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Professional O&P Posters

Professional Posters have been peer reviewed by the clinical workgroup. All presentations take place on Friday, September 8 in the Oceanside Foyer by authors or speakers who conducted the research for the presentations.

Conversion of Hip Disarticulation into transfemoral amputation

'A look at prosthetic management '

Burhan Dhar CPO
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King Faisal Specialist Hosppital & Research Center

Osteosarcoma such as Ewing's, originates in bones with occurrence usually in early years of life. In case of patients with tumor of distal femur and metastasis at proximal level, management often involves amputation at the hip level. For such patients, amputation is always carried out at the hip leading to hip disarticulation. Such amputations are hard to rehabilitate due to difficult prosthetic fitting, which involves use of two prosthetic joints (Hip & Knee) on part of the patient resulting in increased energy consumption.

The novel surgical procedure discussed here converts what would traditionally be a hip disarticulation surgery into a Transfemoral type amputation where in a viable residual limb and functional hip joint is created. Modified and step wise Prosthetic fitting then helps patient ambulate as above knee (Transfemoral) amputee with much improved outcome and acceptance and lot less energy consumption.

The goal of such amputation is to create a hip joint with the help of an implant that a patient can operate and control through his/her muscles and ambulate in conjunction with transfemoral prosthesis with improved quality of gait and balance.

After reviewing the literature, it was concluded that King Faisal Specialist Hospital & Research center is the leading center in performing such procedures, with more than 5 patients having undergone such procedure. The technique of creating Pseudo Transfemoral amputation is championed by two orthopedic surgeons Dr Mahmood Shaheen and Dr. Rajeev pant.. Between two of them, more than six procedures have been successfully accomplished. No other center has reported or published information on such procedure on such a scale.

Introduction

Sarcoma such as Ewing's is a primary bone cancer which often presents itself suddenly. There are no known factors or screening tests to indicate such a cancer taking root .It is neither influenced by life style nor a result of any environmental risks. The consequences of sarcoma particularly that of metastatic one involving amputation can be devastating both physically and psychologically to the patient. About one percent of children between the ages 10 up to adolescents develop Ewing's sarcoma in Saudi Arabia and the ratio is consistent with that of United States. King Faisal Specialist Hospital and Research center, a tertiary care Oncology hospital in Riyadh Saudi Arabia attends to most of these patients with treatment.

The novel procedure described in this paper is based on clinical diagnosis of the patients, who present distal femoral tumor with metastasis of proximal femur. Usual methods of diagnosis such as MRI, PET scan etc. were utilized for positive diagnosis. Traditional approach calls for such patients to be amputated through Hip. However through a novel approach patients were instead converted into Transfemoral amputees with viable and functional residual limb.

In the proximal femur the skin lesions are intramedullary and there is no extra osseous component of tumor. Procedure involves fillet of proximal part of femur without contamination.

Proximal viable soft tissue is preserved also keeping long vascular pedicle intact. An endoprosthesis is then implanted into the acetabulum with muscles sutured around it. Muscles are sutured with flexors to extensors and adductors to abductors. Some fibers are also attached to endo prosthesis. Upon healing the viable residual limb appears like a typical Transfemoral residual limb, with intact flexion, extension, adduction and abduction that can be further improved in strength with aggressive physical therapy.

Such amputation has a far reaching significance in terms of rehabilitation and wellbeing of the patient. Some of which can be summarized below.

- Conversion of an amputation that would otherwise be hip disarticulation into a transfemoral amputation entails patient to operate only one prosthetic joint instead of two (Hip & Knee). While this guarantees patient more control of prosthesis, also due to availability of different suspension modes, it makes prosthesis feel lighter.
- Energy consumption for a transfemoral amputee gait is far less than that of hip disarticulation. This ensures an amputee can ambulate for longer period of time with ease thereby ensuring more acceptability as compared to hip disarticulation prosthesis.
- The physiological and psychological feeling of wellbeing is much better than that of through Hip amputee, therefore enhancing the survival rate chances beyond 5 year period.

Prosthetic management starts immediately with Shrinker application. A patient is usually initiated for evaluation on fitting of prosthesis between four to six weeks. Chemotherapy regimen is taken into consideration before consideration for prosthesis. A patient may fluctuate in weight during chemotherapy. The residual limb allows for sufficiently applying variety of suspension mechanisms, in unison with socket technology available as of now.

Patient Report:

- *Six Amputations* performed till date in King Faisal Hospital. Range of age for patients varies between 12 years to 21years.Two patient's ambulatory for more than six months .One patient dead due to metastasis. Two patients have not received Prosthesis yet.
- *First Case:* 14 year old boy, Right amputee, with conical residual limb, 5 inches long residual limb that includes muscles belly. Amputation secondary to Ewing's sarcoma.
- *Second case:* 17 year old boy slightly obese amputated secondary to metastasized sarcoma of right distal femur. Redidual limb produced was 7 " ling including soft tissue.

- Fitted with transfemoral prosthesis. Prosthetic rehabilitation included Ischial containment socket in conjunction with 3mm silicon liner and pin suspension. Geometric knee joint such as four bar knee used in conjunction with single axis foot.
- *3rd case:* 12 Year old girl with right converted transfemoral amputation secondary to Ewing's Sarcoma. Currently healing and undergoing stamina exercises. Preparing to initiate prosthetic fitting within one month.
- *4th case.* 15 year old boy with converted left Transfemoral amputation. Residual limb length , short four and half inches with conical end. Fitted with partial suction socket prosthesis with stance control (Safety) knee on prosthesis. Deceased six months after gait training due to recurrence and metastasis.
- *5th case.* 14 year old boy, amputated on left limb with converted residual limb. Still awaiting full recovery for prosthetic restoration of limb.
- *6th case* 14 year old girl. Amputated on right residual limb. Short residual limb Currently in process of being fitted with the prosthesis.

Conclusion

Conversion of what would traditionally be treated as Hip Disarticulation into transfemoral amputation goes long way in overall improvement of quality of health of amputee. With anatomical muscle control over gait and control of prosthesis and operation of only one prosthetic joint (Knee) instead of two (hip & knee) amputee is able to return to many activities that would otherwise not be possible. Acceptance and usage of prosthesis is higher due to less consumption of energy and the ambulation is much improved due to presence of Hip Joint. The process of such conversion amputation can be further refined in creating a stronger, productive and viable residual limb that will be for easier to fit with prosthesis and far more beneficial to amputee in day today activities. Such novel concepts have huge effect on returning patient to society as productive member with more acceptability of prosthesis.

A Comparison of Compression and Release Socketd to Traditional Transfemoral Socket Designs: Results of the EMU Comparative Study

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INTRODUCTION

An modern transfemoral (TF) socket design is the High-Fidelity (HiFi) Interface™, created by Randall Alley, CP, of biodesigns, inc. (Thousand Oaks, CA.) The principle of this socket, as the creator claims, is using alternating areas of tissue compression and release to increase intimacy in the relationship of the residual femur and prosthesis.[1] Although claims of its effectiveness have been made by the creator, no publication of its effect on gait of amputees has be produced. The purpose of this study was to design and implement an experimental framework to compare temporal-spatial characteristics, ground reaction force patterns, level of disability, and foot behavior between the High-Fidelity Interface and other transfemoral socket designs in amputee subjects.

METHODS

The study protocol was approved by the Institutional Review Board of Eastern Michigan University. Subjects completed a baseline evaluation which included completion of the Amputee Mobility Predictor (AMPPRO), Oswestry Low Back Pain Disability Questionnaire v2, and Western Ontario and McMaster University Osteoarthritis Index (WOMAC). Kinematics and kinetics were then recorded with an 8-camera Vicon Motion Analysis System. Subjects were fitted with reflective markers and performed 20-30 straight walking trials on an 8-meter walkway with 2 embedded AMTI force plates. The subjects were then fit with a HiFi, given a 4-week acclimation period, and returned to EMU to repeat the protocol. Variables and graphs were extracted from the raw motion analysis data using MATLAB R2013a. Statistical analysis was conducted using SPSS 21 statistical software.

RESULTS

Notable temporal-spatial changes between control and HiFi socket conditions include an increase in walking velocity from .93 to 1.00m/s ($p<0.01$), reduction in lateral whole-body center of mass (CoM) deviation during gait from 3.08 to 2.94cm and 4.25 to 3.30cm on the sound and prosthetic sides, respectively ($p<0.05$), and changes in sound and prosthetic step lengths from 0.53 to 0.55m and 0.61 to 0.59m, respectively ($p<0.05$).

Changes in GRF patterns were also noted between the control and HiFi conditions including reduction in initial medial-directed GRF at initial contact and M-L socket perturbation during stance in the frontal plane and a smoother toe loading sequence in late-stance as seen in the vertical GRF graphs. A more efficient transfer from anterior to posterior GRF in stance was also noted with the HiFi. This finding corroborates the reduction in standard deviation of the sagittal center of pressure rate of change in late stance.

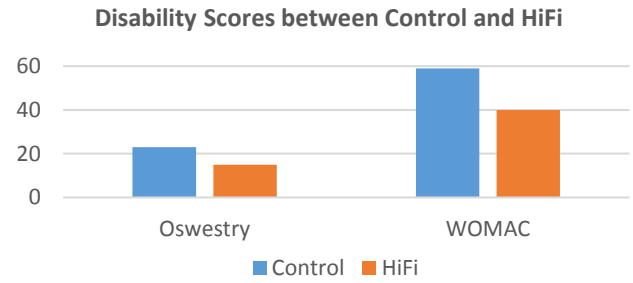

Figure 1. Disability test scores between conditions

A reduction in difficulty of function from 59 to 40 was measured between the control socket condition and HiFi using the WOMAC including reduction in all pain and stiffness items. A reduction in condition-specific disability score from 23 to 15 was measured between control and HiFi socket conditions using Oswestry v2.0. These results are shown in figure 1. No change was found in AMP scores between conditions.

DISCUSSION

This pilot study established a multi-faceted experimental protocol for comparing the High-Fidelity Interface to traditional socket designs. In this presentation, a trend toward symmetry was found in step lengths, CoM deviation, and frontal plane GRF patterns. Gait stability was found to increase between conditions as seen in the increase in gait velocity and general decrease in CoM. Disability was found to decrease between conditions in the significant reduction in Oswestry score which moved one subject from a severe to moderate disability category.[2] A significant reduction was also found in WOMAC score between conditions.[3] These results show that the HiFi Interface has potential for clinical effectiveness and that a systematic clinical trial of the technology is warranted.

REFERENCES

1. Alley RD, et al. *JRRD*; 48(6),679-696, 2011.
2. Fritz JM, Irrgan JJ. *J Am Phys Ther Assoc*; 81(2), 776-788, 2001.
3. Ehrich EW, et al. J Rheum; 27(11), 2635-2641, 2000.

DISCLOSURE

Jeff Ropp, BS, CP, is a licensee of the High-Fidelity Interface from biodesigns, inc.

A Flexible AFO: Contradiction to Traditional thought?

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INTRODUCTION: Research shows Ankle Foot Orthotics (AFO) improve walking ability**,** reduce energy expenditure and improve self-confidence.[1] However, noted disadvantages of AFOs are orthotic size and weight, discomfort, safety issues, poor effectiveness and dissatisfaction with AFOs has been found to be up to 75% with lack of compliance ranging 6% to 80%.[2] Other more flexible designs, while having increased cosmesis and comfort may lack necessary material stiffness for optimal gait.[3] Our orthotic clinic queried charts for a 3 year period and identified those who did not tolerate their prescribed AFO. It was discovered that lack of tolerance by clients included 12 with a solid AFO, 30 with an articulating, 13 with a carbon fiber and 1 with a double upright. The most common problem with non-use was postural instability. Other problems included weight and inadequate ankle varus control. Because of the dissatisfaction and non-use of their AFO, alternatives were pursued. The AFO needed to provide stability, sensory input, improved function and a positive experience. Also needed was optimum shank to vertical inclination angle espoused by Owen as essential for normalizing gait.[4] The result was a custom flexible AFO using EVA thermoplastic to match patient specific needs. Initial response from clients included being light weight and comfortable. More active people who previously used a solid AFO describe increased ability to accommodate to uneven surfaces without losing balance but still have the stability for controlled walking. We have now embarked on a study to evaluate the flexible AFOs (FAFO) effectiveness for improving gait, balance, endurance and client satisfaction.

METHODS: Inclusion criteria of a physician prescribed AFO for clients with stable neurologic conditions receive a FAFO. Exclusion criteria include cognitive impairment, non-ambulatory or recent acute complication (wound or inflammation in the foot, etc.). Baseline measurements taken prior to receiving the FAFO include: ankle range of motion for dorsiflexion and plantarflexion, strength measured with a hand-held dynamometer, ankle and knee spasticity using the Modified Ashworth Scale, standing balance measured by the Berg Balance Scale (BBS), spatial and temporal gait parameters obtained from the GaitRite Walkway System and the 6 Minute Walk test for aerobic capacity/endurance. These same measurements are repeated after the patient uses the FAFO for 2 weeks and again after 3 months. Wear related questions from the Orthotic and Prosthetic Satisfaction Survey (OPUS) are administered at the 2 week and 3 month sessions.

RESULTS: Seventeen adult clients have completed the study, 6 more lack only 3 month data and recruitment is ongoing. Current sample size prevents statistical analysis but early observational findings are promising. Gait velocity for 18 of 23 participants improved an average of 25% at 2 weeks. Two people increased velocity to .85m/s or faster and now meet criteria of a community ambulator. At 3 months, 14 of 17 participants have improved balance with 6 meeting the MCID (minimal clinical important difference) for the BBS. Initially there were 9 people below the criterion score of 45 points on the BBS (criterion for risk of fall) but only 2 remain below the cutoff score at 3 months indicating an important change in reducing the risk of falls. Initial 6MW data found 9 participants scored into the non-community ambulatory category (<318 meter) but at 3 months, 5 of these have improved by at least 150 ft, the MCID for elderly and neurologic patients. No trends have been noted for ROM, strength and spasticity. We have also observed the data for negative effects of the FAFO and found 3 people had a decrease in velocity at 2 weeks (average 4% decline) and 3 others had worse BBS scores at 3 months of 1-4 points. These declines are small and may indicate measurement error rather than a negative effect of the FAFO. Of potential concern is that 5 people showed an average of 177 ft decrease in distance walked during 6MW indicating an important decline. For 8 patients who previously had dissatisfaction using a prior AFO, satisfaction with the FAFO is 85% at 2 weeks and was maintained at 3 months.

CONCLUSIONS: Early data suggests the FAFO is able to provide benefits of increased walking ability, improved balance, good client satisfaction without negative changes in ROM, strength or spasticity.

SIGNIFICANCE: If statistical analysis confirms a positive effect on balance and walking ability, this FAFO will add to the options an orthotist has when prescribing an AFO. The FAFO is no more expensive to manufacture and so far has no greater orthotic service requirements than current AFOs. We expect the flexible nature of the material to result in reduced need for fit adjustments due to leg swelling or weight changes and with less skin irritation. These reductions should result in further decreased health care costs. Future studies should be done to determine if the FAFO is superior to current devices in orthotic maintenance or patient outcomes and provide even greater reduced costs and improved patient quality of life.

REFERENCES:

1. Slijper A, et al. Ambulatory Function and Perception of Confidence in Persons with Stroke with a Custom-Made Hinged vs a Standard Ankle Foot Orthosis. *Rehabil Res Pract*; vol. 2012, Article ID 206495, 6 pages, 2012.
2. Bettoni E, et al. Neurological patients and their lower limb orthotics: acceptance and satisfaction. *Prosthetics and Orthotics International*; 40(2), 158-69, 2016.
3. Del Bianco J, et al. Comparison of Silicone Ankle-Foot Orthosis and Posterior Leaf Spring Ankle Foot Orthosis Using Gait Analysis in a Subject with Charcot-Marie Tooth Disorder. *Journal of Prosthetics & Orthotics; 20(4):155-162, October 2008.*
4. Owen, E. The importance of being earnest about shank and thigh kinematics. P*rosthetics and Orthotics International*; 34(3), 254–269, 2010.

DISCLOSURE: Second author is owner of the clinic providing the FAFO**.**

A NOVEL AUDITORY BIOFEEDBACK SYSTEM FOR IMPROVING AMPUTEE MOBILITY IN THE HOME AND COMMUNITY

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INTRODUCTION

Everyday mobility of unilateral lower limb amputees can be improved through a standardized prosthetic training and exercise program.[1,2] However, clinical judgement suggests that upon completion of the training program, amputees have a tendency to revert to their habit of asymmetrical walking in the home and community. In order to improve retention and reinforce therapeutic intervention away from the clinic, a novel auditory biofeedback system was developed to assess gait parameters and provide real-time corrective biofeedback[3]. The purpose of this study was to determine the efficacy of the novel auditory biofeedback system in improving gait and mobility of unilateral transfemoral amputees (TFAs) when used at home and in the community.

METHODS

The biofeedback system consisted of inertial measurement units (IMUs) for collecting motion data and iPad for processing data and providing audio feedback. Unilateral TFAs (N=21, mean age 53.5±13.7 years) were randomly divided into four test groups: (1) no exercise & no feedback (controls); (2) exercise only (Ex); (3) feedback only (FB) and (4) exercise with feedback (Ex+FB). At initial visit, subjects were fitted with a Rheo microprocessor knee, were provided gait training and instructed on using the system at home for 4 weeks. The feedback system was designed to detect gait deviations through IMUs, and provide verbal cues to correct these deviations via an iPad. The verbal cues were similar to those provided at the time of gait training in the clinic and reinforced corrective gait patterns. Depending on their group assignment, subjects were given home exercises and/or were asked to practice walking with auditory biofeedback. At the initial and final visits, a self-reported outcome measure (Prosthetic Limb Users Survey of Mobility PLUS-M) and a performance-based outcome measure (Timed Up and Go TUG test), were administered, and stance time was calculated. The effect of auditory biofeedback on changes in these outcome measures was determined.

RESULTS

Table 1 shows the effect size for the average change in self-report, performance-based and biomechanical outcome measures between different groups. Based on Cohen's interpretation of effect size,[4] the combination of exercise and audio feedback had a large effect on SLS time and TUG time, and a medium effect on PLUS-M score, compared to the control group.

	PLUS-M Score	TUG Time	Stance Time
Control vs. Ex+FB	0.73‡	0.85*	1.3*
Control vs. Ex	0.6‡	0.53‡	0.94*
Control vs. FB	0.61‡	1.03*	1.03*

Table 1: Comparison of effect size between groups for selected self-report, performance-based and biomechanical outcome measures. * large effect. ‡ medium effect.

DISCUSSION & CONCLUSION

A large effect size indicates a strong influence of auditory biofeedback on SLS time and TUG time. Upon hearing auditory cues, subjects were able to balance on the prosthetic limb for a longer time, resulting in greater SLS time. The ability to balance on the prosthetic foot increased the walking speed, and subjects were able to complete the TUG test in a shorter amount of time. The corrective biofeedback also had a moderate effect on subject's perception of mobility. Therefore, a Rheo knee, in combination with exercise and auditory feedback can reduce gait deviations and improve functional mobility of unilateral transfemoral amputees.

SIGNIFICANCE

Auditory biofeedback in the form of corrective cues, could be a powerful tool for reinforcing gait training in the home and community, and could be used for long term improvement in gait and mobility of unilateral TFAs.

REFERENCES

1. Gailey RS, et al. *J Rehabil Res Dev*; 45(1), 15-29, 2006.
2. Agrawal V, et al. *Prosthet Orthot Int*; 37, 396-403. 2013.
3. Kim KJ. *IEEE Trans Neural Sys Rehabil Eng*. 24(11).
4. Cohen J. Statistical power analysis for the behavioural sciences, pp. 67-68, 1988.

ACKNOWLEDGMENTS

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WIRELESS IMPLANTABLE MULTICHANNEL MYOELECTRIC SYSTEM FOR PROSTHESIS CONTROL

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INTRODUCTION

Complete functional adoption of upper limb prostheses is unacceptably low. Myoelectric device rejection rates are comparable to those of body-powered prostheses, even though these devices should be capable of providing better function. Amputees cite awkward use and lack of perceived utility of their myoelectric prostheses, as well as dissatisfaction with the ability to perform ADLs. Ultimately, poor control of myoelectric systems limits the adoption of advanced hand prostheses.

