  $25.1 \pm 15.0\%$ , and medial hamstrings was  $19.5 \pm 12.8\%$ . The location of COG, muscle activity, and walking posture were greatly different depending on the case. The location of COG was associated with the tibialis anterior (rho= -.61) and vastus medialis (rho= -.36) in the early stance phase. The COG position was also related to the medial gastrocnemius (rho= -.71) and medial hamstrings (rho= .46) in the late stance phase.



### **DISCUSSION AND CONCLUSION**

The kinematic factors may affect muscle activity during assistance walking.[1] Also, the magnitude of the muscle activity during assistance walking greatly varies depending on the participants, and we consider that it is necessary to combine appropriate assistance methods and techniques.

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#### **ACKNOWLEDGEMENTS**

We would like to thank the staff at Therapy Department of Takarazuka Rehabilitation Hospital of Medical Corporation SYOWAKAlfor their advice.



# Influence of Different Joint Designs of Ankle-Foot Orthosis on Walking Parameters in Patients with Sub-acute Stroke

<u>Naruhito Hasui</u><sup>1,2</sup>, Naomichi Mizuta<sup>1,2</sup>, Yasutaka Higa<sup>2</sup>, Yasutada Yamamoto<sup>2</sup>, Ayaka Matsunaga<sup>2</sup>, Tomoki Nakatani<sup>2</sup>, Masako Tsutsumi<sup>2</sup>, Junji Taguchi<sup>2</sup>, Yohei Okada<sup>1,3</sup>

<sup>1</sup>Department of Neurorehabilitation, Graduate School of Health Sciences, University of Kio, Nara, Japan. <sup>2</sup>Medical Corporation SYOWAKAI, Takarazuka Rehabilitation Hospital, Hyogo, Japan. <sup>3</sup>Neurorehabilitation Research Center, University of Kio, Nara, Japan

#### **BACKGROUND**

The ankle-foot orthosis (AFO) improve walking parameters such as step length, shank movement, center of pressure (COP) progression, and activities of shank muscle in stroke patients. Recently, AFO have different designs and the characteristics with variety of ankle joint. Nevertheless, the influence of the difference in the joint of AFO on walking parameters in the stroke patients has not been sufficiently examined.

#### **AIM**

In this study, we examined how the difference of ankle joint designs of AFO affects the walking parameters in sub-acute stroke patients.

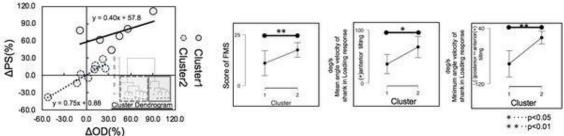
#### **METHOD**

Thirteen sub-acute stroke patients who can walk without assistance were included (age:  $67.0 \pm 13.0$  years, stroke onset:  $123.0 \pm 37.2$ days). Participants walked 6m straight way at a comfortable speed in without AFO condition and then walked in the 3 conditions (ankle joint plantar-dorsiflexion stop (Rigid), dorsiflexion free and plantarflexion stop (Plantar Stop), dorsiflexion free and plantarflexion oil damper (Oil damper)) in random order. We assessed the severity of motor paralysis, walking speed, step length, anteroposterior COP progression in stance phase with force platform, shank movement with a wireless gyro sensor, and activities of shank muscle with electromyography.

#### **RESULTS**

The mean value of lower limb motor synergy score for Fugl-Meyer Assessment (FMS) was 14.7± 5.8 points and walking speedwas 0.4± 0.2 m/s. Walking speed, non-paretic step length, and anteroposterior COP progression in the Plantar Stop and Rigid conditions was significantly higher than without AFO condition. However, the influence of each orthosis on the step length of non-paretic side was different depending on participants. Therefore, we performed cluster analysis based on the rate of change in the non-paretic step length under each condition and classified into two subgroups (Cluster1 and 2). In the Cluster1 group, the improvement was higher in the Plantar Stop than Oil damper. Participants of this group showed severe motor paralysis, and the increased posterior tilting movement of the shank in Loading response without AFO.

Figure 1. Cluster analysis, and FMS and shank movement without AFO between groups



### **DISCUSSION AND CONCLUSION**

The AFO with Plantar Stop and Rigid joint may improve walking speed, non-paretic step length, and anterior weight-shifting in sub-acute stroke patients. The influence of AFO with different joint designs on non-paretic step length varies depending on the patients. The stroke patients with severe paralysis and increased knee hyperextension thrust pattern in stance phase in without AFO condition may be suited for the AFO with plantar stop joint.

## **ACKNOWLEDGEMENTS**

We would like to thank the member at University of Kio and Takarazuka Rehabilitation Hospital for technical supports and helpful discussions.



# Complications of Total Knee Replacement Connected to Osseointegrated Implants for Transtibial Amputees: A Case Series of Eight Patients

Robin Atallah<sup>1</sup>, William Lu<sup>2</sup>, <u>Munjed Al Muderis</u><sup>2,3</sup>
<sup>1</sup>Radboud University Medica Centre, Njimegean, Netherlands. <sup>2</sup>Osseointegration International, Sydney, Australia. <sup>3</sup>Macquarie University, Sydney, Australia

#### **BACKGROUND**

Osseointegration has become an established treatment option for amputees experiencing socket related problems. Owing to its exceptional results, the technique was attempted in cases where a total knee replacement was combined with a transtibial osseointegration implant which resulted in a high failure rate.

#### ΔIM

The purpose of this study is to report on the failures and complications of this procedure.

#### **METHOD**

We retrospectively reviewed 8 patients with transtibial amputation having signs of knee arthritis and/or short residual tibia, which were treated with a combination of a total knee replacement and transtibial osseointegrated implant. There was a minimum of 24 months follow-up. Adverse events were monitored including infection, periprosthetic fracture, implant breakage or loosening, need for additional amputation and death. Functional outcomes were measured using the Questionnaire of persons with a Trans-femoral amputation and mobility level was assessed using the Six Minute Walking Test and Timed Up and Go.

#### **RESULTS**

No patients had an uneventful course without complications. Three patients had minor complications including redundancy of soft tissue, soft tissue infection and decreased range of motion of the knee joint. Five patients experienced severe complications, all as a result of implant infection leading to subsequent transfemoral amputation in four cases. Among these four cases, all patients received transfemoral osseointegration post-amputation. Overall, the rate of complications are significantly (p<0.05) higher in comparison to similar attempts with the hip joint and standard osseointegration procedures in the femur or tibia.

# **DISCUSSION AND CONCLUSION**

Combining transtibial osseointegration with total knee replacement greatly increases risk of infection and subsequent implant loosening. It may be attempted as a last resort to save the knee joint before proceeding to a transfemoral amputation but the risks of implant failure are high. Further research is required to explore better options for this particularly challenging group of patients.



# Free Paper – Poster Presentation Sports & Physical Activity

#### 5.122

# A Questionnaire Survey on Sports Injuries in Japanese Amputee Football Players

<u>Takumi Kobayashi</u><sup>1</sup>, Yukio Urabe<sup>1</sup>, Tetsuhiko Sakamitsu<sup>2</sup>, Junpei Sasadai<sup>1</sup>, Noriaki Maeda<sup>1</sup>
<sup>1</sup>Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan. <sup>2</sup>Sports Medical Center, Hiroshima University Hospital, Hiroshima, Japan

#### **BACKGROUND**

Amputee football is a football played by amputees. The goalkeeper is the upper limb amputee and the field player is the lower limb amputee. No prostheses are worn; instead, the field player plays with using paired Lofstrand crutches. Therefore, amputee football players may be suffering from different injuries than normal football by different type of exercise style from normal football. However, no study on sports injuries in Japanese amputee football players has been conducted.

#### ΔIM

This study aimed to investigate sports injuries of Japanese amputee football players and understand the situation of sports injuries in amputee football.