Prosthesis manufacturers have released substantially improved prosthetic arm technology in the last decade; however, a well-documented challenge with the implementation of current myoelectric devices is the common use of only two surface EMG electrodes for collection of control signals. Limitations in the control signals extracted from surface EMG signals prevent the implementation of advanced control algorithms and intuitive movement. As a result, these advanced prostheses still require serial selection and control of individual joints and grips resulting in slow, unnatural motions.

We report the results of a proof-of-concept study to verify the *in vitro* performance of the system and an *in vivo* trial to validate device function in an animal model.

METHODS

Ripple has developed an implantable system which simultaneously records 32 channels of myoelectric data from multiple residual muscles, and transmits these data to an external transceiver placed in the prosthetic socket. Our objective is to provide simultaneous multi-degree of freedom prosthesis control, ultimately providing an intuitive control experience. This approach supports a high number of independent control signals and provides access to EMG from deep muscles that cannot be accessed with surface electrodes.

The system comprises a hermetic implanted module from which nine EMG leads emerge. Eight of the leads contain four electrode sites each for 32 total recording channels. A ninth lead provides the reference electrode. The implant receives power inductively from an external transceiver and sends digitized EMG data to the external transceiver via infrared light. By using a single subcutaneous module for telemetry from which several leads emerge, power coupling efficiency remains high.

RESULTS

Implants were validated in a canine study at the University of Utah. Devices were implanted in the front limb by placing the electronics package behind the shoulder blades with electrodes implanted in deltoideous and the lateral head of triceps muscles. One week following implantation, each animal was fitted with a backpack carrying an external transceiver coil and a battery-powered data acquisition system, and the dogs were allowed to freely walk down a hallway. EMG recorded from each animal as it walked down the hallway had very low noise and, in conjunction with recorded video, clearly indicated swing/stance phases of gait.

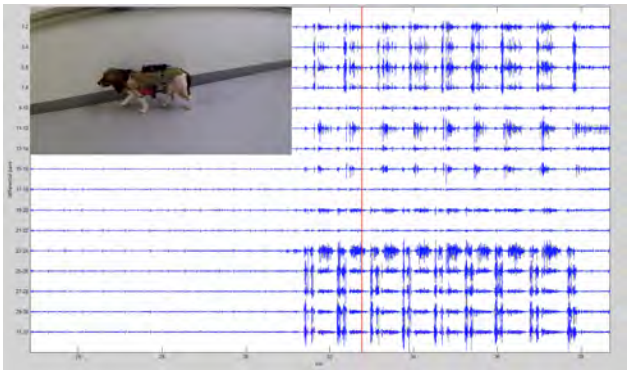

Figure 1. We have demonstrated high data rate transmission using infrared light in chronically implanted canine. Devices were implanted in deltoideous and the long and lateral heads of triceps. Recorded EMG demonstrate very low noise and clearly indicate antagonistic activity of the gait muscles.

DISCUSSION

These efforts demonstrate the ability to amplify and transmit muscle signals and confirm safety and performance requirements. This approach has the potential to provide simultaneous multi-degree of freedom prosthesis control, especially if used with dexterous prostheses, surgical reinnervation techniques (TMR and RPNI), and advanced algorithms.

DISCLOSURE

All authors work for Ripple, a small medical device company developing implantable technologies for high-need humanitarian markets for patients with neurological diseases or disorders. The device described in this abstract is not yet approved for market by the FDA.

ACKNOWLEDGMENTS

This work was supported by NIH U44NS067784 and DARPA HR0011-15-C-0036.

ADAPTIVE CALIBRATION FOR ENHANCED PATTERN RECOGNITION CONTROL FOR UPPER-LIMB PROSTHESES

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INTRODUCTION

Since its commercialization in late 2013, pattern recognition control for myoelectric prostheses has benefitted many individuals with upper limb loss and limb difference[1]. The development of prosthesis-guided training plays an important role in the commercial viability of pattern recognition control by putting the user in control of calibrating (updating) the system whenever and wherever desired. It was described as the "single biggest breakthrough in [Pattern Recognition] in decades"[2]. However, despite the accessibility of the calibration scheme, it remains somewhat rigid: requiring the user to perform a sequence of all available prosthesis movements for each instance. Calibration routine improvements are commonly requested enhancements of the commercial pattern recognition control system.

All human-computer interfaces inherently involve two systems capable of adaptation: the human and the computer (i.e., the algorithm)[3]. It is important that the algorithm adapt to factors including electrode location shift, muscle fatigue, and varying limb orientations during training. In this contribution, an adaptive calibration scheme for improving prosthesis control and potentially reducing the need for recalibration is presented.

METHODS

Seven intact-limb subjects (four males and three females) and five subjects with transradial limb difference (three males and two females) completed the following IRB-approved experiment. A cuff with eight, equidistantly spaced, bipolar electrode pairs was donned on the upper forearm approximately 2 cm distal to the elbow. A software interface guided the collection of the following muscle contraction data: wrist supination and pronation, hand open, key grip, chuck grip, fine pinch grip, and point grip. Subjects completed seven data collection sessions each consisting of eight repetitions of all muscle contractions.

Five classifier-training paradigms were examined: training on the first session and testing on each subsequent session ("Static"), training on session N and testing on session N+1 ("Across"), training with adaptation that remembers all data ("Pooled"), training and testing with adaptation with a fixed memory ("Adapt."), and training and testing within a single session ("Within"). A 2-way ANOVA with classification error as the response variable and training paradigm as a fixed factor was completed. Additionally, the impact of increasing the number of available functional hand grasps on classifier error rate was examined. Finally, a qualitative analysis of clinical use was performed via user feedback.

RESULTS

The results highlight that the adaptive calibration scheme resulted in classification error rates lower than the static classification scheme. Classification error was significantly reduced ($p < 0.05$). The results of the other conditions were not statistically different, but trends toward better performance were noted. It is likely that more subjects are required to achieve an appropriate statistical power. Qualitatively, subjects found that prosthesis control improved and that controller recalibration was not needed as often with adaptive calibration.

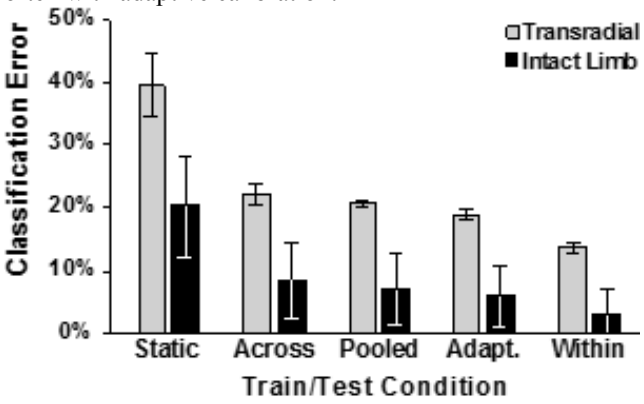

Figure 1: Results showing the classification error rates for all five training paradigms arranged by subject group.

CONCLUSION

While many users express appreciation for the calibration feature of commercial pattern recognition control, the rigidity of the calibration routine has at times proven to be burdensome. An adaptive approach may provide a means not only to reduce the need for recalibration, but also to improve functional prosthesis control. Further investigation into the robustness of adaptive calibration across many different muscle contraction patterns and clinical settings is being explored.

SIGNIFICANCE

Pattern recognition control of upper-limb prostheses is growing in clinical acceptance. Further improvements to the calibration scheme improve the viability of pattern recognition control in comparison with conventional amplitude-based control approaches.

REFERENCES

1. www.coaptengineering.com
2. Kyberd P. *J. Pros. And Orth.*; 54-55, 2012
3. He J. et al. *J Neural Eng.*; 12(4), 2015

DISCLOSURE

Dr. Hargrove has a financial interest in Coapt, LLC.

Additional Weight Added to Ankle Foot Orthoses Could Increase Coordination of Gait in Pediatric Patients

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Introduction

In treating pediatric patients with gait abnormalities due to cerebral palsy (CP) and cerebral vascular accident (CVA) a multi-disciplinary team approach and creative orthotic interventions can yield new treatment pathways. Ankle Foot Orthoses (AFO) are known to improve proprioception and balance[1]. Studies show that patients diagnosed with CP benefit from therapy focused on increasing strength[2] and sensory awareness.

This case series examines custom AFOs with additional weight integrated into the calf section to improve gait.

Methods

After fitting both patients with traditional custom AFOs that did not include additional weight, the physical therapist trialed additional weight cuffs strapped to the patient's calf. When gait improvements were observed, new AFOs were fabricated to incorporate additional weight in the thermoplastic calf section. Images and 2D video were used in clinic to document and review changes in gait.

Results

Patient A, a three year old, was diagnosed with a CVA and presented with decreased right lower extremity strength, decrease weight bearing on the right leg, suspected decreased right lower extremity proprioception, and a leg length discrepancy so the right leg was shorter than the left. Patient A was delayed in walking at 3 years of age and was only walking with a rear facing rolling walker. She had plateaued in physical therapy. A traditional AFO facilitated heel strike but the patient was not able to walk independently more than 3 steps until a weighted cuff was trialed.

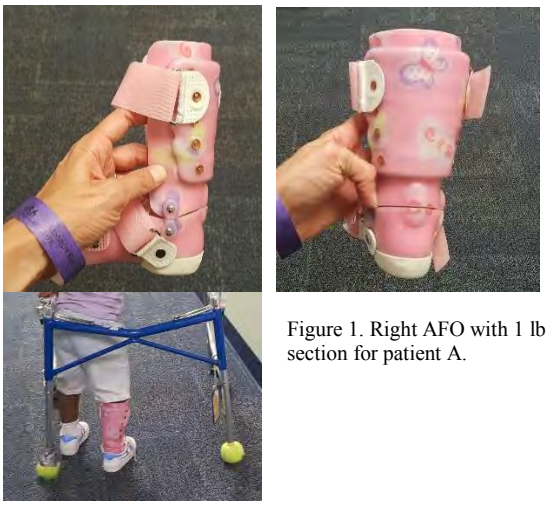

Figure 1. Right AFO with 1 lb weight in calf section for patient A.

With the AFO including a built-in 1 lb weight, patient A began walking further distances independently because she was able to coordinate the heel strike position of her right lower extremity and weight shift over to her right side.

Patient B, a 4 year old, was diagnosed with CP and exhibited hypotonia and dystonic lower extremity posturing that included exaggerated hip flexion, scissoring, and poor heel contact. This patient required 100% body weight support by during gait training. Standard AFOs did not change this patient's gait pattern and the patient plateaued in treatment.

With the weighted AFOs (1 lb weight bilaterally), patient B was able to "find the ground", making heel contact. This allowed the patient to walk more effectively in his gait trainers because heel contact allowed for forward momentum during stance. Patient B's recipircal gait pattern also improved because he gained control over his more dystonic (right) side, and his sitting posture also improved since his lower extremities were grounded.

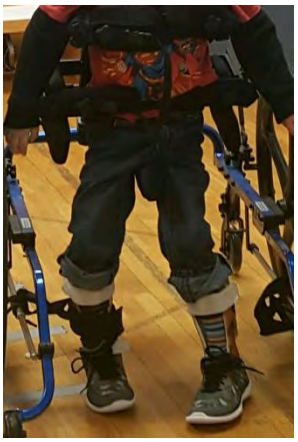

Figure 2: Bilateral AFOs with 1 lb weight for patient B to use in gait trainer

Discussion

Weight can provide an extrinsic factor that promotes proprioceptive feedback and may contribute to improved body awareness and coordinated motor tasks required during gait. These patient cases demonstrate how an AFO can be designed to incorporate a desired amount of additional weight and highlight the benefits that the weighted AFO may have over a traditional AFO for some patients.

Limitations to adding weight to AFOs should be considered, such as the added weight a parent must transfer when handling a dependent child, the potential risks to joints, and lack of carry-over when weights have been removed. However, the potential benefits of improved coordination of movement and reduced dependencey on ambulatory aids outweigh any perceived risks, especially when patients have plateaued in physical therapy.

Conclusion

This case series highlights a new AFO intervention which incorporates additional weight intended to increase proprioception and improve weight bearing in pediatric patients diagnosed with CP and CVAs. Future embodiments of this design may include removable weights and designs that allow weight to be changed for an optimal effect.

References

1. Santos, et al. (2014) Brazilian journal of physical therapy 18.3: 237-246.
2. Engsberg et al (2006) Pediatr Phys Ther18(4):266-275

Adjustable Liners and Sockets for Prosthetic Devices

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INTRODUCTION

Ras Labs' Synthetic Muscle™ will allow amputees to continue their active lives without needing to adjust the fitting of their prosthetic device(s) throughout the day. This technology will resolve major issues facing amputees, most notably the pain of prosthetic slippage and the inconvenience of adding or removing prosthetic socks. Synthetic Muscle™, comprised of electroactive polymers (EAPs), actively expand or contract at low voltages, while offering impact resistance and pressure sensing, all in one integrated solution. The main objective of this project is to determine the feasibility of the EAP pads to be incorporated into prosthetic liners. This is a continuation of the first phase of the project, which demonstrated how the volume of the EAP pads can be changed upon applying a low voltage for use in adjustable prosthetic liners and sockets.

METHODS

The EAP networks were developed by ultraviolet photo-polymerization of ionic monomers with specialized cross-linking agents. The desired pore sizes, and elasticity in the final networks were achieved by controlling the cross-link density and aqueous solvation during polymerization, followed by equilibration of the EAP in electrolyte solution to its final volume. The electroactivity of each EAP was determined using an electrode encircling the sample while the opposite electrode was inserted into the EAP, which was all immersed in an electrolyte solution. Each contraction or expansion cycle begins by application of 5V. The weight and shore hardness measurements were reported after each cycle. In the first electroactivity experiment, a rod of 1 lb., 2.5 lb., or 5 lb. was placed on top of the material after each 15-minute contraction or expansion cycle for 2 minutes. The purpose was to determine whether the material expands back to its original height after the weight is applied. The second electroactivity experiment tested the electroactivity properties in different temperatures: 30°F, 50°F, 70°F, 85°F, 100°F. Each cycle was 15 minutes and there was a total of 8 cycles alternating between contraction, relaxation, and expansion. To determine changes in mechanical properties in extreme temperatures, two chambers were created to place the EAP and a sample of a standard prosthetic liner in 150°F and -30°F. The samples were placed in these environments for 60 minutes, measuring the shore hardness of the samples at time points 0 minutes, 30 minutes, and 60 minutes.

RESULTS

Preliminary results of Ras Labs' Synthetic Muscle™ prosthetic pads are promising. An encapsulated EAP system will be further evaluated to determine a true comparison with the standard liners. The results from the first electroactivity experiment testing the rebound after a weight is added to the sample after contraction, relaxation or expansion cycles are promising. The results show that the polymer rebounds back to its original height after only 5-10 seconds. Under load, the polymer was significant compressed under heavier weight and after expansion cycles. Results from the second electroactivity experiment in different temperatures show that 85°F is an optimal operating temperature, however the polymer is operational between 30°F and 100°F. In Figures 1 and 2, there was a larger change and weight and durometer when the polymer was electroactive in 85°F solution. When tested for survivability in -30°F, the polymers froze and had a significant increase in shore hardness (Table 1). In -30°F, the standard liner samples did not freeze, but they also had a significant increase in shore hardness (Table 1). Within 10 minutes of being placed in room temperature solution after the experiment completion, the Ras Labs' polymer and the standard liner both returned to their respective shore hardness (47 to 50 OO). There were slight changes in shore OO hardness for both samples in the environment set to 150°F (Table 1).

Figure 1 ΔWeight vs. Time; Operating Temperatures

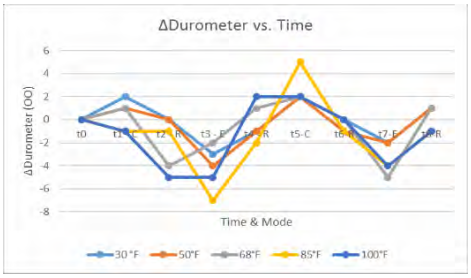

Figure 1 ΔDurometer vs. Time; Operating Temperatures

Sample	Time	Temperature (°F)	Durometer (OO)	Temperature (°F)	Durometer (OO)
Ras Labs' EAP	t_0	-35	47	150	47
	t_{30}	-36	44	152	44
	t_{60}	-38	42	153	42
Standard Liner	t_0	-38	50	150	50
	t_{30}	-34	49	152	49
	t_{60}	-36	48	153	48

Table 1 Changes in durometer; -30°F and 150°F environments

DISCUSSION

This technology is expected to provide for an adjustable prosthetic liner or socket that can maintain perfect fit throughout the day. Our results indicate that Ras Labs' technology can provide for a more advanced standard of care for amputees. Because Ras Labs' Synthetic Muscle™ are also able to sense pressure, there is potential for self-adjusting prosthetic liners with no need for the patients to adjust their device. The ultimate goal is to give amputees natural locomotion with a dynamic worry-free prosthesis.

ACKNOWLEDGMENTS

We gratefully acknowledge the Children's Hospital of Philadelphia/Philadelphia Pediatric Medical Device Consortium, CASIS, the US DOE, and the US DOD for funding of the synthetic muscle project. This project is in collaboration with United Prosthetics, Inc and an additional partner.

ADVANCED PROSTHETIC COMPONENTS IMPROVE STANDING BALANCE AND LIMB LOAD SYMMETRY FOR TRANSFEMORAL AMPUTEES USING MICROPROCESSOR KNEES

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INTRODUCTION

Studies have shown that lower limb amputees, particularly transfemoral amputees (TFA), have reduced balance control during quiet standing, and rely disproportionately on their sound limb for support[1]. In recent years, microprocessor knees (MPK) have sought to assist TFAs with enhanced standing support. Other prosthetic components, such as articulating, hydraulic ankles have shown to improve standing balance in transtibial amputees, on level and inclined surfaces[2]. This study sought to identify the effects of MPKs and hydraulic ankles on balance and loading symmetry.

METHODS

The study was a case series, with a crossover, randomized design (MP control was double-blinded; ankle type was not blinded).
A mixed cohort of K2 and K3 TFAs (n=5), along with able-bodied controls (n=5), volunteered for this study. Each TFA was fitted with an MPK with enhanced standing support (Orion3, Endolite) and both a hydraulic ankle (HA – Echelon, Endolite) and a rigid ankle (RA – Elite, Endolite).
The participants stood facing down a 5° slope for 15 second periods at a time, for four test conditions: standing support on and off for each of the two feet. The ground reaction force (GRF) and center-of-pressure (COP) under each foot was measured and the degrees of asymmetry (DOA) of each were used as outcome measures. Lower limb joint angles were recorded to identify compensatory strategies.

RESULTS

For the fixed ankle foot, the activation of standing mode reduced the vertical GRF DOA, from a 19% difference between the sound and prosthetic limbs, to only 3% difference. GRF DOA in the anterior-posterior direction (down the slope) also decreased.
At the joints, the sound ankle and knee moments were reduced by 23% and 22%, respectively. In terms of balance, although there was no significant difference in COP RMS under the prosthetic foot, with standing mode active, this factor was reduced under the sound limb.
When comparing an HA to the RA (with standing mode active), the RA required more kinematic compensations. As a result, the HA reduced the DOA of joint moments at the ankles and knees.
COP RMS beneath the prosthesis decreased.
Of the four prosthetic conditions, the combination of standing support active and an HA brought the TFA results closest to those of the control participants.

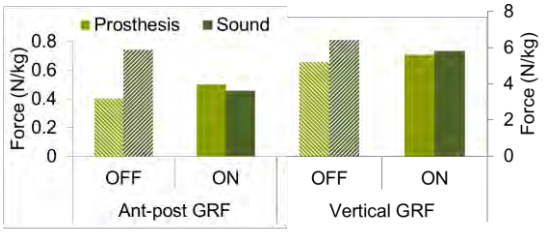

Figure 1: Mean load distribution with enhanced standing support active (ON) and deactivated (OFF)

CONCLUSION

Asymmetrical loading is a causal factor in the progression of secondary health conditions such as the development of back pain, osteoarthritis and osteoporosis, increasing the cost of care[3]. Enhanced standing support provided by MPKs improves indices of balance and symmetry of loading for TFAs, during quiet standing on sloping ground. These advantages are further augmented when used in combination with a hydraulic ankle.
Improvements in balance are beneficial for TFAs, as they are particularly susceptible to the risk of falling[4].