#### **METHOD**

A questionnaire survey using the Internet was conducted for 91 players of all Japanese amputee football teams (9 teams). The survey collected information on individual profile (age, height, body weight, crutch type, experience period of amputee football, practice time per week etc.) and sports injuries (diagnosis, trauma or overuse, location, mechanisms of injury etc.). Sports injury was defined as injuries suffered while playing amputee football and if the player met one or more of the following criteria; (1) canceled to play, (2) absent from practice or game for more than one day, (3) treated, (4) took a medical examination.

#### **RESULTS**

Responses were obtained from 66 players (72.5%). The respondent's age, height, weight and amputee football experience were 37.2±10.7 years, 169.4±7.4 cm, 63.3±9.8 kg, and 4.8±3.0 years, respectively. Practice time per week was 3.3±3.3 hours. Most field players (54/55) used closed-cuff type crutches. There were 71 trauma injuries, consisting of 15 fractures (21.1%), 13 muscles injuries (18.3%), 9 bruises (12.7%), and other minor injuries. These injuries occurred in the lower limbs (50.7%), upper limbs (36.6%) and trunk (9.9%). The main causes of injuries were falling and clashing with crutches. There were also 22 overuse-related injuries in field players, consisting of 3 finger tenosynovitis, 2wrist tenosynovitis, 2 plantar fasciitis, 2 shin splint, 2 patellar tendonitis, 2 Achilles tendonitis and other minors. These injuries occurred in the lower limbs (63.6%), upper limbs (27.2%), and trunk (9.1%).

### **DISCUSSION AND CONCLUSION**

In normal football, the almost all sports injuries are composed by lower limb injury [1]. However, this study demonstrated that upper limb injuries are likely to occur in amputee football. These results may be caused by the hardness of the crutches, shape of the cuff or grip, and loading on upper limb which does not support whole body weight originally. To prevent these injuries, it is necessary to develop more appropriate tools for exercise style of amputee football.

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# Free Paper – Poster Presentation Other Topics

#### 5.123

# A Way of Long Term Evaluation of the Prosthesis in the Crisis Areas, and PAC Experience in this Filed

### Ali Serhan

Physicians Across Continents / Turkey, Kilis, Turkey

#### **BACKGROUND**

In the prosthetic centers it is important to follow up the amputees months after providing them the prosthesis. By this, the quality of the prosthesis could be evaluated. In PAC-prosthetic and orthotic center in Kilis: there were a big number of patients` monthly and the patients were living in other country (in Syria) or in Turkey but in far cities, so we had to made a way of long term evaluation of our prosthesis.

#### AIM

we want to introduce a way for long term evaluation of the prosthesis in the prosthetic centers in the crisis areas. Also, we want to share our experience in this field.

#### METHOD

we designed a questionnaire which could be applied in a crises work circumstances. We were giving this questionnaire to the patients before delivering them the prosthesis and we were asking them to send this questionnaire after about 6 months. Also we were applying this questionnaire for our patients who were coming back to the prosthetic center, aiming to avaluate as much number as possible of our patients. Also, we designed a computer software for collection and analysis of the data.

#### **RESULTS**

From 1/7/2015 till 1/7/2018 we delivered 654 lower extremity prosthesis for 605 patients (49 patients were bilateral). From those patients we could evaluate 202 patients (33.4%). The average of daily walking was 2.3 hours. The average of daily wearing of the prosthesis were 7.52 hours. The evaluation marks according to the questionnaire was 79.8. Also we got some other results: 63.6% of our patients were not using crutches.

# **DISCUSSION AND CONCLUSION**

the PTEG questionnaire could be used in the prosthetic centers in the crisis circumstances because the patient who is at home can use it easily, and it could be applied in a short time for the patient who visit the center. One of the most important reasons of that we evaluated only 33.4% of the patient is that we had not a full time employee for this job.



# Social Inclusion Challenges Confronted by Physically Disabled Persons in two Cities of Pakistan

Zia Ur Rehman<sup>1,2</sup>, Kiran Siddigi<sup>3</sup>

<sup>1</sup>Pakistan Institute of Prosthetic & Orthotic Sciences (PIPOS), Peshawar, Pakistan. <sup>2</sup>ISPO Pakistan, Peshawar, Pakistan. <sup>3</sup>Rawalpindi Medical University, Rawalpindi, Pakistan

#### **BACKGROUND**

Disability is regarded as a global issue that is more prevalent in developing countries. Our study examines how the lives of disabled people are challenged physically, financially and due to society's attitude towards them in two cities (Rawalpindi and Peshawar) of Pakistan. These challenges must be acknowledged and addressed to accommodate them in society and uphold their rights by enabling disables with a peaceful and productive life.

#### **AIM**

To develop the firm recommendations for future policy implications and providing the researchers with a better understanding of the demographic characteristics of disabled persons in urban areas of Pakistan.

#### **METHOD**

A qualitative, cross-sectional, descriptive study was conducted to identify the challenges confronted by physically challenged persons visiting the disability centres of Rawalpindi and Peshawar. A total of 100 men and women of age 15-60 years with crippling physical conditions were asked to fill a specifically designed questionnaire. Both independent variables (demographic information) and dependent variables (social relationship and participation) were considered in this study. Perceived perception of the respondents was recorded and checked by using the Likert scale. Data was entered, tabulated, summered and analyzed by using SPSS version 21. The p-value was set on 0.01 alpha level.

#### **RESULTS**

Out of 100 respondents, 50 were from Rawalpindi while 50 were from Peshawar. The results indicated that most of the respondents are dependent financially on their families (51%). The literacy rate shows that 26% of disabled persons are university graduates. Majority of physically disabled persons felt the need of having special transport services (92%). However, only 14% of physically challenged can travel independently. A significant role of gender in social relationship and participation has been found. The bivariate analysis depicted, that physically challenged females, are more affected in terms of a social relationship with community members than males. Though, the multivariate analysis revealed that disabled females who are educated and employed have a less terrible social relationship and are participating more actively in social activities.

#### **DISCUSSION AND CONCLUSION**

The findings conclude that disabled persons are facing challenges in education, employment and transportation sector. Existing policies should be revised with the main focus on the inclusion of disables in education hence combating the iniquitous attitudes of agencies towards disables. Our findings complement the previous research on the role of gender in social inclusion. The pre-eminent limitation is the small sample size hence not reflecting the entire disable community of Pakistan.



# 5.1253D Printing Pilot in Niamey, Niger

Amadou Abdoulaye<sup>1</sup>, Amadou Bassirou<sup>1</sup>, <u>Lamine Hassane</u><sup>2</sup>

1 Hôpital National de Niamey (HNN), Niamey, Niger. Hôpital National de Niamey, Niger

#### **BACKGROUND**

Niger with 22 million people currently has 2 functional centers providing orthotics and prosthetics services and a small number of professionals able to provide these services (5 active licensed P&Os)Access to services is severely limited, both centers together have served during 2018, 843 persons, a number far away to cover the estimated needs (0,5 of the population (ISPO/USAID/WHO): 110.000). 3D printing is an innovative technology in Africa, its use could potentially facilitate the access

#### ΔIM

To gather beneficiary feedback on two different type of lower limb orthotics (3D and conventional) and to analyze the interest and limitations of the use of innovative technology (3D printing) in the physical rehabilitation process in Niger.

#### **METHOD**

The study has been done with 25 patients and two different types of Orthotics; orthotics for service users with a drop feet and/or knee instability (dynamic orthoses) and night splints (postural orthoses) for service users with Pie Equinus or Genu Valgum/varum being less than 8 years old. All the service users have received one conventional orthoses and one orthoses 3D printed. One group received one before the other and vice versa. After orthotic use a battery of tests was performed in order to quantify several parameters, same tests were done after the use of the other orthoses.