SIGNIFICANCE

The prescription of advanced technology could be beneficial to a patient's quality of life by reducing the likelihood of falls injuries and comorbidities associated with long-term prosthesis use.

REFERENCES

1. Ku PX, et al., *Gait & Posture*, 39(2), 672-82, 2014.
2. Kristal A, et al. *AAOP Annual meeting*, Orlando, FL, USA, 2011
3. Gailey R, et al., *J Rehabil Res Dev*, 45(1), 15-30, 2008
4. Kulkani J, et al., *Physiotherapy*, 82(2), 130-6, 1996

DISCLOSURE

The authors are employees of the manufacturer of the prosthetic components tested in this research

EFFECTS OF PROSTHETIC SOCKET SUSPENSION ON GAIT IN UNILATERAL TRANSTIBIAL AMPUTEES

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INTRODUCTION

Socket suspension is essential in prosthetics and plays an important role in the control of artificial limb. Though vacuum assisted socket system (VASS) has been favorably accepted in the clinical practice, its benefits particularly to control residual limb volume and promote residual limb health (e.g. wound healing) have not been sufficiently justified. VASS is still treated as experimental and investigational. Furthermore, little is known about its effects on gait. The objective of this pilot study was to quantitatively investigate the effects of prosthetic socket suspension including VASS, suction and locking-pin on gait characteristics in unilateral transtibial amputees.

METHODS

Subjects: five unilateral transtibial amputees using locking-pin suspension (age (mean±SD): 65.5±6.3 yr; body height: 1.73±.13 m; body mass: 80.6±15.6 kg) participated in the study.

Apparatus: eight-camera optical motion analysis system with AMTI force plate were used to collect kinetics and kinematics of gait.

Procedures: test sockets with a built-in expulsion valve were fabricated for each individual participant. With suspension sleeve and/or vacuum pump, we were able to obtain two other types of suspension: suction and VASS. Participants visited the lab three times and were instructed to walk at self-paced speed and target the force plate with either side. Signals were collected at 100 Hz. Walking trial was repeated three times for each side.

Data Analysis: gait parameters including spatiotemporal characteristics and kinematics/kinetics of the joints of both sides in the sagittal plane were obtained using Visual3D. Data analysis were conducted in MATLAB with alpha level set at .05.

RESULTS

Table 1 Temporospatial characteristics of gait (mean (std)).

			Amputated side		Sound side	
	Double Support Time (s)	Speed (m/s)	Stance %	Step Length (m)	Stance %	Step Length (m)
Locking pin	0.23 (0.02)	0.94 (0.18)	67 (2)	0.57 (0.12)	70 (2)	0.54 (0.12)
Suction	0.24 (0.03)	0.85 (0.26)	70 (3)	0.56 (0.14)	69 (2)	0.59 (0.13)
VASS	0.23 (0.03)	0.96 (0.22)	70 (2)	0.59 (0.11)	70 (3)	0.54 (0.1)

Table 2 Gait kinematic and kinetic parameters of amputated side (mean (std)).

	Ankle peak dorsiflexion (deg)	Ankle peak plantarflexion (deg)	Frist Peak Knee Flexion (deg)	Second Peak Knee Flexion (deg)	Peak Ankle Plantar Flexion Moment (Nm/Kg)	First Peak Ground Reaction force Z (BW)
Locking pin	8.89 (2.34)	-1.62 (1.31)	5.63 (7.87)	61.98 (6.41)	1.38 (0.15)	1 (0.02)
Suction	13.25 (7.19)	1.43 (3.36)	15.8 (11.85)	59.76 (14.39)	1.32 (0.26)	1.12 (0.06)
VASS	9.31 (6.14)	-2.42 (2.84)	12.45 (7.49)	54.66 (10.49)	1.35 (0.32)	1.07 (0.11)

The self-selected walking speeds were 0.94 (0.18), 0.85 (0.26) and 0.96 (0.22) m/s when using locking-pin, suction and VASS respectively. Temporospatial data was summarized in table 1. The peak ankle dorsiflexion angles were 8.89 (2.34), 13.25 (7.19) and 9.31 (6.14) degrees, and the peak knee angles during stance phase in the sagittal plane were 5.63 (7.87), 15.8 (11.85) and 12.45 (7.49) when using locking-pin, suction and VASS respectively. When using suction the ankle torque was 1.32 (0.26) Nm/kg on the amputated side while the sound side generated a torque of 0.92 (0.31) Nm/kg.

DISCUSSION

This pilot study indicates that the overall performance of suction is poorer than the other two suspension types. Suction or VASS not only influence the ankle/knee kinematics but also lead to distinct characteristics of gait kinetics. Particularly, participants generated larger ankle torque on the amputated side than the sound side. The outcomes of this pilot study could help practitioners in selecting the appropriate type of socket suspension and likely improve the functional performance of the patients.

REFERENCES

1. Beil, T.L. *J Rehabil Res Dev*, 41, 821-8, 2004.
2. Board, W.J. *Prosthet Orthot Int*, 25, 202-9, 2001.
3. Ferraro, C. *J Prosthet Orthot*, 23, 78-81, 2011.
4. Sanders, J.E. *J Rehabil Res Dev*, 48, 1231-48 2011.
5. Fillauer, C.E. *J Prosthet Orthot*, 1, 92, 1989.

ACKNOWLEDGEMENTS

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AN 18-MONTH REVIEW OF IMPLEMENTING OUTCOME MEASURES IN CLINICAL PRACTICE

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PURPOSE

There is an increased need for an evidence-based approach to practice in Orthotics and Prosthetics, requiring the documentation of interventions[1]. Standardized outcome measure (OM) use is increasing; However, commonly reported barriers include time and resource limitations, lack of knowledge, and a perceived lack of relevance[2]. Many clinicians are looking for information on how to overcome these barriers. This presentation will share insight with regards to the (1) feasibility of implementing standardized OMs, (2) impact on single patients, (3) and development of interpretability parameters.

METHODS

In 2015, Barber Prosthetics Clinic in Vancouver, Canada committed to a standardized OM protocol. This process began with selecting OMs to use by evaluating their psychometric properties, interpretability and ease of use. We then chose a set of OMs that covered several domains of interest (comfort, pain, balance and mobility) and defined time intervals within each care episode where these measures would be used. Four practitioners (three C.P (c) and one prosthetic resident) implemented this protocol and documented examples of how this data has proven useful. We also retrospectively extracted and analyzed data using descriptive statistics from patients receiving care between 2015-2017.

RESULTS

Through using OMs routinely in clinical practice, we have found:

(1) Although challenging at times, it was feasible to routinely utilize OM. Tools to ensure success included monthly reports, pre-assembled toolkits, and shared accountability between clinicians facilitated this implementation.

(2) Individually, this data allowed us to evaluate our patient process and adjust interventions based on how they were achieving their goals. On several occasions, this data transformed how we made decisions and resulted in improved, more data-informed care. By sharing OM scores, we both motivated our patients and improved communication with them and the rehabilitation team.

(3) By using the collective data, we began to extract normative values for various populations at specific points within their care episodes. This created evidence for interpretability parameters and allows us to share how to interpret these measures in clinically relevant ways (Figure 1).

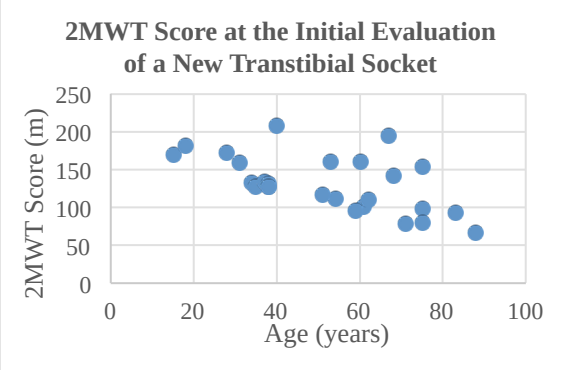

Figure 1. Normative data extracted from clinical data, demonstrating the relationship between participants' age and 2 Minute Walk Test score.

CONCLUSION

By using standardized OMs in clinic, we are able to make data-informed decisions, motivate our patients and improve communication. We are also able to contribute to the evidence on normative values and interpretation of OMs, enabling others to incorporate these into practice in a more meaningful way.

SIGNIFICANCE

We have demonstrated that implementing OMs in a standardized way in a small, private clinic with several practitioners is feasible and there are several benefits, both to the individual clinic and to the larger research community.

REFERENCES

1. Chui K, Wong RA, Lusardi MM. *Orthotics and Prosthetics in Rehabilitation*, pp. 72-103, 2013.
2. Duncan EAS, Murray J. *BMC Health Services Research; 12(1), 96, 2012.*

ASSESSMENT OF PROSTHETIC MOBILITY AND ITS RELATIONSHIP TO FALL HISTORY IN PEOPLE WITH LOWER LIMB AMPUTATION

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INTRODUCTION

The Timed-Up-and-Go (TUG) test is frequently used to assess mobility in people with lower limb amputation (LLA).[1-4] The Centers for Disease Control (CDC) cites a 12-second cut-off time on the TUG as a predictor of increased fall risk in the elderly. The component TUG (cTUG) is a modified version of the traditional TUG that allows for examination of requisite component subtasks[5], enabling quantification of individual prosthetic mobility tasks. The purpose of this study was to identify limitations in prosthetic mobility using the cTUG, and investigate the potential relationship to falls in the amputee population.

METHODS

A cross-sectional study design was employed using a convenience sample of people with unilateral LLA. Participants performed the cTUG in both directions, where a total time plus 5 individual component times were recorded: 1) sit to stand, 2) walk to turn, 3) 180° turn, 4) walk exiting turn, and 5) turn to sit. The number of steps to perform component 3 was also collected. Demographic, amputation specific variables, fall history, single limb balance, hip range of motion and strength were collected. All data was recorded using a custom mobile application on an iPad Air 2.

RESULTS

Seventy-four community ambulating prosthetic users with LLA participated in the study, with a mean age of 47.6 ± 14 years. Subjects were categorized as "faller" or "non-faller" based on a history of at least one fall in the past 12 months, with 48.7% (N=36) classified as fallers. Those within the fall group were younger, with 64% being amputated at the transfemoral (TFA) level. The most common reasons for falling were trips, stumbles, and performing unfamiliar tasks. Additionally, fallers had been amputees for a shorter amount of time (p=.003) and had lower scores on self-report outcomes of mobility (p<.001) and balance confidence (p=.001). Significant differences existed between the groups for cTUG total time and most component times (p<.05) (Fig. 1). Correlations between cTUG and perceived mobility fell considerably when examining the non-faller (r_s=-.75, p<0.001) and faller groups (rs=-.27,p=0.11).

Outcome measures by fall categories

Variable	Fallers (n=36) μ ± SD	Non-fallers (n=38) μ ± SD	p value
Age (y)	45.3 ± 14.3	49.8 ± 13.9	**.005**
Time since amputation (y)	6.6 ± 8.5	11 ± 10	**.003**
ABC	85.8 ± 15.6	94.1 ± 1.6	**.001**
PLUS-M™	55.3 ± 7.6	61.8 ± 7.2	**<.001**
Hip Extension ROM (degrees)			
Sound	-.8 ± 9.1	-7.63 ± 6.5	.16
Prosthetic	-6.7 ± 7.9	-2 ± 9.5	.23
Hip Extension Strength			
Sound	36.9 ± 5.6	36.9 ± 4.7	.25
Prosthetic	33.1 ± 8.3	33.9 ± 9.2	.11
Single Limb Balance (sec)			
Sound	19.7 ± 13.1	20.3 ± 12.6	.42
Prosthetic	1.1 ± .8	1.36 ± .7	**.02**
cTUG test			
Total time (sec)	12.5 ± 4.2	11.9 ± 5.4	**.02**
Component 1 (sec)	1.9 ± 1.0	2.11 ± 1.64	.46
Component 2 (sec)	2.2 ± .8	1.99 ± .7	**.01**
Component 3 (sec)	3.3 ± 1.0	3.1 ± 1.3	**.03**
Component 4 (sec)	1.9 ± .6	1.8 ± .5	.13
Component 5 (sec)	3.1 ± 1.1	2.9 ± 1.7	**.007**
	Median (Interquartile Range)	**Median (Interquartile Range)**	
Number of steps Component 3	6 (7-5)	5 (6-5)	**.006**

Figure 1. Comparison of group characteristics and performance.

CONCLUSION

Despite the cohort being community ambulators, approximately half reported a recent fall, which is consistent with LLA literature.[5] Unlike previous TUG research in amputees[1], cTUG total time is consistent with CDC cut-off for fall risk, and activities such as slower performance of walk to turn, 180° turn, and turn to sit are characteristic of fallers. The observed decrease in correlation of the cTUG with self-perceived mobility in the fall group may indicate that use of only self-report measures is insufficient when investigating fall risk.

SIGNIFICANCE

The cTUG can discriminate people with LLA based on fall history, and could help identify what mobility subtasks are limited in order to guide prosthetic intervention and rehabilitation.

REFERENCES

1. Dite W, *Arch Phys Med Rehabil*; 88, 109-114, 2007.
2. Resnick L, *Phys Ther*; 91, 555-65, 2011.
3. Schoppen T, *Arch Phys Med Rehbil*; 80, 825-28, 1999.
4. Clemens S, *ISPO World Congress*, Lyon, France, 2015.
5. Wong K, *J Rehab Med*; 48, 80-85, 2016.

IS IDIOPATHIC SCOLIOSIS ≥40º AMENABLE TO BRACING AT THE LATER STAGES OF SKELETAL MATURITY?

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INTRODUCTION

When a moderate or severe idiopathic scoliosis is detected at a later phase of growth (Risser 4), patients are often not referred for bracing. Similarly, braced patients whose scoliosis progresses to ≥40º are typically weaned from bracing once they reach Risser 4. While growth velocity slows between Risser stage 4 and 5, there is still the potential for residual growth[1] and risk of additional curve progression. The current weaning protocol is, essentially, a second phase of "wait and see" which may lead to more patients becoming candidates for surgery. There is minimal literature to support late-stage bracing, however, early-stage bracing research validates the importance of in-brace corrections for halting curve progression[2]. The purpose of this investigation is to assess in-brace correction for patients with idiopathic scoliosis of ≥40º at Risser 4.

MATERIALS AND METHODS

We conducted a retrospective analysis of 28 patients from two practitioners using the same 3D bracing system. The brace utilized was the Gensingen Brace (Cheneau-style TLSO) which has an asymmetric design and is produced with CAD/CAM technology. Patients in the cohort included 4 males and 24 females, with an average age of 13.89 years (SD: 1.17; 12-17). All 28 patients had primary curves of ≥40º (M: 47.03°; SD: 8.16°; 40°-64°) and were at Risser stage 4. For patients who previously wore a brace, their initial Cobb angle was measured from an x-ray taken 24-hours out-of-brace.

RESULTS

Percent in-brace correction varied among patients, but all cohort participants experienced some improvement (M: 38.96%; SD: 16.55; 13.16-80%). The mean in-brace correction among the various curve types is shown below (Figure 1).

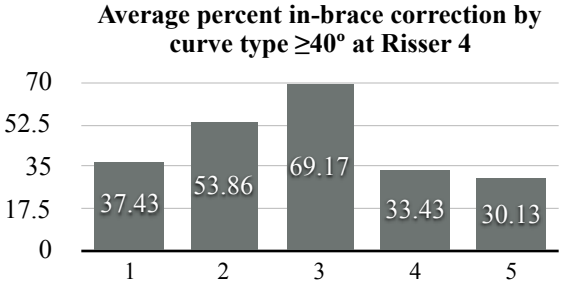

Figure 1. Group 1 = thoracic (n = 13); Group 2 = thoracolumbar (n = 5); Group 3 = lumbar (n = 2); Group 4 = double major, thoracic (n = 8); Group 5 = double major, lumbar (n =8).

DISCUSSION

There are conflicting views on when the cessation of bracing should occur for idiopathic scoliosis, mainly due to the fact that determining the end-point of growth is complex. Historically, the belief has been that "a Risser sign of 4 correlates with the cessation of spinal growth."[3] An opposing opinion in the literature states, "Clinicians should remain cognizant…that vertebral growth can persist even at Risser Stage 4."[4] In addition to Risser class, with female patients, clinicians often use the standard of two-years post-menarche for concluding brace-wear, but this has also been debated[5]. Though not widely-investigated, there is some evidence to suggest that lasting radiological and postural improvements can be made, even in skeletally mature scoliosis patients[6-8], due to remaining spinal flexibility[9]. Our investigation demonstrates that many patients, even those with moderately-severe scoliosis, can achieve significant in-brace correction as a result of 3D asymmetric bracing. It is notable that nearly all patients in the cohort were x-rayed in the brace within 24 to 48 hours of the initial fitting. While continued brace-wear compliance may be difficult for some patients, practitioners must consider the psychological ramifications of ceasing brace treatment too early, only to have the patient eventually go on to need surgery. Additional studies are needed to study the effectiveness of newer Cheneau-style braces in treating larger scoliosis curves, both at early and late maturity.

REFERENCES:

1. Noordeen MH et al. Spinal growth and a histologic evaluation of the Risser grade in idiopathic scoliosis. *Spine*. 1999;24:535–538.
2. Landauer F, et al. Estimating the final outcome of brace treatment for idiopathic thoracic scoliosis at 6-month follow-up. *Pediatric Rehabilitation.* 2003 Jul-Dec;6(3-4): 201-7.
3. Lonstein, JE, et al. Moe's Textbook Of Scoliosis And Other Spinal Deformities. 3rd ed. Philadelphia, Pa.: Saunders, 1995; 76.
4. Hacquebord JH, Leopold SS. In brief: the Risser classification: a classic tool for the clinician treating adolescent idiopathic scoliosis. *Clin Orthop Relat Res*. 2012; 470(8):2335–8.
5. Minnella S, et al. Risser stages, menarche and their correlations with other growth parameters in a cohort of 3,553 Italian adolescent idiopathic scoliosis patients. *Scoliosis*. 2013;8(Suppl 1):O13.
6. Brooks WJ, et al. Reversal of childhood idiopathic scoliosis in an adult, without surgery: a case report and literature review. *Scoliosis*. 2009;4:27.
7. Negrini S, et al. Efficacy of bracing immediately after the end of growth: final results of a retrospective case series. *Scoliosis.* 2009; 4(Suppl 2): O49.
8. Weiss HR, et al. Scoliosis bracing and exercise for pain management in adults—a case report. *Journal of Physical Therapy Science*. 2016;28(8):2404-2407.
9. Hawes, M and O'Brien J. The transformation of spinal curvature into spinal deformity. *Scoliosis*. 2006; 1:3.

DISCLOSURE:

Senior author is the North American distributor of Gensingen Brace.

Case Study: Gait Analyses of Tuning AFOFC for an Adult with Ankle Plantar-flexed Contracture

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INTRODUCTION

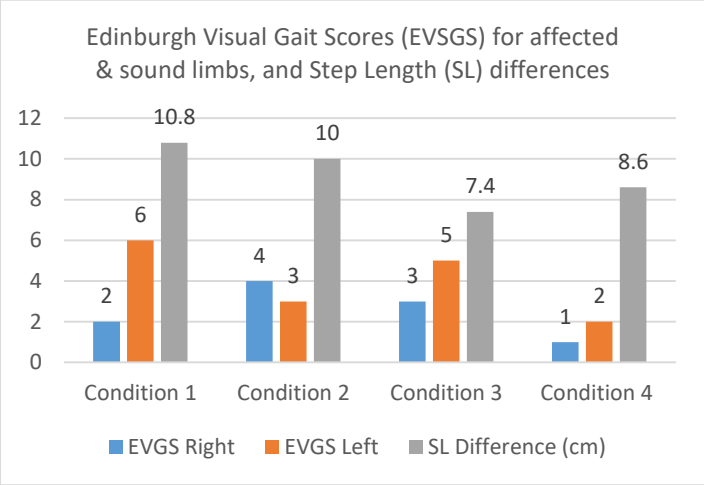
Elaine Owen's tuning AFO-footwear combination (AFOFC) method was developed primarily for patients with cerebral palsy (CP) and spina bifida (SB), in which bilateral treatment is often required. This study examined the biomechanical effects of different degrees of shank to vertical angles (SVA) and shoe modifications, following Elaine Owen's clinical algorithm for AFOFCs during gait for an adult with a unilateral ankle plantar-flexed contracture[1]. Unilateral plantar-flexed contractures typically cause a shortened step on the unaffected side to compensate for the inability to attain second rocker on the affected side. Thus, a secondary purpose of this study was to compare gait parameters between the affected and sound limbs to see what influence the AFOFC method had on gait symmetry as well.