#### **RESULTS**

It is not possible to provide definitive results of the study as we are currently half way through, for the congress we will have the results of the Project, therefore we can anticipate presenting the whole study. Strengths identified so far: during the research the Nigerien P&Os were trained on the new technology and therefore our expertise improved. To have a choice of technology it is something also that can be rated as positive. Limitations detected so far: the material used for the 3D printing needs to improve, so far it is too heavy and rigid (therefore fragile). And also the centralized printing process has been showing some logistics challenges.

### **DISCUSSION AND CONCLUSION**

This study is nowadays evidencing that there is still a way to go to improve this technology in order to provide high quality and accessible devices. Precisely because of that, research is very much needed. The possibilities of this new technology need to be further studied and developed and more energy and time should be spend into it.

# **ACKNOWLEDGEMENTS**

To Humanity and Inclusion (holders of the project) and ICRC for the support.



# Intervention Effect of Walking Preparation Exercise for Trans-femoral Prosthesis Simulator

<u>Isao Ojima</u>, Akio Nakagawa Faculty of Rehabilitation, Kobe Gakuin University, Kobe, Japan

#### **BACKGROUND**

A trans-femoral prosthesis simulator is used for evaluation and research and development of lower limb prosthesis parts by gait analysis through the simulated experience of healthy individuals. Trans-femoral amputees acquire the ability to walk using lower limb prosthesis through mechanisms of 1. weight supporting method; 2. control method for preventing sudden buckling; 3. learning voluntary control of knee joint by hip joint extending muscle; 4. learning by basic and practical walking and movement practice.

#### ΔIM

In this study, we examined the intervention effect of weight-bearing exercise and dynamic balance practice during the walking preparation practice stage in the process of acquiring walking by a trans-femoral prosthetic simulator.

#### **METHOD**

Subjects were ninety-four adults with an average age of 21.5±0.2 years old, Subjects were divided into two groups of forty-seven subjects with gait exercise (exercise group) and forty-seven subjects without gait exercise (no exercise group) in order to compare the intervention effect of walking preparation practice.

Ten minutes each of weight-bearing exercise and balance exercise including the voluntary control practice of knee joint by hip extension practice to prevent buckling of knee joint of prosthesis were performed before conducting the gait evaluation for the exercise group. The evaluation includes 10m gait speed, cadence, TUG, 6MD, and physical cost index (PCI) for 6 MD.

#### **RESULTS**

The exercise time required until being able to start gait evaluation after wearing the right lower limb prosthesis was average time of 10'33"±5'42" for the non-exercise group, and that of 4'47"±3'44" for the exercise group; therefore the time was significantly shorter in the exercise group. The number of buckling and falling by the gait evaluation was average of 9.5 times for the non-exercise group and 3.2 times for the exercise group; the number was significantly fewer for the exercise group. The 10m gait speed, walking rate, TUG (timed up and go test), 6MD and 6MD-PCI for the non-exercise group and the exercise group, respectively. No significant difference was observed.

#### **DISCUSSION AND CONCLUSION**

In the group with gait exercise, the time required until gait evaluation when being judged to be used to walking and the number of buckling was significantly lower compared with the non-exercise group. Weight-bearing exercise, as well as balance exercise including voluntary control of knee joint by hip extension practice, exhibited immediate intervention effect. However, after the gait evaluation, no significant difference was observed in 10m speed, cadence, TUG, 6MD, and 6MD-PCI between the exercise group and the non-exercise group.

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# Sustainable Alternatives for Prosthetic Layup: A Review of Basalt and Flax Fibre

Kylee Kuchta, Jessie Leith George Brown College, Toronto, Canada

#### **BACKGROUND**

Sustainability balances environment, economy, and social well-being.[1] Presently, prosthetic sockets primarily contain light-weight synthetic materials with high strength and stiffness. However, they are expensive, difficult to recycle, non-biodegradable, energy-consuming to produce, and can be hazardous to the fabricator.[2, 3] According to literature, flax and basalt fibres may be functional, sustainable alternatives for prosthetic layup material.[4, 5] Despite potential benefits, experts have reported conflicting findings regarding socket finish and material feasibility.[6, 7]

#### **AIM**

This poster will explore flax and basalt fibres as alternative prosthetic layup materials and relate the findings to workplace sustainability. Prosthetic professionals will be surveyed regarding feasibility and satisfaction with the fibres.

#### **METHOD**

A literature review was conducted using PubMed, OVID, and references suggested by subject matter experts. Terms searched were 'sustainability', 'sustainability AND prosthetics'; 'basalt AND prosthetics'; 'flax AND prosthetics'; and 'sustainable alternatives for prosthetic layup'. The inclusion criteria applied were: (1) published between 2000-2018 (2) sustainable options for prosthetics (3) flax fibre (4) basalt fibre. Due to limited peerreview article availability, anecdotal data obtained from manufacturing companies was also used. A subjective survey addressing rationale and satisfaction with the materials was compiled and sent to O&P-L Listserv. The survey is being filled out in an online forum and interpreted by the researchers.

#### **RESULTS**

Fourteen articles met the inclusion criteria and demonstrated that flax and basalt fibre were high in impact and tensile strength, lightweight, cost effective, and healthier for the fabricator.[1-7] Flax, basalt, and a hybrid of

Resin	Orthopoxy Resin		Acrylic Resin		
Layup Material	Flax	Basalt	Flax-Basalt Hybrid	Carbon Fibre	Glass Fibre
Tensile Strength (MPa)	122	269	184	106	27.3
Flexural Strength (MPa)	115	363	184	93.3	59.1

50% of each, were tested to ASTM standards for tensile and flexural strength.[5] Table 1, below, summarizes the tensile and flexural strengths of the alternative fibres with orthopoxy resin compared with carbon and glass with an acrylic resin.[5] Alternative fibres were reported as having lower energy costs in their production compared to traditional glass and carbon fibre.[1] Using alternative fibres resulted in a decreased health risk to the fabricator as they are non-carcinogenic, and non-respirable.[1, 5, 7]

### **DISCUSSION AND CONCLUSION**

Flax and Basalt fibres were identified as sustainable layup materials that reduced fabricator health risks.[2, 3, 4] Limbtex found that flax and basalt fibres with orthopoxy resin yielded higher flexural and tensile strengths than carbon and glass fibre with acrylic resin.[5] While use of different resins is a limitation, the alternative materials achieve ASTM standards.[1, 5] The poster will further discuss limitations. Pending survey collection, the poster will examine satisfaction from prosthetic facilities.

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#### **ACKNOWLEDGEMENTS**

Gord Ruder, B.SC., M.Sc., C.O.(c), F.C.B.C; Amy Richardson, B.Sc., M.Sc., C.P.(c); Sarah Levesque & Diana Le.



# Need Assessment for Benchmarking International P&O Standards in Lebanon

Habbouba Aoun<sup>1</sup>, <u>Jad Arab</u><sup>2</sup>, Issam Mawla<sup>3</sup>
<sup>1</sup>Balamand University, Beiruth, Lebanon. <sup>2</sup>ICRC, Beiruth, Lebanon. <sup>3</sup>PO syndicate Lebanon, Zahle, Lebanon

#### **BACKGROUND**

In Lebanon, prosthetic and orthotic services are offered by multiple providers offering varied pricing categories. There is no systemic-based approach, the Ministry of Public Health is the major provider of services, with an outdated pricing system. Subsequently, 69 P&O specialists are working with no clear standards for benchmarking. Service provision is problematic due to limited budgeting for the disability sector. There are 104'000 disabled people in Lebanon. The rate of lower extremity amputation is 1.40 per 10'000.

#### ΔIM

To compile a preliminary (yet comprehensive) situation analysis of the PO sector in Lebanon, in order to develop a benchmarking based on international standards and to identify the gaps.

#### METHOD

A desk review of currently existing systems (facilitated by Academicians from the University of Balamand) is initiated with all relevant stakeholders: Ministry of Public Health, the Ministry of Social Affairs, Local Disabled People Organizations, International Disabled People Organizations, and ISPO. In parallel to the desk review, indepth interviews are conducted with P&O specialists and focus group discussions with service end-users feedback take place. Findings of these quantitative and qualitative data collections would support the analysis of the current situation and on existing gaps, helping to identify the relevant benchmarking to implement international standards in Lebanon.