METHODS

This is a case study. The subject has a seven degree rigid plantar-flexed ankle contracture on the left side, due to peroneal nerve palsy following pelvic reconstruction surgery. One custom solid AFO with an ankle angle of seven degrees was made to accommodate the subject's ankle contracture. Two pairs of low ballistic boots were used to make different shoe modifications. The following five conditions were designed to provide comparison between SVAs and AFOFCs on the affected ankle joint: 1. AFO with 0 degree SVA and no shoe modification. 2. AFO with a 5 degree inclined SVA and no shoe modification. 3. AFO with a 5 degree inclined SVA with basic shoe modification. 4. AFO with a 10-12 degree inclined SVA, with Elaine Owen shoe modifications.

An I-pad was used to take sagittal and coronal videos, placed 19'-9" from the walking path and at a height of 28 inches from the floor. PnO Data Live software was used to analyze the gait vides and to measure SVA, joint and segment angles, and step length. The Edinburgh Visual Gait Score (EVGS) and Step Length (SL) were used to compare each study condition. Step lengths were averaged in each condition, and the differences between the affected and sound sides were used to gauge which condition produced a more symmetrical step pattern.

RESULTS



DISCUSSION

The data shows that the AFOFC, following Elaine Owen/s modifications (Condition 4), has an improved EVGS over Condition 1, where neutral alignment (SVA=0) was observed. While a general decrease in EVGS for both limbs was observed across the conditions, changes in hip flexion in swing and hip extension in stance translated into an increased right (sound) limb EVGS from Condition 1 to 2. The left (affected) limb EVGS increased from Condition 2 to 3 as a result of hip flexion and extension scores just outside of normal ranges. Improved clearance in swing on the affected limb was seen in only Condition 4. A decrease in step length differences, used to quantify step symmetry, was improved across conditions with the exception of a slight increase in Condition 4. The patient reported that the AFOFC and shoe modifications (Condition 4) helped make ambulating feel smoother, despite a slight increase in step length asymmetry. While this case study shows an overall improvement in EVGS and step length symmetry with AFOFC and shoe modifications, further study with more subjects should be done to examine the effects different SVAs and shoe modifications have on patients with unilateral plantar-flexed ankle contractures.

REFERENCES

1. Owen E. *Prosthetics and Orthotics International*. 2010;34:254-269.

Case Study: Gait and Functional Analysis of Three Carbon Fiber Ankle Foot Orthoses (AFOs) and Their Effectiveness Addressing Drop Foot

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INTRODUCTION

Carbon fiber is lighter and stiffer with a greater strength-to-weight ratio than alternatives, and has energy storing properties, making carbon fiber an advantageous material for orthotic fabrication.[1] There is a lack of comparative studies on different types of orthoses, attempting to achieve cohesive treatment goals and outcomes; studies are often carried out comparing different types of AFOs irrespective of their treatment goal.

METHODS

This is a case study. The subject has equinus on the left side, due to peroneal nerve palsy following pelvic reconstruction surgery. Three typical (off the shelf) carbon fiber AFOs such as a posterior leaf spring, a medial strut with posterior cuff, and an anterior toe off were fit. The participant performed a modified Emory Functional Ambulation Profile (mEFAP) with shoe only and with either one of the AFOs. The mEFAP included a 5-m walk test, timed up and go (TUG), an obstacle course, and ascending and descending 5 stairs. The participant walked with shoes only and with each orthosis for video recording to measure the Edinburgh Visual Gait Score (EVGS). Gait parameters of EVGS were analyzed based on the video recording and compared to pre-determined normal values. Each test was performed three times at random and with adequate rest allowed between trials. An I-•-pad was used to take sagittal and coronal videos, placed 19'-•-9" from the walking path and at a height of 28 inches from the floor. PnO Data Live software was used to analyze the gait videos.

RESULTS

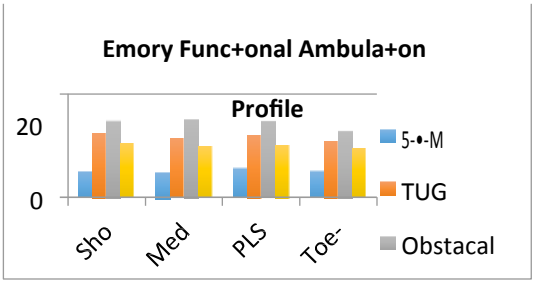

Figure 1. mEFAP scores for participant wearing shoes only, and three AFOs. Data were collected for 5-m walk, TUG, obstacle, and stairs.

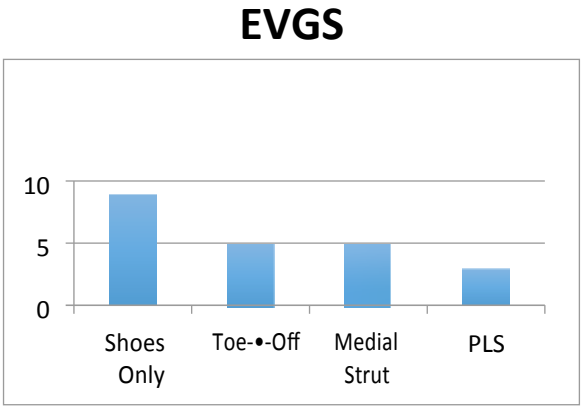

Figure 2. EVGS scores of participant wearing shoes only, toe-off AFO, medial strut AFO, and PLS AFO

DISCUSSION

The data collected indicated when looking at gait parameters used in the EVGS, the PLS AFO showed to have superior results when compared to shoes only or the other two AFOs. However, when analyzing the mEFAP data, the results suggested that for function tasks used in the mEFAP the Toe-off AFO proved to shorter overall times for completing the tasks. The patient also commented that she "felt more comfortable" using the toe-off orthosis. The results could be due to providing the patient with increased stability by assisting with knee extension during midstance while wearing the toe-off AFO. Further research involving more participants and a greater number of trials is needed to draw conclusions from the data presented.

REFERENCES

1. Sheehan, C., & Figgins, E. (2016). A comparison of mechanical properties between different percentage layups of a single-•-style carbon fibre ankle foot orthosis. *Prosthetics and Orthotics International*.

Challenging Current Practices and Beliefs in Using AFOs for Pediatric Patients with Cerebral Palsy

For years pediatric patients diagnosed with cerebral palsy have been managed with standards of practice and beliefs that are now being challenged by new paradigms and research. Clinicians have held to beliefs and practices such as: AFOs should be fabricated to a vertical anatomical alignment in the shoe, AFOs have little or no effect on hip stability, the gastrocnemius (GN) must be strong if the child has an equinus deformity (EQD), accommodating an EQD will not decrease the plantar flexion (PF) contracture, articulating AFOs help reduce PF contractures, AFOs prevent foot deformities and "tone reducing" modifications reduce tone and spasticity. This article will address these existing beliefs of current practice and the new paradigms that have begun to challenge them as myths.

Joint Alignment Myths

One common belief is that the ankle or talocrural joint (TCJ) should be in neutral (90 degrees relative to the floor) resulting in a vertical tibial "neutral" alignment of the AFO when in the shoe. Vertical tibias only exist for a brief moment just prior to midstance in the developed gait and in the pre and early walking patient [1]. Vertical tibias allow the toddler to explore the frontal plane, stabilize the ankle, build strength and practice weight shifting prior to them learning how to walk and move their tibias in the sagittal plane. In the ambulatory patient a bench alignment in the shoe to verticality will place the weight line too far posterior in relation to the base of support. This posterior displacement will create compensatory flexion at the knees and hips and hyper-lordosis of the lumbar spine to achieve and maintain upright stability. The other important factor here is that a predetermined vertical tibia gives no reference to the actual GN length of the patient. This disregard for the GN length can produce a serious negative compensatory pattern for the patient as they reach midstance. Elaine Owen talks extensively about the mutual independence of the patient's actual ankle angle as a measure of the available GN length and the shank to vertical angle (SVA) that is needed to have proper shank kinetics and kinematics during the gait cycle (GC) [2]. Ignoring the GN length is a significant error in the treatment of any patient with respects to AFO management.

The hip is often neglected when talking about AFO management of the LE. Clinicians often insufficiently address the hip dynamics or the understanding of the influence that distal orthotic alignments can have on hip joint ROM and stability. If tibial advancement is halted to verticality in midstance and is not allowed to achieve a determined degree of inclined SVA, the patient will compensate with hip flexion and possible instability at the hip. Through proper tuning of the AFO with the shoe it is possible to get the ground reaction force (GRF) closer to the knee and hip joint centers. This allows the GRF to move anterior to the knee and posterior to the hip joint axes resulting in correctly timed hip and knee extension at terminal stance. (Figure 1) This hip extension moment occurs in opposition to the inguinal ligaments and will result in hip stability and maintenance of hip joint range of motion through the critical phases of weight transfer during walking.

Muscle Myths

As the patient develops GN tightness the belief is that the muscle must be strong to produce and solidify this EQD. It has been shown through muscle strength testing using a dynamometer that all muscle groups tested in children with CP were weaker than those of their nondisabled peers [3]. When the GN acquires a shortened position it is unable to generate significant power during the GC. Clinical findings show that the muscles recruited for upright maintenance gradually transform by shortening and stiffening, this results in an already weakened muscle becoming even weaker.

When considering TCJ neutral alignment it is often accepted that if the AFO is set in PF it will capture or increase the existing contracture. There is no evidence of this and in fact serial casting refutes this myth [4]. When casting for an AFO the orthotist must respect the length that the GN is capable of providing and not force a sagittal plane alignment even if the ankle angle is in residual PF. This respect for the patients GN length will allow them to use the available extensibility of the GN and through proper tuning of the AFO and the shoe, (Figure 2) chronic tonic recruitment of the GN at loading response (most commonly as a result of no heel loading and a dorsiflexion moment from a forefoot strike) is relieved. This reeducation allows the GN to be used more optimally during stance phase instead of being recruited (out of phase) for upright stability.

One of the most ubiquitous beliefs is that an articulating AFO with a PF stop and free dorsiflexion will correct an EQD by stretching out the GN during standing and walking. There is no clinical evidence of this outcome and in fact this leads to all the major fitting problems commonly observed in these types of AFOs. This AFO design is incapable of controlling the forces within the plastic when the GN is shortened. As the tibia is halted by the short GN the calcaneus will be held in relative PF and eventually evert. Once this happens the talus will drop off the sustentaculum tali and travel "down and in". This creates an internal rotation as the tibial has no choice but to follow the talus through the bony lock the talocrural joint dictates. Now the foot is no longer congruent and it is in a position of instability with no chance to recover. The clinical telltale signs are; redness over the navicular, medial malleolus, distal 5th metatarsal shaft and base. The AFO is now relegated to trying to halt the resulting foot deformity as the midfoot has substituted for the forefoot rocker. In fact it could now be argued that such poorly designed AFOs can create foot deformities rather than prevent them.

The holy grail of beliefs is that "tone reducing" modifications within an AFO help reduce tone and spasticity. In some instances it is irrefutable that reduced tone is observed with the application of such

AFOs but the cause and effect cannot be proven when referring to these modifications. There is no clinical evidence that these unique bumps and pads reduce tonic reflexes. However if the resistance of rapid elongation of the shortened GN is reduced and its extensibility is increased, the argument could be made that the tone in the muscle has been reduced. [4]

Myth Busting

The good news is that through the research and clinical practice of therapists and clinicians like; Beverly Cusick, Elaine Owen, Tom DiBello, Bryan Malas, Donald McGovern and others new paradigms are emerging and old beliefs and practices are becoming myths. It is important for the orthotist to evaluate the CP patient more closely and determine the individuals GN extensibility and available length and incorporate these findings into their AFO design. GN length does matter a lot! Limiting degrees of freedom will increase patient tolerance allowing and encouraging appropriate freedoms that they can participate in during upright standing and walking. In prosthetics, the importance of alignment during stance is critical. The same holds true in orthotics in that the AFO in combination with the shoe are critical in optimizing the shank kinetics and kinematics of the GC. New research and paradigms should be explored and embraced, and the myths that prevent the achievement of better outcomes should be critically reviewed and dropped. AFOs can do more than pick up the foot during swing, they can be a very effective therapeutic tools for patients diagnosed with cerebral palsy and lower extremity dysfunctions.

References

[1] Sutherland D.*"The Development of Mature Gait".* Gait Posture. 1997;6:163-170. Sutherland DH. Olshen RA, Biden EN, Wyatt MP. *"The Development of Mature Walking".* London: MacKeith Press;1988. Sutherland DH, Olshen RA, Cooper L, Woo S. *"The Development of Mature Gait".* J Bone Joint Surg. 1980;62-A:336-353.

[2] Owen E. *"Tuning of ankle-foot orthosis combinations for children with cerebral palsy, spina bifida and other conditions"*. Proceedings of European Society of Movement Analysis in Adults and Children (ESMAC) Seminar 2004.

[3] Damiano DL, Quinlivan J, Owen BF, Shaffrey M, Abel MF. *"Spasticity versus strength in cerebral palsy: relationships among involuntary resistance, voluntary torque, and motor function"*. Eur J Neurol. 2001;8 Suppl 5:40-9. Damiano DL, Martellotta TL, Quinlivan JM, Abel MF. "Deficits in eccentric versus concentric torque in children with spastic cerebral palsy". Med Sci Sports Exerc. 2001;33(1):117-122. [4] Cusick B. *"Serial casting and other equinus deformity management strategies"* Progressive GaitWays, LLC, 2010:35-36.

CHANGES IN PRESSURE DISTRIBUTION WITH AN ADJUSTABLE SOCKET

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INTRODUCTION

An appropriate distribution of pressure within a prosthetic socket is essential for biomechanical control, containment, comfort, and maintaining skin integrity.[1] Pressure distribution is dependent on socket configuration, shape, volume, and the socket materials. Prosthetists justify socket billing based on their view that shape and construction of the socket affect distribution of forces on the residual limb and clinical outcomes. However, little research has been done to quantify and validate this assumption.
Our hypothesis is that targeted shape changes in an adjustable socket will result in changes to the pressures applied by the socket onto the residual limb during gait.

METHOD

Strain gauges and thin force sensors were integrated into an adjustable ischial containment socket. The strain gauge was incorporated into the socket's closure system. Force sensors were attached to the socket's distal end, along the long axis of the socket and at the ischial containment aspect of the socket. These sensors effectively mapped pressure distribution within the socket and the tension within a proximal strap. Triplanar motion sensors were incorporated to the socket to measure socket movement. Sensor data were recorded while the participants performed functional tests.
A convenience sample of 10 randomly selected participants were instructed to find a perceived neutral fit then increase and decrease the tensioner by 25 lbs. to create a tight/smaller volume and loose/larger volume variable. Adjustment of the tension value for this adjustable socket system directly correlates with socket shape and volume. L-test, two-minute walk test, and FSST functional outcomes measures were conducted at these variables and associated with sensor data. Participants also recorded a Socket Comfort Score at the conclusion of functional outcomes measures at each variable.

RESULTS

Data analysis across different users showed statistically significant trends. Taking the neutral position as baseline, the participants generated greater pressure in the proximal and ischial containment aspects of the socket, while reducing pressure on the distal end by tightening the closure system and thereby reducing socket volume. Conversely, when the participants loosened the closure system, the pressure in the proximal and ischial containment aspects of the socket decreased, and the pressure on the distal end increased. When performing outcome measures, a loose closure system generated greater data variability for a given sensor (a large difference between high and low values). When the closure system was tightened, the average pressure increased in the proximal sensors, and sensor data variability was lowest.

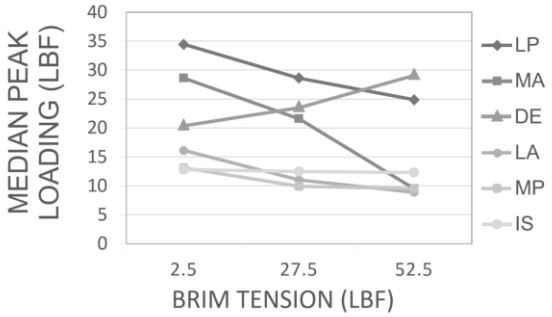

Figure 1: Effect of Varying Brim Tension on Pressure Readings within the Socket

DISCUSSION

Results indicate a direct correlation between socket shape and resultant forces on the residual limb, functional outcome measures, as well as Socket Comfort Score. When the closure system was loose, participants experienced higher distal pressure. When the socket tension was tight, pressure in proximal and ischial containment aspects of the socket increased.
Functional outcome scores and socket comfort scores were lowest at the loose setting. This correlates with the increased variability in pressure distribution data during functional outcomes measures. These results indicate decreased biomechanical control and higher peak pressures when the socket fit was loose. Conversely, when the closure system was tight, variability in pressure readings decreased for each sensor, indicating good connectively between the limb and socket. Functional tests performed with the tightened brim yielded better outcomes, which can be explained with better connectivity and thus better biomechanical control.

Data quantifying the relationship between the profile of pressure distribution on a residual limb and patient outcomes are critical for rational prosthetic socket design and may further help to justify costs when payers challenge the need for socket adjustability or socket replacements.

REFERENCES

1. Brienza DM, et al. Arch of Phys Med and Rehab; 82, 529–33, 2001.

DISCLOSURE

Authors are employees of LIM Innovations.

NOTIFICATIONS

This study was funded by LIM Innovations and in part by defense funding.

CHANGES IN PRESSURE DISTRIBUTED WITH ALIGNMENT CHANGES

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INTRODUCTION

There is general consensus in the prosthetic community that prosthetic alignment is directly related to clinical outcomes. There is, however, not enough clinical outcomes data to adequately support and understand stresses experienced at the residual limb.[1] Such studies can advance prosthetic socket design, and can further help meet the demand for evidence-based care and payment justification by health care payers.

METHOD

Motion sensors and thin force sensors were integrated into an adjustable trans-tibial socket design. Force sensors were integrated to the socket's distal end, along the long axis of the socket, and at the proximal aspect of the socket. Data was recorded while the volunteers performed subsequent functional tests.

A convenience sample of 10 randomly selected volunteers were fit with and aligned in a subject and practitioner perceived neutral fit and alignment. From this neutral alignment, distal componentry alignment was shifted/offset lateral, medial, anterior, and posterior a specified amount (20 mm / 0.79 Inches) for offset variables. L-test, two-minute walk test, and FSST functional outcomes measures were conducted at these variables 3 times each in random order. volunteers also recorded a SCS at the conclusion of functional outcomes measures at each variable.

RESULTS

Data analysis across different users showed statistically significant trends. Compared to the neutral alignment position, greater peak pressures occurred in the proximal-medial and lateral-distal aspects of the socket when alignment was shifted medially. When shifted laterally, greater peak pressures occurred in the proximal-lateral and medial-distal aspects of the socket. When shifted anteriorly, greater peak pressures occurred in the proximal-anterior and distal-posterior aspects of the socket. When shifted posteriorly, greater peak pressures occurred in the proximal-posterior and distal-anterior aspects of the socket.

Functional outcomes measures and SCS were generally best at the user and prosthetist perceived neutral alignment but were not consistent as such and in some cases not significantly different.

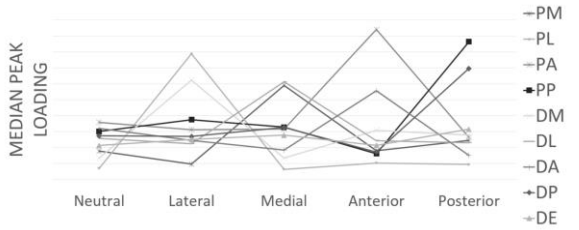

Figure 1: Mean peak pressures during functional outcomes measures for the given variables.

DISCUSSION

Altering the alignment of distal componentry relative to the socket caused only minor differences in functional outcome measures (FOMs) for the participants tested. However, pressure sensors within the socket showed a significant change in pressure distribution with the different alignment variables. Hence, the alignment changes did not significantly hinder the subject's speed or distance of functional outcomes tests but did significantly affect the peak forces within the socket. Some of the participants reported lower SCS with increased peak pressures but the subjective reporting does not appear to have a direct correlation with the peak forces. This may be explained by different levels of pain tolerance and sensitivity as well as different regions of residual limb sensitivity.

Increased peak forces were expected with alignment variation but it was not expected that the participants would still be able to perform the FOMs at the same or similar speed. Interestingly, SCS and FOMs did not seem to have a direct correlation with alignment changes in these conditions but changes in force sensors did show significant change. It should be noted that changes in SCS or FOMs not have shown up as significant only because the study method only included a small duration of use. With time the changes in peak pressures within the socket that were measured could have caused discomfort, pain, or even ulcers and thereby decreased SCS and potentially FOMs.

Results suggest that alignment does affect forces within the socket and that force sensors within the prosthetic socket may be helpful in determining appropriate alignment. More specifically, regional profiling of socket pressures applied to the residual limb can help guide proper prosthetic alignment by giving specific recommendations on the direction and magnitude of alignment shift needed to reduce peak pressures.

While some of these results maybe intuitive to most prosthetist, quantifiable data to support the significance of alignment is helpful for the entire field of Prosthetics to validate our work and reimbursement.

REFERENCES

1. Al-Fakih, et al. *Sensors* 16.7 (2016): 1119.

DISCLOSURE

Authors are employees of LIM Innovations.

NOTIFICATIONS

This study was funded by LIM Innovations and in part by defense funding.

Choosing the optimal Passive-Dynamic Ankle Foot Orthosis for your patient

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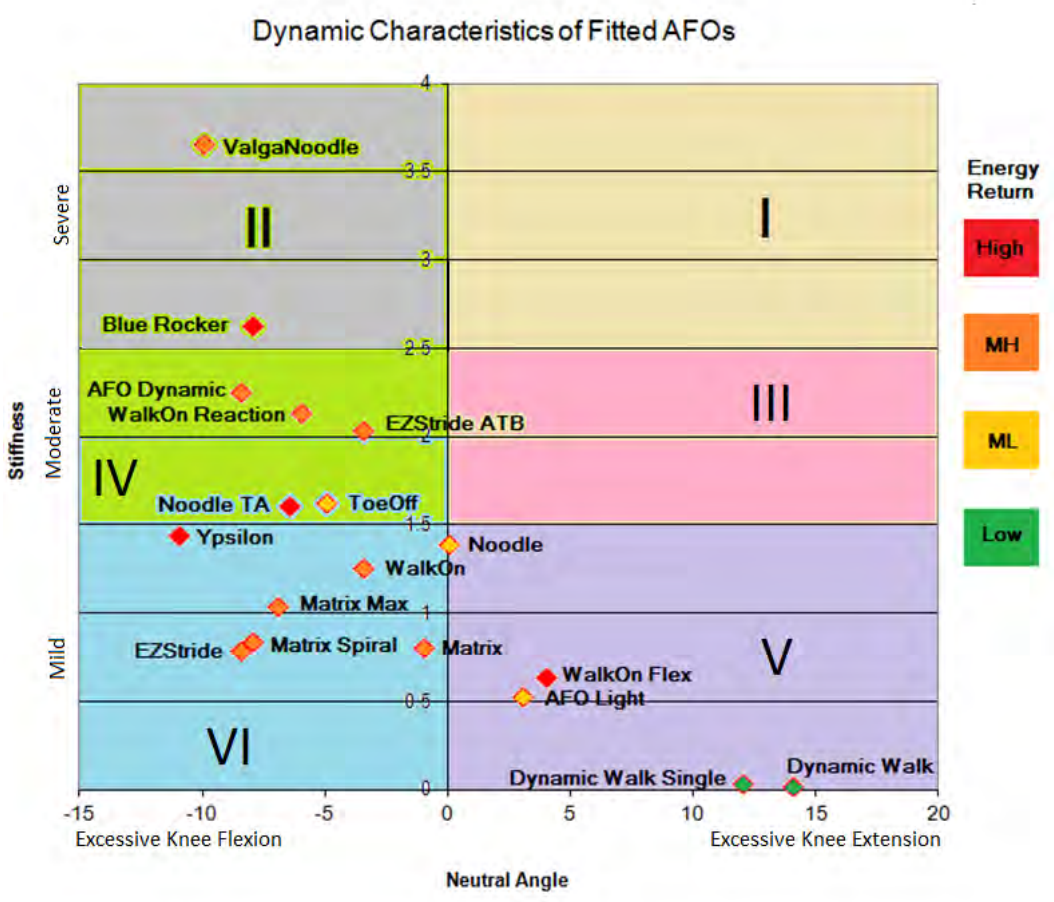
Selecting the correct AFO for your patient involves many tiny decisions that lead to a final selection. This course guides the orthotist through the selection process based on sound biomechanical principles and scientific data. The four primary selection criteria are: Stiffness, Range of Motion, Neutral Angle, and Energy return. An analysis of the four criteria is provided for a selected subset of the available off-the-shelf AFO's that are currently available. The final orthotic selection is based on careful consideration of all the variables by a competent clinician. There are benefits and gait-related costs associated with each AFO variant, by considering each of these aspects during the selection process, patients will maximize their benefits and minimize the costs. A "map" of these AFO's will be provided that gives the clinician insight into the range of options that are available and whether or not they meet the needs of their individual patients.



Clinical results on the use of a microprocessor controlled prosthetic knee component for above-knee amputees of low mobility

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Background

Evidence is accumulating that microprocessor controlled exo-prosthetic knee joints (MPKs) may be beneficial in the support and rehabilitation of above-knee (AK) amputees with diminished mobility [1,2,3,4]. This population has a prominent need to support safe walking, sitting and standing as well as a proper functioning whilst using additional walking aids.

Objective: We present the investigation of the effectiveness of an innovative MPK (Kenevo (K), Ottobock) addressing the specific needs of AK amputees with low mobility. We strive to significantly increase the methodological evidence level for a fundamental contribution to the debate.

Method

K was investigated in a prospective randomized controlled x-over trial conducted in three countries in Europe. A total of 16 centers participated in data collection. All regulatory requirements including authorization, IRB approval and full compliance with ISO 14155 were fulfilled. Validated instruments were used to evaluate subjects performance and perception (Timed up and go (TUG), Locomotor Capability Index (LCI) , Quest 2.0, SF-36 and # of falls). The primary hypothesis was based on TUG. Subjects were eligible if they were using a non MPK in their daily practice and did correspond to ICF items d4601 & d4602 (MOBIS 1-2, K2), with a minimum daily walking capacity of 300m and a base line result of TUG > 19s. Data were retrieved at baseline, 3 months after initial fitting with K and 1 month after returning to the original prosthesis

Results

Thirty five subjects were included. Demografic characteristics were: age: 65,1 ys [48-85], gender: 27m, amputated since 5.3 ys [0.3-27], etiology: vascular disease 46%, diabetes 11%, trauma 23 %, tumor 11%, infection 4%. 89% of the subjects were rated MG2. Original prosthetic knee components were locked knee 34%, hydraulic 31%, break knee 17%, pneumatic 12%. Intention to treat (ITT) analysis showed a reduction in TUG form 24.8 ± 8.3s to 21.6 ± 9.0s, p = 0.001 (Per protocol (pp) 23.1 ± 5.4s zu19.4 ± 5.1s, p = 0.001). LCI improved by 8% (p=0,006) and QUEST 2.0 by18.9%, p=0,002. SF-36 showed improvements in the mental scoring (8%, p=0.01). Falls were assessed in the respective last four weeks per group. Four falls were counted in the non-MPK group, one fall in the K group. The results were not significant.

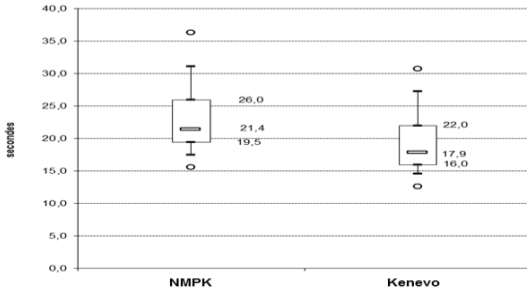

Fig. 1: TUG times were significantly reduced

Discussion and Conclusions

The clinical observations are highly relevant. The reduction in TUG time is associated with a significant reduction in risk of falling. LCI indicates significant increase in mobility and here specifically in the advanced mobility score section. Subjects perceive substantial improvements in their satisfaction with the prosthetic component and quality of life.

Striking is the high level of statistical significance specifically with the primary hypothesis. Together with the study being multicentric this study fulfills the criteria set by the German and French HTA authority allowing to derive with a recommendation based on a single trial. The results led to the acceptance of K with the French reimbursement system. The study presents, to our understanding, the highest level of evidence in exo-prosthetic investigations.

REFERENCES

1. Kannenberg et al, 2014, JRRD 51(10)1469-1496
2. Hahn et al. 2015, JPO 27(3)86-95
3. Kaufman et al, 2016, AOPA, Proceedings
4. Hahn et al. 2016, Medicine 95(45)e5386

Disclosure

A.Hahn is full to time employee at Otto Bock, the manufacturer of K and represents the study sponsor.

Clinical Trials are the Future for P&O

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INTRODUCTION

Prospective, randomized clinical trials (CTs) are the highest level of medical evidence, and the frontier of modern medical research, from AIDS to Zika. Our incredible advances in many disease conditions is the result of focused research in the form of CTs; The National Institutes of Health's ClinicalTrials.gov lists tens of thousands of trials for heart failure, cancer, auto-immune disorders, and diabetes. Of nearly 250,000 total listings, there are fewer than 500 trials listed for limb prosthetics and fewer than 300 for orthotics.The NIH welcomes device-based trials, so why are there so few P&O trials listed?

PROBLEM STATEMENT

We identify three major factors limiting the adoption of a CTs mindset within the P&O community: 1) communication, 2) complexity, and 3) culture.

Communication. Successful design and planning of a CT requires substantial communication across the profession. Critical points of discussion include obtaining consensus targets for treatment allocations, outcome measures, effect size, patient population (inclusion and exclusion criteria), and experimental protocol. Professional organizations, trade periodicals, and ad hoc working groups all provide valuable forums for information exchange and open deliberation.

Complexity. CTs typically require years of planning and millions of dollars to operate. Multi-site CTs can involve dozens of clinical sites, hundreds of staff, and thousands of patients. CTs typically require self-sustaining coordinating centers employing team members with focused effort on data collection, transcription, warehousing, and analysis, as well as day-to-day operations, e.g. payroll, patient compensation, interfacing with regulatory agencies, etc. This intensive enterprise is typically funded either through grantsmanship with a federal agency, or through industrial investment.

Culture. Within P&O, there may be adequate "pieces" to the cultural 'puzzle'. There is the State of the Science. There is ever-increasing organization around central key issues by our professional organizations. Now there is a potent mix of clinical professionals, both those with decades of experience and those with recently-minted graduate diplomas from accredited institutions, ready to apply fresh textbook wisdom to real world problems. Given the recent groundswell of interest in developing clinical trials in P&O [1-3], it may be that the culture is ripe for growth into CTs.

OUR PLATFORM

Clinical trials are an inevitability for P&O: without CTs, the field cannot substantiate itself as a legitimate sub-discipline of contemporary medicine; with CTs, P&O practitioners will be propelled into the highest level of evidence-based practice. On this, the auspicious 100th anniversary of AOPA, and at the AOPA World Congress, we seek a platform to discuss the next evolution as a field, to demystify the mysterious, and to accelerate our advancement into the future of P&O.

REFERENCES

1. Alexander A and Houck K. O&P News launches research trials section. O&P News. 2016;25(10):22-28.
2. Wininger M. Research trials in O&P: Turn enthusiasm into engagement. O&P News. 2016;25(11):10.
3. Wininger, Formulating Clinical Trials in P&O and Allied Health Fields, *Journal of Prosthetics & Orthotics*, 26(1):2-6, 2017.

COMORBIDITIES, PHYSICAL FUNCTION, AND DAILY STEP COUNTS AMONG ADULTS WITH A UNILATERAL TRANSTIBIAL AMPUTATION WHO ARE USING A PROSTHETIC

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BACKGROUND AND PURPOSE

Reduced physical function has a negative impact on quality-of-life post-amputation.[1] Post-amputation, advanced age, sex, and time since surgery are known covariates that impact physical function.[2-4] Performance-based outcome measures allow for objective, clinical assessment of a patient's physical function, while accelerometers enable assessment of a patient's physical activity level (per daily step counts) in their home, work, and social environments.[5] Among adults with lower-limb amputations, to date, there has been little research exploring comorbidities that impact performance-based outcome measures and physical activity. The study's purpose was to explore body systems comorbidities to determine which systems are most important to physical performance and activity among adults with a lower-limb amputation. We hypothesized that the musculoskeletal-integumentary systems would be significantly more-related to physical performance and physical activity than the other body systems.

METHODS

Participants: 50 prosthetic users, aged 18-85 years, with a unilateral transtibial amputation were included in this study. Participants had to report that they wore their prosthetic at least 8 hours/day inside and outside the home to be included. Individuals with bilateral amputations or with weight-bearing restrictions of the residual limb were excluded. The project was approved by the University of Delaware Institutional Review Board for Human Subjects.

Procedures: After signing the informed consent, participants provided information on their past medical history, current medications, and concurrent medical conditions. The Cumulative Illness Rating Scale (CIRS)[6] was used to quantify comorbidity burden for the cardiovascular-respiratory, musculoskeletal-integumentary, and neuropsychiatric systems; lower scores indicate less comorbidity burden. The CIRS specifically assesses body systems impairments and whether or not treatment is necessary. Participants completed the 10 Meter Walk Test to determine self-selected gait speed and the Amputee Mobility Predictor (AMPPro). Participants wore a StepWatch 3 activity monitor around the prosthetic pylon for 7 days following the on-site examination to determine average daily step counts. Individuals with ≥5 days of StepWatch data were included in this analysis (n=47).

Data Analysis: Linear regression modeling assessed relationships between body systems comorbidity burden *and* physical function obtained from clinical outcome measures and accelerometers, while controlling for sex, age, and time elapsed since the initial amputation ($p<.050$). Covariates were entered into the 1st step of the model, while system scores from the CIRS were entered using a stepwise approach in the second step of the model, to determine the system most predictive of gait speed, AMPPro score, and average daily step counts. Assumptions for regression modeling were met.

RESULTS

The sample was predominantly male (n=31). Mean age was 58.5±12 years, while mean time elapsed since the initial amputation was 12.7±14.5 years. Mean comorbidity systems scores were as follows: cardiovascular-respiratory (max. 16.0): 5.8±4.1, musculoskeletal-integumentary (max. 4.0): 1.4±0.6, and neuropsychiatric (max. 8.0): 1.5±1.4. Mean gait speed was .96±.23 m/sec, while mean AMPPro was 38.6±5.4. The participants took on average 5491±4043 steps/day. Above and beyond covariates, the cardiovascular-respiratory systems comorbidity score explained an additional 5.4% of the variance in self-selected gait speed (unstandardized beta: -.013; $p=0.045$) and 6.0% of the variance in AMPPro score (unstandardized beta: -.334, $p=.042$), while the neuropsychiatric systems score explained an additional 6.4% of the variance in average daily step counts (unstandardized beta: -747; $p=.044$).

DISCUSSION

Surprisingly, dysfunction of the musculoskeletal-integumentary systems was less associated with physical performance and physical activity than the cardiovascular-pulmonary and neuropsychiatric systems, respectively. Our results suggest clinical assessments of physical function, specifically the 10 Meter Walk Test and the AMPPro, may be most influenced by dysfunction in the cardiovascular-pulmonary systems while daily step counts may be most influenced by dysfunction of the neuropsychiatric systems. So, if the outcome measure of interest is gait speed or increased functional level, as assessed with the AMPPro, then practitioners might target the cardiovascular-pulmonary systems, while targeting the neuropsychiatric systems might be critical for improving daily physical activity. As this is a cross-sectional study, further research is warranted to longitudinally explore the potential for body systems comorbidities to predict physical performance and activity. If causal relationships are established then interventions may target reduction and/or management of system comorbidities to enhance physical function and activity, which may improve the quality-of-life for individuals with lower-limb amputations.

SIGNIFICANCE & CONCLUSION

Clinicians should consider cardiovascular-pulmonary and neuropsychiatric comorbidities when interpreting outcome measures among individuals with lower-limb amputations.

REFERENCES

1. Furtado, S., et al. *Bone Joint J*. 97-B: 1284-1290, 2015.
2. Plouvier, S., et al. *BMC Musculoskelet Disord*. 17: 178, 2016.
3. Sansam, K., et al. *J Rehabil Med*. 41; 593-603, 2009.
4. Li, L., et al. *J Rehabil Med*. 47; 466-471, 2015.
5. Albert, M., et al. *PloS one*. 8, pe65340, 2013.
6. Hudon, C., et al. *J Clin Epidemiol*. 58, 603-608, 2005.

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Comparative Effectiveness of Microprocessor Controlled and Carbon Fiber Energy Storing and Returning Prosthetic Feet in Persons with Unilateral Transtibial Amputation

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Introduction

Advancements in microprocessor prosthetic ankle-feet (MPA) allow additional functionality for lower limb amputees. Evidence on MPA includes 3D kinematic and kinetic data[1], gait symmetry[2], energy expenditure[3], and socket pressure[4]. Further comparative effectiveness research is needed in larger samples. This study compares differences in perceived balance, mobility, functional capabilities, socket comfort and ramp ambulation between energy storing and returning (ESAR) and MPA with a large sample size.

Methods

Institutional review board (IRB) approved, randomized crossover protocol with ankle-foot configurations consisting of participant's current ankle, ESAR (Paccifica LP) and a MPA (Kinnex, Freedom Innovations).

Figure 1. Kinnex Microprocessor Prosthetic Ankle and Pacifica LP Energy Storing and Returning Foot

Subjects: 4 unilateral transtibial amputees enrolled with average age (54), mass (97 Kg), K-level (3.75)

Apparatus: Prosthesis Evaluation Questionnaire – Mobility Subscale (PEQ-MS), Prosthetic Limb User Survey of Mobility (PLUS-M), Orthotic and Prosthetic User Survey Satisfaction with Device (OPUS), Activities Specific Balance Confidence (ABC) and Socket Comfort Score (SCS); Amputee Mobility Predictor with Prosthesis (AMPPRO), L Test of Functional Mobility (L Test), 5 times Sit-to-Stand (5x STS), 6 min Timed-Walk-Test (6min TWT), Physiological Cost Index (PCI); Hill Assessment Index (HAI), prosthesis side ankle and knee angles at mid-stance of gait during ramp ascent and descent measured with 2D video motion analysis (PnO Data Live, iPad Air 2).

Procedures: Ankle-feet were assembled/aligned to participants' current socket by a certified prosthetist. Markers were placed on the greater trochanter, knee center, lateral malleolus and base of the fifth digit. A 6 ft long ramp with 15 deg slope was used for HAI and 2D motion analysis. Testing was performed after initial assembly and after a 4-week accommodation period.

Data Analysis: A two-factor repeated measures ANOVA model tested participant responses to the ankle-foot configuration, time (initial vs final), and type by time interaction (SAS SAS package JMP). If effects were found to be statistically significant (α=0.05), pairwise t-tests were used.

A Pilot study was completed (N=4) and a sample size estimate was used to design a full study (N=26) to be completed before May 2017.

Results

Effect of ankle-foot was found to be statistically significant in five measures. The initial-final effect did not reach a level of significance. A significant interaction effect was found in the 6min TWT and PCI. P-value of the measures which reached a statistical significant effect are depicted in Table 1 and the pairwise comparison of the ankle and knee angles across ankle-foot devices is depicted in Figure 2.