#### **RESULTS**

Expected results include an Arabic-translated version of the international standards, an empowered P&O Order advocating for standards benchmarking. Furthermore, a document presented to ministries opened to discuss the topic, and approved by the Council of Ministers that, in turn, would submit it to the Lebanese Parliament for adoption as a law regulating the sector.

# **DISCUSSION AND CONCLUSION**

At the time of abstract submission, the buy-off of concerned stakeholders is achieved, and the current P&O Syndicate is fully engaged. Data collection has started. At the time of the Conference in October, data collection should be completed, and findings validated through consensus workshops.

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# Ototake Project: A Case Report of Walking Training of a Patient with Congenital Limb Deficiency using Robotic Prosthetic Knee Joints

Ken Endo<sup>1,2</sup>, Hirotada Ototake<sup>3</sup>, Hirozumi Takeshima<sup>1</sup>, Tetsuya Konishi<sup>4</sup>, Atsuo Okino<sup>5</sup>, Naoki Uchida<sup>6</sup>
<sup>1</sup>Sony Computer Science Laboratories, Tokyo, Japan. <sup>2</sup>Xiborg, Tokyo, Japan. <sup>3</sup>Xiborg, Tokyo, Japan. <sup>4</sup>exiii design, Tokyo, Japan. <sup>5</sup>Okino Sports PO, Tokyo, Japan. <sup>6</sup>D'ACTION, Tokyo, Japan

#### **BACKGROUND**

London Paralympic promotion of Channel4 made a huge impact to the community in 2012. As Tokyo Paralympics are approaching, people has still changed their way of thinking of disabilities. Furthermore, combination of technology and human shows great performance in various fields, and sometimes, it becomes competitive with the normal. For better understanding of physical disability, one great idea would be disclosing a success story where human becomes able to do what he could not do before.

#### ΔIM

Awareness-raising for understanding physical disability by disclosing a well-known congenital limb defect patient's rehabilitation process of walking with a robotic prosthetic knee joint technology

#### **METHOD**

Our team includes a patient, engineers, a prosthetist (PO), a physical therapist (PT), and a product designer. We involve a well-known patient with congenital limb defects(both AK and AE), Mr. Hirotada Ototake to raise people's awareness. Engineers develop a small and affordable robotic prosthetic knee to prepare for various motions. A PT and PO set-up a environment, for example, by starting with short prosthetic legs, and making them longer as the patient gets used to. They also change the height of parallel bars to remove any fear of falling down. A PT also extends patients range of hip joint motion, as the hip extension motion is limited congenitally.

### **RESULTS**

After 6 month rehabilitation, Mr. Ototake becomes able to walk with his knee joints kept straight for short distance. The robotic knee joints always generates extension torque for safety purpose. Though the knee joint can mimic normal human knee joint walking motion, this control is not implemented, as he cannot have enough stance period to flex the knee joint during the other leg swing phase. Whole body shape with legs looks natural, even though his own body is quite unique, where the product design contributes. We disclosed the movie of our activity (<a href="https://vimeo.com/300902391">https://vimeo.com/300902391</a>) in November, 2018. A huge number of people watched it and tweeted via SNS. Furthermore, we raised over 15,000,000 JPY from 1756 people through a crowdfunding.



Figure 1. Mr. Hirotada Ototake on robotic prostheses

#### **DISCUSSION AND CONCLUSION**

Mr. Ototake is still not able walk naturally with a flexion of swing leg. He also stopped walking in 7.3m due to fatigue. This is because his muscles around hip joints do not work properly, and need enough activation to stable his stance phase. Further practice would improve both his walking motion and distance. As a result, we enable Mr. Ototake to "walk", and attract a number of attention.

#### **ACKNOWLEDGEMENTS**

This project was supported by JST CREST Grant Number JPMJCR1781, Japan.



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