Measure	p-value
HAI ramp descent	0.0368*
Ankle angle walking ramp ascent	0.0027*
Knee angle walking ramp descent	0.0045*
Ankle angle standing ramp ascent	0.0013*
Knee angle standing ramp descent	0.0379*

Table 1. Measures that reached a statistically significant main effect (*) between ankle-foot configuration (α=0.05)

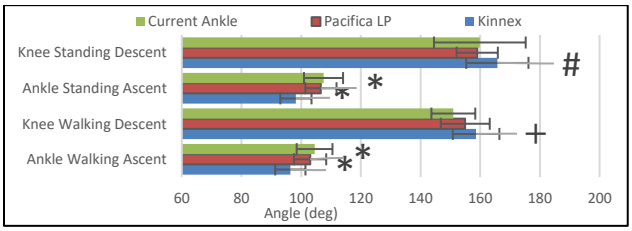

Figure 2. Ankle and Knee angles on the prosthesis side when using different ankle-foot configurations. (*) denotes Kinnex and Pacifica LP significantly different than Current Ankle, (+) denotes Kinnex significantly different than Current Ankle, (#) denotes Kinnex significantly different than Pacifica LP and Current Ankle

Discussion

Pilot study results that did not reach a level of statistical significance (α=0.05) were not displayed in the results section for lack of room in this abstract. HAI on ramp descent showed improved function with Kinnex, and a significant difference between Kinnex and Current Ankle. Angle measurements showed a trend of the Kinnex providing more accommodation at the ankle during slope ascent and a more stable knee position at mid-stance in slope descent. Several differences in knee and ankle angle between ankle-foot configurations reached statistical significance.

These benefits were highlighted in a N=4 pilot study, and a power analysis yielded a feasible sample size target for the full study of N=26 participants. Based on the pilot study results and the lack of significant effect of time (initial vs final timepoint) outcome measrues will only be administered following the 4 week accommodation period. Additionally, several outcome measures were deemed to be redundant with other measures and were removed for the full study. To date, 21 participants have completed the full research protocol and recruitment and enrollment of the final 4 are expected in the coming months. The full study will be completed by May 2017.

Conclusion

The pilot study showed statistically significant benefits with the Kinnex on ramp ascent and descent, while other measures showed positive trends of improved balance, mobility, and socket comfort with the Kinnex.

This study will represent the largest investigation of MPA ever completed and will include the type of outcome measures that clinicians, physicians, patients and payer sources care about. The full study results will be presented at the conference once statistical analysis is completed.

References

1. Struchkov, Clinical Biomechanics 32 (2016): 164-170.
2. Agrawal, Journal of rehabilitation research and development 50.7 (2013): 941.
3. Darter, Prosthetics and orthotics international 38.1 (2014): 5-11.
4. Wolf, Clinical Biomechanics 24.10 (2009): 860-865.

COMPARING RESIDUUM-SOCKET INTERFACE PRESSURE AND SOFT TISSUE DEFORMATIONS FOR THREE TRANSTIBIAL TRIAL SOCKET DESIGNS

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INTRODUCTION

The residuum-socket interface is one of the most crucial factors in rehabilitation after amputation. Researchers have used pressure sensors to measure the distribution of load across the residuum surface[1], and structural analysis (FEA) to predict it[2]. However, such studies have considered a limited number of socket designs, largely without volume imaging to help interpret loading mechanisms. This pilot study aimed to collect a range of imaging and loading data for multiple patients and socket designs, to evaluate the link between pressure loading, socket rectifications and underlying anatomy.

METHODS

Two established unilateral transtibial prosthetic limb users consented to participate (Fraunhofer IPA protocol ref. 2016_BLM_0009). Each was provided with three all-polymer trial sockets with total surface bearing (TSB), Zweckform and Kondylen-Bettung-Münster (KBM) rectifications. Flexible pressure sensor arrays (Pliance S2098, Novel GmbH) were applied to the anterior and lateral aspects of each socket. Triaxial force plates (Accugait, AMTI) were used to measure the ground reaction forces under the amputated and intact limbs. A height adjustable platform ensured consistent socket placement during loading and level hip alignment.

Participants were asked to perform three double-single-double stance transitions on their intact limb, and each test was repeated twice on two days. Pressure data at each sensor cell were cropped to the time where the participant was in a quasi-static double-legged stance, and filtered.

T1-weighted MR images of the amputated limb were taken (MAGNETOM Skyra, Siemens, Fig.1, left), to identify the pressure sensors' correspondence to bony landmarks. A 3D scanner (Go!SCAN 3D, Creaform) was used to capture the shape of the sockets and the residuum with a liner.

RESULTS

The geometric anatomical data from the surface scans and MRI were used to interpret the pressure data, presented for a single day of testing for participant B. Substantially different profiles were observed for each socket (Fig. 1), which illustrate different mechanisms of load transfer. The Zweckform socket had the largest interference between the residuum shape and the socket (approximately 8mm around the patella tendon, and medial/lateral tibial flare). These rectifications, and the fibula head bony prominence, corresponded with the observed pressure peaks. The TSB socket had a relatively uniform interference (~3mm), which resulted in a more even pressure distribution over the anterior surface. The shorter KBM socket employs suspension around the femoral condyles and had a gap of 2-4mm over the bulk of the distal residuum. Soft tissue deformations observed in the MR images demonstrated how this translated the residual soft tissues posteriorly, leading to a more distal loading pattern.

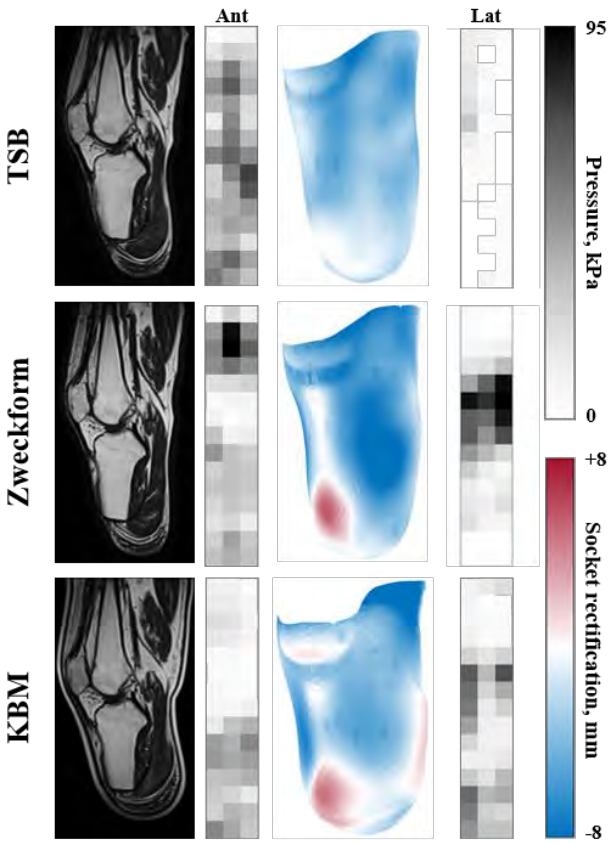

Fig. 1: Sagittal MRI, anterior and lateral pressure distributions, and socket rectifications from 3D scanning

In addition to well-established limitations of pressure mat sensors, this study is limited by quasi-static loading, and measurement of interface pressure without shear[3].

CONCLUSION and RELEVANCE

This study shows the value of combining pressure sensor data with surface scanning and MR imaging to understand the mechanisms of socket-limb load transfer. Whilst MRI may not be feasible as a standard part of clinical assessment, there is scope to enhance the evidence base for socket design. To this end, these data will feed and validate FEA models of the residuum-socket construct, allowing broader parametric analysis of socket design and the resulting soft tissue loading and deformation patterns.

REFERENCES

1. Dumbleton et al, *J Rehabil Res Dev*; 46, 405-415, 2009.
2. Dickinson et al, *Med Eng and Phys*; IN PRESS, 2017
3. Laszczak et al, *Med Eng and Phys*; 37, 132-137, 2015.

DISCLOSURE and ACKNOWLEDGMENTS

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COMPARISON OF TIMED SUBGMERGED SWIMMING (SCUBA) TRIALS WITH AND WITHOUT LOWER EXTERMITY PROSTHESES

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INTRODUCTION

It is known that controlled aquatic activities can have a normalizing effect across many physiological differences: cardiopulmonary, musculoskeletal, respiratory, geriatric, and athletic training.[1] It has been hypothesized that impact of lower extremity amputation on swimming activity can be minimized in the buoyant environment of submerged swimming. It is further known that land based activity at differing amputation levels require increasing energy expenditure.[2] The purpose of this study was to examine preliminary data on the level of exertion measured by heart rate (HR) and compare a 50m swimming trial completed with and without swim prosthesis and level of amputation.

METHODS

The study protocol was approved by the institutional review board at the University of Hartford. Utilizing an outdoor pool six (6) lower extremity amputees of varying amputation side and level (5 male, 1 female; 3 unilateral trans-femoral, 2 unilateral trans-tibial, and 1 bilateral trans-tibial) participated in two (2) trials of three (3) attempts of a 50m length submerged swim at a minimum of 1.2m depth from surface[3]; the first task utilizing of swim specific prosthesis and second task being without. All participants have been cleared for participation in SCUBA activities by various certification agencies. Subjects were instructed to maintain bilateral upper extremities in fully extended position and wrist grasp pattern. This position was an attempt reduce drag, but more so to keep visible real-time HR monitoring as the focus of the participant. Each participant was assigned a target HR based of 60% of maximum HR equations. HR monitoring was achieved with use of chest mounted Polar H7 Heart Rate monitor and wrist mounted Polar M300 display units utilized to water compatibility. Wrist unit displayed subject current HR in one second intervals throughout all swim attempts. After each attempt the subject was given a 20 minute cool down period as to reduce fatigue and reset base HR. After six attempts were completed subject was released from pool.

RESULTS

Results show that no significant difference in time was required to traverse 50m submerged with or without prosthesis. In this sample population a statistically significant difference in the participants' ability to reach the 60%HR_{max} target was observed (Fig.1).

Heart Rate and Time Compared Across With and Without Prosthesis Swim Trials

Subject	HR Diff w/ PRO	HR Diff w/o	Time Diff w/ PRO	Time Diff w/o
A	6.7	3	76.67	84.33
B	6.3	15.7	72.33	87.67
C	3.7	16.3	107.00	124.00
D	4	8.3	68.67	106.00
E	7	16	116.67	102.67
F	2	16	80.67	85.67
Avg of Abs Difference	**4.95**	**12.55**	**87.00**	**98.39**
p-value	0.019		0.296	
Avg of Reported Difference	**-0.05**	**-12.55**		

Figure 1. Data table for mean HR and Time.

DISCUSSION AND CONCLUSION

It was noted that average 60% HR_{max} in the non-prosthesis trials was lower than in trials with prosthesis. It is hypothesized that this may be due the subjects not being able to maintain focus on the target value of 60% of HR_{max} as without their prosthesis the swim pattern is unnatural. Furthermore, these results may be explained by the fact that all of the participants were veterans prior to amputation and received extremely specialized training related to fitness both mentally and physically. Current physical condition and familiarization with swimming prosthesis may also explain the variance in swim trial completion time. Future work will continue to explore these variables and the relationship between aquatic activities and prosthesis.

REFERENCES

1. Becker, BE. *PM&R* 1.9, 859-872, 2009.
2. Göktepe, AS, et al. *J Prosthet Orthot Int* 34.1, 31-36, 2010.
3. Pendergast, D. R., et al. "Energetics of underwater swimming with SCUBA." Medicine and science in sports and exercise 28.5 (1996): 573-580.

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CONTROL WITHIN A VIRTUAL ENVIRONMENT IS CORRELATED TO FUNCTIONAL OUTCOMES WHEN USING A PHYSICAL PROSTHESIS

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INTRODUCTION

Pattern recognition is a commercially available alternative to conventional amplitude based control of myoelectric upper-limb prostheses. Pattern recognition systems are most often tested in offline situations, often with non-amputee control subjects. More recently, studies have begun to test pattern recognition systems using online tests within virtual environments [1]. However, there is no data showing that outcomes measured within virtual testing environments are related to outcomes from real-world test and function.

METHODS

Nine individuals with transhumeral level amputations who had undergone targeted muscle reinnervation (TMR) were recruited for the study. All subjects were previous myoelectric prosthesis users prior to enrolling into the study, but at the time of enrolment, not all subjects were routinely using their prostheses. A custom fabricated prosthesis was created for each patient using a Boston Digital Elbow (Liberating Technologies Inc.), a Motion Control Wrist Rotator (Motion Control Inc.), and a single degree-of-freedom terminal device of their choice. The system was equipped with a pattern recognition control system developed at the Shirley Ryan AbilityLab which was subsequently licensed to Coapt (Coapt LLC).

After being fit with the prosthesis, subjects received occupational therapy and functional use training. Individuals took the device home for a minimum of 42 days (6 weeks) of home-use. At the end of the trial, subjects returned to complete a battery of outcome measures. Two of these tests were the Target Achievement Control (TAC) test [1], and the Assessment for Capacity for Myoelectric Control (ACMC) [2]. The TAC test is a 'Simon Says' type game where the user has to position a virtual limb into a specified target posture. Outcome metrics include the number of postures successfully acquired within 15 seconds, and the average time taken to match the posture. The ACMC is a validated an observational test that is scored by a trained clinician observing the patient perform selected activities of daily living. The result of the ACMC is a rating from 0-100; scores lower than 37.2 have a suggested clinical interpretation as being non-capable myoelectric control users.

RESULTS

Users were able to achieve 96.7% ± 2.5 (Mean ± Std. Error) of all presented postures when performing the TAC test. The completion times for the TAC test were 5.8 ± 0.6 seconds. The scores of the ACMC were found to be 44.9 ± 4.6. The Pearson correlation coefficient between the TAC test completion time and ACMC score was -0.76. This was found to be statistically significant ($p<0.01$) and is generally considered to be a strong relationship [3].

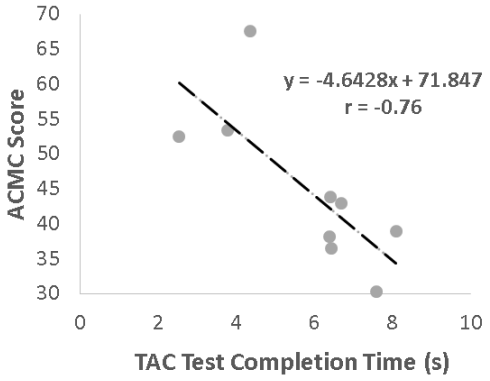

Fig. 1: Data showing a strong correlation between the completion time measured from the virtual environment test and the ACMC measured when using the physical prosthesis.

DISCUSSION

There are many practical benefits associated with virtual environment tests. They are inexpensive to perform, can be performed reasonably quickly, and can be completed prior to constructing a physical prosthesis. The results of this study are important because they suggest that virtual environment tests are strongly correlated with use of the physical prosthesis. The equation of the regression line shown in Fig 1, in addition to the clinical interpretation of the ACMC, suggests that people who achieve completion times of less than 7.5 would have some capability for pattern recognition based myoelectric control.

CONCLUSION

Pattern recognition myoelectric control systems are gaining clinical acceptance. We have shown that transhumeral patients who have received TMR are capable of completing both virtual environments tests and functional tests with a physical prostheses. Importantly, we have shown that the virtual performance metrics are strongly correlated with the ACMC score.

ACKNOWLEDGEMENTS

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DISCLOSURES

Drs. Hargrove and Kuiken have financial interests in Coapt, LLC.

REFERENCES

1. Simon, AM et al, J Rehabil Res Dev, 48, 619-627, 2011.
2. http://acmc.se/
3. Katz, M. *Multivariable Analysis,* 3rd Edition, 2011.

COST-EFFECTIVENESS OF ADVANCED HYDRAULIC MICROPROCESSOR CONTROLLED KNEE PROTHESES IN PATIENTS WITH LOWER LIMB AMPUTATIONS

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INTRODUCTION

One of the primary aims of rehabilitation after major lower limb amputation is the most appropriate prosthetic fitting to support social functioning and participation A new generation of advanced hydraulic microprocessor controlled knee (MPK) components is tailored to the needs of individuals with of lower mobility grades. The potential of such individuals to benefit from such technology had been shown repeatedly[1,2,3]. With the increase of chronic diseases with elevated risk for amputation the health economic assessment of such fittings is of high societal relevance. The reduction of concomitant factors such as falls may significantly improve cost-effectiveness.

OBJECTIVE

Aim of this investigation is to assess the cost effectiveness of advanced hydraulic MPKs vs non-MPKs..

METHODS

A health economical decision tree based model was developed on the basis of existing clinical results [4,5]. The model population (n=1.000, transfemoral amputees, no gender specification) is of either vascular or non-vascular etiology and aged between 55 and 75 years.

The incremental cost-effectiveness (ICER) is calculated to assess the economic efficiency of advanced hydraulic MPKs. Depending on the etiology and the chosen prosthetic fitting, the risk of falls, the number of falls, the severity of injuries and the injury related mortality are modeled over a five years horizon. Parameters related to costs and quality of live assessments are taken from the literature. To verify model assumptions and uncertainties in the chosen parameters a univariate analysis of the sensitivity is performed [6].

RESULTS

The comparison of MPK and non-MPKs yields an ICER of 14.210,95 € per QALY for vascular and 16.679,13 € per QALY for non-vascular etiology. The largest impact on the model is due to quality of life and prosthetic cost.

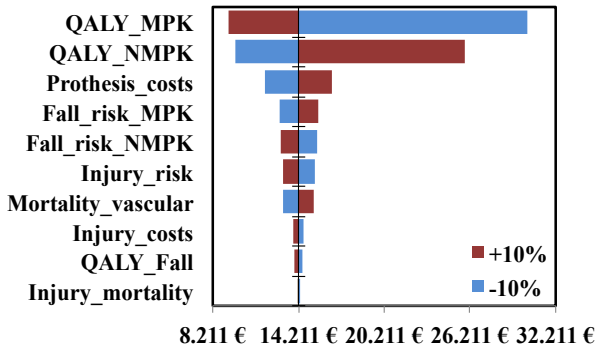

Figure 1. Results of sensitivity analysis for ICER "vascular".

DISCUSSION & CONCLUSION

Results of the analysis indicate the cost-effectiveness of advanced hydraulic MPKs in patients with lower limb amputation. The sensitivity analysis highlights the strong relevance of the factor „quality of life" for the determination of cost effectiveness.

We identify a significant demand for additional research with respect to the factors relevant for the model. Next to a more detailed analysis of costs the impact of parameters related to risk of falling, fear of falling, comorbidities and frequency of falls as well as the related risks of injuries for subjects with major lower limb amputations and their related impact on quality of life are required.

References

[1] Kannenberg et al, 2014, JRRD 51(10)1469-1496

[2] Hahn et al. 2016, Medicine 95(45)e5386

[3] Kaufman et al., 2016, AOPA, Proceedings

[4] Gerzeli et al., 2009, HEPAC 10(1)47-55

[5] Seelen et al., 2009, T&D, 21(1)25-34

[6] Krüger, 2016, Master Thesis

DISCLOSURE

Krüger is M.Sc. of the Leibniz University Hanover. Hahn is full-time employee of Otto Bock HealthCare. Kuhlmann is Senior Research Associate at the CHERH of the University of Hanover.

Cranial Remolding Orthosis Quality Management in Patients with Bracycephaly and Plagiocephaly

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Introduction

Cranial Remolding Orthoses (CRO) are prescribed for infants with brachycephaly and plagiocephaly. A recent publication called into question the efficacy and effectiveness of CRO (van Wijk 2014), but also showed that without intervention the deformity did not improve naturally. Consideration must be taken to the modifications that were made to the helmets of the patients involved in this study and also whether the helmets were fitting appropriately.

Routine documentation of outcome measures is necessary for evidence based practice and performance improvement. Cranial Vault Asymmetry Index (CVAI) and Cephalic Ratio (CR) as well as circumferential measurements are routinely measured and used for individual patient treatment decisions at Ability Prosthetics and Orthotics, Inc., but these values were not entered into the Electronic Medical Record (EMR) in a way that facilitated data reporting.

To establish best practices in the monitoring of patient outcomes, standardized recording and reporting of CVAI and CR within the patient EMR were adopted. This allowed Continuous Quality Improvement (CQI) efforts with CRO and benchmarking against published data. Results from one clinic were queried for interpretation and to inform adoption across all locations.

In routine practice, measurements were taken from a Rodin 4d laser scan and stored in the EMR. De-identified patient data including age, CR and CVAI at initial and final laser scan were exported from Ability P&O's EMR, OPIE Software (Gainesville, FL) over an 11-month period. Patients were separated by diagnosis (plagio- vs brachycephaly).

Results

Twenty records were queried (7 brachycephaly, 13 plagiocephaly). For brachycephaly, average age in months at CRO delivery was 5.86 (4-7) and average reduction in CR was 5.1 (SD 2.19). 100% of patients showed a reduction in CR with 43% reaching a normal threshold (CR ≤ 92.9).

For plagiocephaly, average age in months at CRO delivery was 6.23 (3-12) and average reduction in CVAI was 4 (SD 3.55). 85% of patients showed a reduction in CVAI with 38% reaching a severity level 2 (CVAI ≤ 6.25).

The following figures and tables depict initial/final CR with age at delivery of CRO for brachycephaly (Figure 1), the reduction in CVAI severity (Table 1) and initial/final CVAI with age at delivery of CRO for Plagiocephaly (Figure 2).

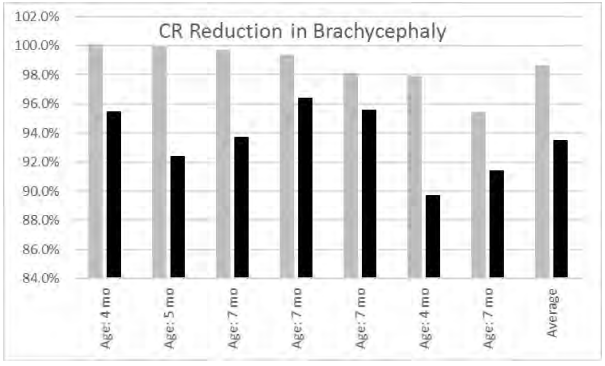

Figure 1: Patient initial (black) and final (grey) CR measurements based on age in months ranked from most severe initial scan (left) to least (right).

Severity	Proportion CVAI at Initial	Proportion CVAI at Final	Ave reduction
5	54%	15%	6.01
4	15%	23%	1.55
3	23%	23%	2.77
2	8%	31%	-0.80
1	0%	8%	n/a

Table 1. Proportion of patients falling in each severity level at initial and final scan in the second and third column. Average reduction in CVAI based on severity at initial scan in the fourth column.

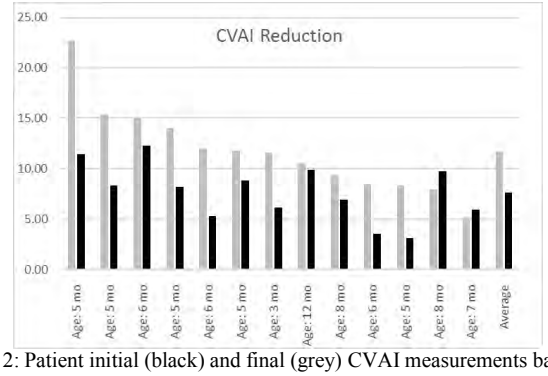

Figure 2: Patient initial (black) and final (grey) CVAI measurements based on age in months ranked from most severe initial scan (left) to least (right).

Discussion

Severity of deformity was reduced in the majority of patients with brachycephaly (43% reaching normal range) and plagiocephaly (38% reaching severity level 2). Patients with more severe deformity at initial scan experienced the greatest correction with CRO. Several patients experienced little reduction in CVAI and two even showed an increase. Due to the many variables associated with each patient, such as the presence of torticollis, compliance of the user, age of patient at time of treatment, etc, it may not be feasible to follow a strict guidelines and expect uniform results for each patient. Documenting and monitoring outcomes of CRO is important to enable the clinician to gauge whether or not their techniques, modifications, and overall treatment plans are meeting patient needs.

Conclusion

We will continue to work to implement changes in the way we practice in order to improve our outcomes. Circumferential measurements will need to be included in our EMR system in order to measure the amount of total growth of each patient. This will help us analyze the change in CVAI and CR in relation to how much circumferential change occurred. Inclusion of the duration of the treatment as well as the age of the patient will be analyzed in future reports. The data that we are collecting and analyzing will allow us to develop best practices and also provide us with appropriate benchmarks in comparison with published data.

References

1. van Wijk, et al. (2014) Bmj. 348: g2741.
2. Kelly KM, Littlefield TR, Pomatto JK, et al. Importance of early recognition and treatment of deformational plagiocephaly with orthotic cranioplasty. Cleft Palate-Craniofacial Journal 1999;36(2):127-130.

DEVELOPMEMT OF A BENCH TESTING PROCEDURE IN QUANTIFYING THE MECHANICAL PROPERTIES OF ANKLE-FOOT ORTHOSES IN ADDITIVE MANUFACTURING

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INTRODUCTION

The ankle-foot orthosis (AFO) is an assistive device commonly prescribed to individuals with lower extremity neuromuscular or musculoskeletal impairments, to address biomechanical gait abnormalities. The additive manufacturing (AM) of AFOs has shown transformative potential in augmenting conventional fabrication processes. Some materials used in AM-AFOs are Nylon-11, Nylon-12, Polylactic Acid and Polycarbonate (PC). Previous literature has highlighted the critical need to accurately analyze the mechanical properties of AFOs for quality assurance in the industry. However, there is a paucity of scientific evidence to justify that current AM-AFO designs are mechanically sound. The aim of this study is to develop a bench testing procedure to determine if the use of PC AM-AFO is mechanically suitable for clinical application, in comparison to the polypropylene (PP) AFO.

METHODS

A PC AM-AFO is replicated from a conventionally fabricated PP AFO with the exact material thickness and trimlines, through fused deposition modeling. Both AFOs are tested for their mechanical properties. A bench testing apparatus (Figure 1) was designed and constructed to measure:

1. Stiffness of the AFO at the ankle joint through 12 degrees of deflection.
2. Stiffness of the AFO at the metatarsophalangeal (MTP) joint through 20 degrees of deflection.
3. Mediolateral splaying of the ankle joint with 12 degrees of deflection.
4. Fatigue resistance of the ankle joint during cyclic loading of 500,000 cycles. Tests 1 and 3 are repeated after every 50,000 cycles to monitor if the material properties change over a period of loading.

The stiffness of the AFO is defined as the moment exerted by the AFO per degree of deflection. Tests 1-3 are repeated five times by a single tester to ensure the reliability of results.

Figure 1. Bench testing apparatus

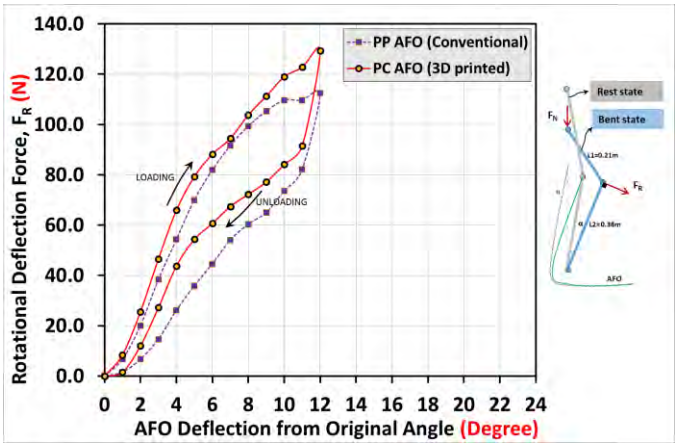

Figure 2. Average rotational deflection force required to deflect AFOs to 12 degrees at the ankle joint.

RESULTS

The standard deviations of tests 1-3 were low and insignificant. The stiffness of the PC AM-AFO (7.85 Nm/deg) is 35% higher than the PP AFO (5.83 Nm/deg) at the ankle joint (Figure 2). The stiffness of the PC AM-AFO is similar to the PP AFO at the MTP joint. Both AFOs exhibit similar mediolateral splaying of the ankle joint during 12 degrees of deflection (PC AM-AFO 19mm; PP AFO 21mm). During cyclic loading, the PP AFO survived 500,000 cycles without significant failure. The PP AFO also exhibited strain hardening up to the 150,000th cycle with increasing stiffness of the ankle joint, before returning to original stiffness values at 500,000 cycles. The mediolateral width of the PP AFO (at rest state) increased by 1.6mm at 500,000 cycles. The PC AM-AFO started to crack after 18,000 cycles, but did not fail catastrophically and managed to maintain its integrity till 50,000 cycles.

CONCLUSION

The bench testing apparatus has shown to be reliable during repeated testing. The PC AM-AFO is a stiffer material than the PP AFO, but showed to have decreased fatigue resistance after repeated loading. The use of PC in AM-AFOs is hence not advisable unless the design is enhanced to account for the difference in mechanical properties, and re-tested on a mechanical testing apparatus. However, the use of PC may still be possible in applications such as the AM of fracture braces whereby the increased stiffness will be favorable. This research is ongoing in the testing of other AM materials in the use with AFOs.

SIGNIFICANCE

With the absence of strong evidence in the mechanical properties of AM-AFOs, this novel research advocates for a robust mechanical testing procedure to ensure the safe use of AM devices among users. This is imperative and relevant especially with the increasing popularity of AM in the Prosthetics and Orthotics industry.

DEVELOPMENT OF AN ACTIVE COOLING SYSTEM FOR IMPROVING COMFORT AND RESIDUAL LIMB SKIN CARE

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INTRODUCTION

The daily use of a prosthetic socket often results in excessive heat and perspiration that can lead to residual limb skin issues and decreased use of the prosthesis due to discomfort. Reducing residual limb surface temperature by removing excess heat from within the socket can improve socket comfort and residual limb skin health. Current residual limb heat management methods include heat-absorbing phase-change liners and frequent doffing of the socket. These methods can have drawbacks such as only temporary heat removal and the time spent doffing and re-donning the socket. Vivonics, Inc. and Liberating Technologies, Inc. (LTI) have developed an active cooling socket that successfully reduced the residual limb skin temperatures of 5 lower limb amputees by greater than the clinically significant level of 2° C [1].

METHODS

To reduce the residual limb skin temperature quickly, a cooling unit was designed to remove excess heat from the prosthetic socket. To aid in the design and materials selection process, a bench-top test system was created. This system was capable of simulating the skin temperature of a residual limb, and was also used to measure the heat-transfer capabilities of each prototype cooling unit. The cooling unit was designed for ease of integration into a prosthetic socket during socket fabrication. In the case of the human test subjects with transtibial amputations, the cooling device was mounted on the posterior side of the socket, whereas the human test subject with a transfemoral amputation had the cooling device mounted on the medial side. A National Instruments LabVIEW controller was created to monitor the residual limb skin temperatures and output the correct corresponding excitation voltages to the cooling unit. In order to gauge system efficacy in more detail, the surface temperature of each residual limb was measured using an array of low-profile thermistors placed at strategic locations. The single-blinded study required each test subject to don the active cooling socket, have their baseline limb temperatures recorded, and then walk on a treadmill at a self-selected speed for 10 minutes while temperatures were recorded continuously. After walking, each subject was seated and remained sedentary for approximately 1 hour while additional temperature data was recorded during one of two randomized conditions. For one condition, the cooling device was turned on (experimental) and in the other the device was left off (control).

RESULTS

The residual limb skin temperatures of all test subjects rose above baseline during the 10-minute walking task. During the control condition (cooling socket powered off), all test subjects experienced little to no skin temperature reduction and did not return to baseline, *even after sitting for ~1 hour*. During the experimental condition (cooling socket powered on), all test subjects on average exhibited a return to baseline temperature in 7 minutes (less time than the 10-minute exertion activity). The clinically relevant 2° C of cooling was achieved in an average of 15 minutes. After 1 hour, a total average temperature drop of 3.4° C was observed (2.4 C° below the average baseline temperature). Figure 1 shows the average temperature changes and the 95% confidence internal (CI) across all test subjects. The graph depicts the limb temperatures beginning immediately after the subject is seated following the 10-minute walking task. The average power consumption across all 5 subjects indicates that a single, 5.5 Watt-hour battery would likely be sufficient for daily use as an entirely portable system.

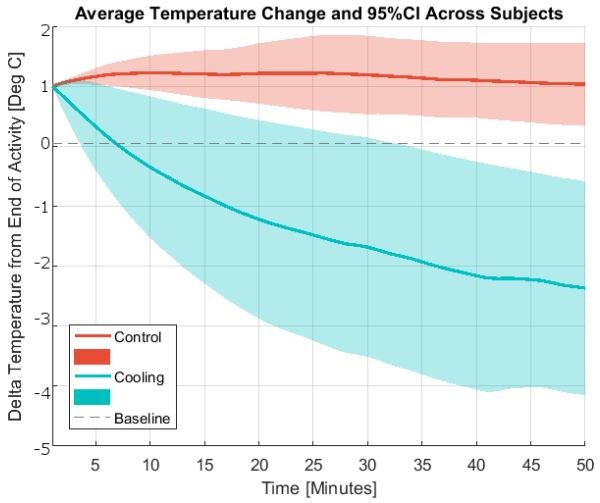

Figure 1. The temperature changes across 5 amputee test subjects while using the cooling device (blue), and while not using the cooling device (red).

DISCUSSION

The results from the first series of human subjects testing suggests that the presented socket cooling unit is a viable means of heat management for amputees suffering from heat and perspiration related discomfort. In 2017, LTI is conducting an ongoing survey and has collected responses from over 100 Certified Prosthetists (CPs) regarding the incidence rate of heat-related discomfort and skin break-down. The current results of the survey indicate a need for the realization of a commercially available cooling device. Future work will include evaluating the compatibility of the cooling unit with different socket suspension types, improving socket integration techniques, and eventual commercialization.

REFERENCES

1. Peery JT, et al. *J Rehabil Res Dev*; Journal of Rehabilitative Research & Development, 42(2), 147-154, 2005.

ACKNOWLEDGMENTS

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DIFFERENCES IN SOUTHAMPTON HAND ASSESSMENT PROCEDURE SCORES WITH AND WITHOUT THE USE OF POWERED PARTIAL-HAND PROSTHESES

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INTRODUCTION

There are almost two million individuals living with limb loss in the United States, with 35% involving the upper limb[1]. Partial-hand loss can significantly impact daily living tasks. The use of an externally powered partial hand prosthesis can potentially restore user function, but the type and significance of improvement is unclear. The Southampton Hand Assessment Procedure (SHAP) is a standardized assessment that measures hand function utilizing both abstract objects and activities of daily living[2]; and has been used in several studies of prosthesis performance. The objective of this investigation was to identify how individuals with partial hand amputations perform the SHAP with and without their prosthesis, as well as to assess kinematics during tasks. We hypothesized improved SHAP scores and kinematics during the prosthesis condition.

METHODS

Recruited participants included adults with a 5-digit or 4-digit (thumb intact) partial hand amputation, had a minimum of 10 hours of occupational therapy with their prosthesis, and had good skin integrity, strength and motion of remaining joints of the residual limb. Participants performed the data collection protocol with and without their prosthesis (order randomized) with a fifteen-minute break between collections. Two trials were completed for each SHAP task, with the best used for analysis. Kinematic analysis was completed on the jar lid opening task. Three-dimensional motion capture (Vicon) was used to determine joint range of motion (ROM) at the shoulder, elbow, and wrist. Healthy two-handed participants completed the protocol with their dominant and non-dominant hands for comparison. Conditions were statistically compared using a mixed-effect model with a within-subject (prosthesis vs. no prosthesis; dominant vs. non-dominant) and between-subjects (prosthesis users vs two-handed) design with an alpha level of 0.05.

RESULTS

Six male individuals with limb loss (35.7±15.5 yrs; 3 4-digit, 3 5-digit) and 6 male controls (25.5±3.9 yrs) completed testing after providing IRB approved informed consent. Four were amputated on their dominant right side (3 4-digit) and 2 on their non-dominant left side. Five of the 6 prosthesis users showed improvement in the SHAP Index Scores, though this change was not statistically significant. The 4-digit subgroup demonstrated no significant SHAP differences. The 5-digit subgroup had significantly different scores in 4/6 categories, and the other 2 trended towards differences (Table 1).

Kinematic analysis of "jar lid opening" indicated that participants utilizing their prosthesis had joint ROM similar to healthy controls, and had much larger ROM without their prosthesis (Table 2). The 4-digit group scored better during this task according to the SHAP without their prosthesis, however, their movement pattern was more normative with their device.

Table 1. Best SHAP scores 5-digit group (n=3) with and without prosthesis. Results presented as group mean (SD).

Category	Prosthesis	Non-Prosthesis	P-Value
Spherical	77.7 (2.3)	37.0 (2.6)	**0.002**
Tripod	53.3 (18.0)	14.7 (10.7)	*0.07*
Power	67.7 (12.7)	14.7 (4.0)	**0.02**
Lateral	70.7 (18.1)	11.7 (0.6)	**0.03**
Extension	46.0 (25.5)	10.0 (6.1)	*0.09*
Tip	77.0 (10.4)	31.7 (19.4)	**0.03**
Index (Overall)	71.7 (13.7)	25.3 (5.9)	**0.02**

CONCLUSION

The 4-digit group could successfully complete every task and completed them with similar scores for both conditions. The 5-digit group were unable to complete at least 13 tasks without their prosthesis; but for all tasks completed, improvements were shown with the prosthesis. While the whole group analysis showed no significant differences, 5 of 6 individuals with limb loss scored higher with the prosthesis. Only 1 participant (4-digit) had higher SHAP scores without their prosthesis (Index score: 95 vs 76), and this score fell within normal limits for an intact hand. A limitation to this study is population size resulting in a weak power to detect differences in scores across conditions. Additional participants are currently being recruited to improve upon these preliminary results.

SIGNIFICANCE

The 5-digit group demonstrated significantly improved functional capability with their prosthesis. However, the 4-digit group demonstrated that the SHAP may be inadequate in assessing overall function, as it is based purely on time. The kinematic results indicated more normative function with the prosthesis even though the SHAP timings were slower.

REFERENCES

1. Zielger-Graham, et al. *Arch Phys Med Rehabil* **89**, 422-429, 2008.
2. Light CM, et al. *Arch Phys Med Rehabil* **83**, 776-783, 2002.

Table 2. Ensemble averages (SD) of ROM outcomes for two-handed and prosthesis user groups. Units in degrees. The following key is used to indicate significant findings ($p<0.05$): [a] for prosthesis vs non-prosthesis, [h] for dominant vs non-dominant, * for non-prosthesis vs dominant, ^ for non-prosthesis vs non-dominant.

Outcome		Prosthesis	Non-Prosthesis	Dominant	Non-Dominant
Shoulder ROM	Flexion/Extension	17.7±7.3	32.9±18.6 *	9.7±8.1 *	15.9±5.4
	Adduction/Abduction	17.4±9.4	29.3±18.2 ^	17.0±6.0 [h]	12.4±3.2 [h] ^
	Int/Ext Rotation	16.8±8.6 [a]	47.2±22.9 [a] ^ *	12.0±4.3 *	21.7±9.3 ^
Elbow ROM	Flexion/Extension	19.0±15.9	35.0±20.9 ^	21.9±11.3	14.8±2.5 ^
	Adduction/Abduction	6.8±4.0	16.2±16.7	4.8±2.5	7.5±2.6
	Supination/Pronation	32.0±17.3	35.6±16.0	24.5±8.1	19.6±13.6
Wrist ROM	Flexion/Extension	20.7±22.3	25.6±44.1	21.3±8.0	29.1±15.1
	Ulna/Radial Deviation	9.9±8.5	17.5±10.5	8.4±2.9 [h]	19.6±8.2 [h]
	Hand Rotation	6.1±6.3	12.1±13.5	8.4±2.6	6.9±2.2

Differences in Stepping and Functional Level While Using the Genium and C-Leg Microprocessor Knees

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INTRODUCTION Preliminary comparisons between the C-Leg and Genium microprocessor knee systems (MPKs) have revealed biomechanical improvements with the Genium system. Some of these were observed during hill walking and some on flat ground. Data also suggest stair ascent is also improved with Genium use. However, multidirectional stepping, observational analysis of hill walking and functional level have not been formally compared between these two MPK systems. These are specific functions observable to clinicians and appreciable to users themselves. Thus, the purpose of this report was to determine if functional level, observational analysis of hill ascent and multi-directional stepping are improved with Genium relative to C-Leg.

METHOD *Subjects*: 20 TFAs (19 Male, 6 Female) were studied. Study protocols were approved by the University of South Florida's IRB, and informed consent was obtained prior to data collection.

Randomized experimental A-B crossover. The 4 square step test (4SST) was assessed by time with a stopwatch to assess multi-directional stepping. The amputee mobility predictor (AMP) was assessed in accordance with published protocols to rate functional level through walking, mobility and transitional movements. The Hill Assessment Index (HAI) was used to rate the quality of subject's ability to ascend a 5deg ramp and finally, the Galileo (Orthocare Innovations. Washington, U.S.) was used to monitor step activity and calculate functional level using the manufacturer's proprietary algorithm which considers multiple aspects of step activity.

Procedures: TFAs were randomized to C-Leg or Genium knee for phase A testing. After an accommodation and training period(Highsmith et al., 2014), subjects performed the aforementioned assessments. Subjects switched knee type, and re-accommodated and re-trained, prior to returning for phase B testing.

Data Analysis: Step activity data were monitored for 1 week in accordance with manufacturer specification and laboratory test steps were not included in functional level determinations. The 4SST was tested 3 times per condition with a rest between trials to mitigate fatigue. Other tests were only rated a single time given their ordinal scaling.

Statistical significance was determined by comparing means or medians of the dependent variables between knee conditions using either paired sample t tests when data sets were continuously scaled, and normally distributed and complete. Otherwise, non-parametric equivalent tests were used. Significance was set a priori at $p \leq 0.05$.

RESULTS

All four of the assessments resulted in statistically significant improvements with Genium use. See results in table 1:

Table 1. Outcome Measures:

TEST	C-Leg		Genium		*p* value
	Central Tendency	Variance	Central Tendency	Variance	
4SST	12.2	3.3	11.1	3.4	0.04
AMP	42	33 to 45	44	39 to 46	≤0.001
HAI	5	3 to 11	11	3 to 11	0.001
Funtional Level(SA)	3.4	1.8 to 4.0	3.6	2.0 to 4.3	0.01

4SST is 4 square step test. AMP is amputee mobility predictor. HAI is hill assessment index. Functional Level is determined via Step Activity (SA) monitoring. Central Tendency is mean(SD) for 4SST and is median(range) for all other tests. Statistical Significance is $p \leq 0.05$.

DISCUSSION

Use of the Genium system significantly ($p<0.05$) improved multi-directional stepping, transitional movements, hill ascent quality and functional level as determined by step activity. The addition of kinetic and kinematic feedback at both the knee and ankle regions seems to enhance the ability of the knee to respond in a manner enabling the patient to walk more confidently and safely thus performing at a higher level on these multiple different tasks. Further, the addition of the axial load sensor and and gyroscope seems to improve the ability to step multi-directionally (i.e. laterally, rearward) and uphill. These improvements ultimately resulted in improved community use and a higher functional level based on step activity monitoring (community based) and also during transitional movements as measured with the AMP. These improvements in stepping and mobility skills are clearly important in contributing to higher levels of functional capability.

CONCLUSION

Genium knee use seems to improve stepping ability and transitional movements resulting in higher functional levels. in community ambulating persons with unilateral TFA.

CLINICAL APPLICATIONS

Genium knee use may be beneficial for users who want or need to walk hills or multi-directionally on a routine basis.

REFERENCES

Highsmith et al., Technology & Inovation, 15**,** 349-358, 2014.

Gailey et al., APMR, 83, 613-627, 2002

Do Foot Orthoses Work? Outcomes from a Multi-Clinic Study of 6,658 Pedorthic Patient Visits

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INTRODUCTION

Since Gordon Guyatt coined the term 'Evidence Based Medicine' in 1991 there has been increasing awareness of empirical assessment of diagnostic testing, prognosis and therapeutic effect.[2] There are few meta-analyses and high quality systematic reviews in the field of musculoskeletal and sports medicine; and fewer still concerning the efficacy of foot orthoses and the value of pedorthic care. Given the value of prescription foot orthotics is estimated to be around US$180 million in the United States alone, and the projected cost of treatment for plantar fasciitis alone to third-party payers has been shown to range from $192 to $376 million[3], it is imperative to provide cost-effective and clinically efficacious treatments. Increasingly, clinical researchers are appreciating that data analytical approaches are needed to provide best-practices and truly patient-centered care.[1]

The objective of the present study is to report on preliminary effectiveness and comfort outcomes in patients seen in 9 pedorthic clinics in Vancouver, Canada in 2016 using a prospective clinical software management system (Kiwi, Surrey, Canada).

METHODS

All patients were seen by a Canadian board certified pedorthist and were fit with custom foot orthoses. All orthoses were manufactured from a 3-dimensional impression of the patient's feet using either a foam-box semi-weight-bearing or infrared-light 3D scanner method. The custom orthoses were CAD processed using Delcam software (Birmingham, UK) then either directly milled from polypropylene using a computer numerical control (CNC) router; or used vacuum pressed thermoplastic or soft-shelled material to a CNC milled positive mold of the CAD processed patient foot.

Follow-up reports were completed either through email, or in-person, using an online based questionnaire consisting of four items: a global indication of change, a 11-point numerical rating scale for worst pain in past 7 days, a 11-point numerical rating scale for orthosis comfort, and a Likert-based scale for frequency of orthosis use.

RESULTS

6,658 new patients were seen for a pedorthic consult in the 12-month period from January 1st to December 31st, 2016 with 1,756 follow-up reports being submitted a mean of 87.9 (+/-127.8) days following orthosis fitting.

Most patients reported having plantar foot pain on initial assessment with 73% of these indicated as plantar fasciitis followed by metatarsalgia, patellofemoral knee pain and osteoarthritis of the knee in order of frequency. Eighty-four percent of patients reported improvement in their primary area of concern, with 60.6% rating themselves as either "much improved" or "completely recovered" (Figure 1). The mean comfort rating was 8.2 +/- 2.3 (with "10" indicating "extremely comfortable") and 64.7% reporting using their orthoses greater than 6 hours per day.

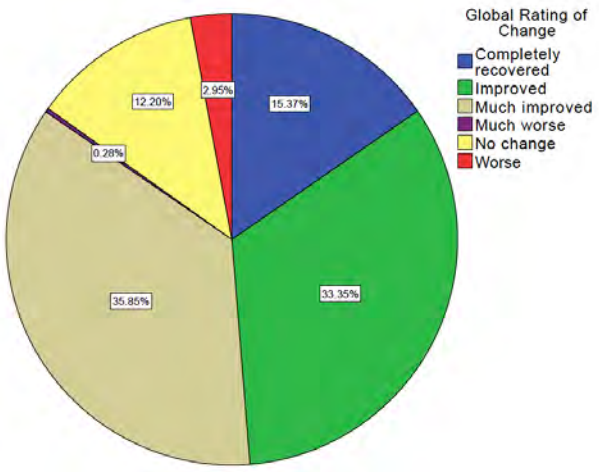

Figure 1. Summary of clinical effectiveness outcomes from the use of foot orthoses

CONCLUSION

The outcomes from this analysis offer important insights into the clinical effectiveness of custom foot orthoses for lower extremity injuries on a large-scale sample. There is also good support from this study on the overall usage and perceived comfort of custom foot orthoses. Further research in this area will examine patient-centered factors (anthropometry, activity level, chronicity, etc.) that are correlated with orthosis success, as well as improving sampling methodology to optimize data integrity.

SIGNIFICANCE

This study will be the largest repository of clinical effectiveness for foot orthosis outcomes to-date and could play an important role in defining best practices approaches to orthotic management of lower extremity injuries, and verifying the economic utility of these devices.

REFERENCES

1. Djulbegovic B, Guyatt GH. Progress in evidence-based medicine: a quarter century on. *Lancet.* Feb 16 2017.
2. G. G. Evidence-based medicine. *ACP J Club.* 1991;A-16:114.
3. Tong KB, Furia J. Economic burden of plantar fasciitis treatment in the United States. *Am J Orthop (Belle Mead NJ).* May 2010;39(5):227-231.

DISCLOSURE

Dr. Ryan is a salaried employee of Kiwi Orthotic Services.

DOES A VACUUM ASSISTED SUSPENSION SYSTEM IMPROVE ELDERLY TRANSTIBIAL AMPUTEES GAIT AND BALANCE CLOSE TO NON-AMPUTEE SCORES?

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INTRODUCTION

Vacuum assisted suspension systems (VASS) extract air from the socket decreasing limb volume changes and improving prosthesis control and propioception[1]. VASS have been found to be useful to improve functional capability in dysvascular trans-tibial amputees[2]. Despite the importance for amputee's health and mobility, there is lack of conclusive evidence of VASS prescription, and their use may not be appropriate for all people with limb loss[1]. This study aimed to examine the improvement in gait capability and functional mobility of elderly trans-tibial dysvascular amputees using a VASS and to describe the differences compared to a non-amputee control group.

METHODS

A before-and-after and case-control study was designed. Unilateral trans-tibial amputees over 65 years were included and mobility grade was evaluated based on the Medicare Functional Classification Levels (MFCL)[2]. Trans-tibial amputees were initially assessed using their prosthesis with the regular socket, and afterwards, they were re-evaluated after fitting a vacuum-assisted socket system (Unity-Assure®, Ossur, Reykjavík, Iceland). Gait capacity was assessed by timed-distance using the 6-min walk test. Functional mobility was assessed using the Timed Get Up and Go test (TUG) and the Four Square step test (FSST) also considered as a balance test. The Rivermead Mobility Index (RMI) was also considered to measure mobility.

RESULTS

The final sample of the study was 10 unilateral trans-tibial dysvascular amputees. Mean age (range) was 69, 97 (66,61-74,59) years. A total of 5 participants were assigned to the MCFL 2 and 5 to the MCFL-3. The control group comprised 10 non-amputee men matched by age, gender, functional level and comorbidity. Trans-tibial amputees with VASS significantly improved gait and functional mobility. Distance (standard deviation) walked was improved from 283 (83,03) m to 365,7 (83,63) m, (p=0,02). Time required for the TUG and for the FSST was decreased in 2,71 (p=0,016) and 5,56 (p=0,028) seconds, respectively. When using the VASS, trans-tibial amputees walked less meters (365,7 (DS 83,63) m) than non-amputees individuals (426 (DS 64,49) m) (p=0,04), however, no differences between groups were found in the TUG and FSST. The most active amputees (MFCL-3) obtained gait and mobility scores comparable to non-amputees.

DISCUSSION

Trans-tibial amputees with VASS improved gait and mobility achieving comparable results to the control group in the TUG and FSST. The improvement of distance in the 6-min walk test using the VASS is clinically relevant according to the minimal detectable change (MDC) described by Resnik et al[3], although distance achieved is not comparable to the non-amputees. The improvement obtained in the TUG is lower than the MDC described by other groups[3] but when using the VASS, trans-tibial amputees obtain results considered normal for general population in the TUG and FSST what is comparable to other studies using a VASS in trans-tibial amputees[2]. Despite the limitation of the small size of the subgroup, amputees with higher mobility grade could achieve gait and mobility scores comparable to that of non-amputee individuals.

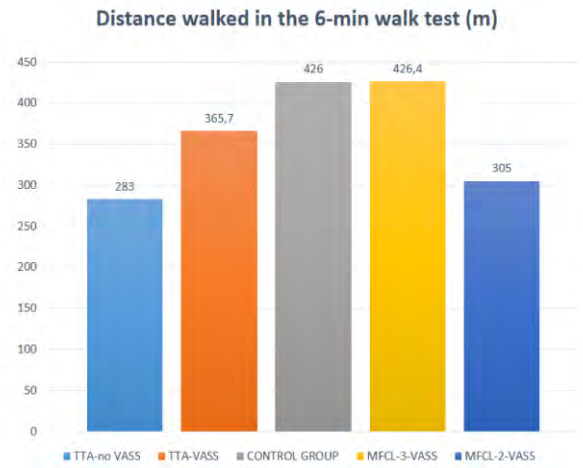

Figure 1: Meters walked in the 6-min walk test by: trans-tibial amputee with conventional socket (TTA-no VASS), transtibial amputee with VASS (TTA-VASS), non-amputee (control group), amputee with VASS grade of mobility MFCL-3 (MFCL-3-VASS) and amputee with VASS grade of mobility MFCL-2 (MFCL-2-VASS).

REFERENCES

1. Gholizadeh, H., Lemiare, E.D., Eshraghi, A. The evidence-base for elevated vaccum in lower limb prosthetics: Literature review and profesional feedback. Clin Biomech (Bristol, Avon). 2016 Aug;37:108-16.

2. Samitier, C.B., Guirao, L., Costea, M., Camós, J.M., Pleguezuelos, E. The benefits of using a vacuum-assisted socket system to improve balance and gait in elderly trans-tibial amputees. Prosthetics Orthot. Int. 2016, Vol. 40 (I) 83-88.

3. Resnik, L., Borgia, M. Reliability of outcome measures for people with lower-limb amputations: distinguishing true change from statistical error. Phys Ther 2011; 91:555-565.

DISCLOSURE

The study was sponsored by Ossur R&D, Iceland, Medical Office. The sponsor had no role in the study activities. The sponsor was provided a summary of study results.

ECONOMIC IMPACT OF BRACE USE TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS ON TOTAL CHARGES IN THE UNITED STATES

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INTRODUCTION

Surgical management of Scoliosis ranks second only to appendicitis as the most common surgical procedure among adolescents. Despite billions of dollars spent in the US alone on this procedure, there is no current literature evaluating the potential economic impact of conservative management.

METHODS

The population eligible for brace treatment was split into treatment categories based on the typical distribution of curve types/magnitude presenting for scoliosis evaluation. SRS bracing guidelines were used for the estimates and a comparison made of natural history and surgical costs compared to bracing history with surgical and bracing costs. Ancillary costs such as physician fees, office visits, are assumed equivalent for the two groups. All costs were adjusted to 2016 USD using the Consumer Price Index (Medical Care). Success rates based on those found in the BrAIST study are used to compare the relative costs associated with brace use vs observation alone. A sensitivity analysis was performed

RESULTS

We estimate 59,638/yr children present for AIS with 21,084 recommended for observation only, 27,546 for bracing and 11,007 for surgical intervention. The surgical differential is 7,713 additional children progressing surgery in the comparison groups. We estimate potential reduction in total charges of more than $500,000,000 when bracing with SRS guidelines compared to observation alone.

CONCLUSIONS

The use of braces to treat adolescent idiopathic scoliosis has a significant economic advantage over observation alone in the United States and improving bracing success even by a modest degree will also substantially decrease overall health care costs. Future research is needed to evaluate the economic implications of bracing to patients and families particularly in relationship to unexplored indirect costs.

SIGNIFICANCE

Bracing has been demonstrated to successfully limit progression of scoliosis curves – but at what cost? This study illustrates that brace use to treat scoliosis may reduce the rates of surgery in a highly cost-effective manner. Input sensitivity highlights further potential cost savings and impact opportunity.

REFERENCES

Goldstein, R. Y., Joiner, E. R., & Skaggs, D. L. (2015). Insurance Status Does Not Predict Curve Magnitude in Adolecent Idiopathic Scoliosis at First Presentation to an Orthopedic Surgeon. *Journal of Pediatric Orthopedics, 35*(1), 39-42.

Lange, J. E., Steen, H., & Brox, J. I. (2009). Long-term results after Boston brace treatment in adolecent idiopathic scoliosis. *Scoliosis*.

Negrini, e. a. (2016). Braces for Idiopathic Scoliosis in Adolescents. *SPINE*, 1813-1825.

Weinstein, S. L., Dolan, L., Wright, J. G., & Dobbs, M. B. (2013). Effects of Bracing in Adolescents with Idiopathic Scoliosis. *The New England Journal of Medicine*, 1-10.

DISCLOSURES

[1] None
[2]Greensun – Advisory Board/Panel, Stock/Shareholder
[2]General Electric – Stock/Shareholder
[2]Abbot Labs – Stock/Shareholder
[2]Abvie – Stock/Shareholder

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EFFECT OF SACROILIC BELT ON ACTIVITY PATTERN OF LUMBOPELVIC MUSCLES IN PATIENT WITH UNILATERAL SACROILIA JOINT INSTABILITY IN DIFFERENT LOADING CONDITION

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PhD candidate in USWR, IRAN[1], professor in IUMS, IRAN[2], professor in TUMS, IRAN[3]

INTRODUCTION OR PURPOSE

The sacroiliac joint (SIJ) is one of the potential sources of low back pain (LBP) , and the prevalence of sacroiliac joint pain (SIJP) is reported to be 13-30% in patients with non-specific LBP[1, 2]. The main function of the SIJs has been often described to transferring the load of the upper body weight to the legs, and transmitting ground reaction force from the lower limbs to the trunk. It is often recommended that patients suffering from SIJP wear the SIJ belt while walking and standing, and many clinicians have incorporated the use of the SIJ belt into their routine therapy. The purpose of this study was to compare the effects of the SIJ belt on lumbopelvic muscle activation patterns during different loading condition in subjects with unilateral sacroiliac joint instability.

METHODS

Thirteen patients (thirteen young women) with unilateral SIJ instability volunteered to participant in this study. Inclusion criteria were positive ASLR and in three of the five provocation tests[3], exclusion criteria were past or present orthopedic surgeries, severe deformity in spine or lower extremity, history of fracture in trunk and lower limbs and neurological disease. The tasks were done in six different conditions (standing on two legs with same and counter same loading - standing on involved side with same and counter same loading - standing on uninvolved side with same and counter same loading). The six conditions were done with and without belt. loading was equivalent with %10 of body weight ,and in line with the involved and uninvolved side. Surface electromyography (EMG) data(signal amplitude) was collected from lumbopelvic muscles.

RESULTS

We found significantly decreased LD muscle[in two conditions :one leg standing on involved side with counter same loading (P v =0 .032) - one leg standing on uninvolved side with counter same loading (P v= 0.009) ,TrA/IO muscle[in three conditions :one leg standing on involved side with counter same loading (P v=0.021) - one leg standing on uninvolved side with same loading (P v= 0.034) - double standing with same loading (P v= 0.036) and BF muscle [in two conditions : one leg standing on involved side with same loading (P v = 0.011) - one leg standing on involved side with counter same loading (P v= 0.006) activities and significantly increased GM muscle [in one condition : one leg standing on involved side with same loading (P v = 0.044) activity during different loading condition in double standing and one leg standing when the SIJ belt was applied .

CONCLUSION

We suggested to Wearing Sacroiliac joint belt leads to increased force closure in lumbopelvic girdle and finally stability of this region.

REFRENCES

1. Slipman, C.W., et al., *Sacroiliac joint pain referral zones.* Archives of physical medicine and rehabilitation, 2000. 81(3): p. 334-338.
2. Maigne, J.-Y., A. Aivaliklis, and F. Pfefer, *Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain.* Spine, 1996. 21(16): p. 1889-1892.
3. Laslett, M., et al., *Diagnosis of sacroiliac joint pain: validity of individual provocation tests and composites of tests.* Manual therapy, 2005. 10(3): p. 207-218.

EFFECTS OF PROSTHETIC SOCKET SUSPENSION ON KNEE PROPRIOCEPTION AND DYNAMIC BALANCE IN TRANSTIBIAL AMPUTEES

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INTRODUCTION

Prosthetic socket suspension offers a critical means to intimately integrate the prosthetic device with the human body. Though several studies highlighted the benefits of using vacuum assisted socket system (VASS), the outcomes have been shown only marginal and/or amputee dependent. The limited scientific evidence fails to justify its clinical necessity. To further extend our knowledge base on the effectiveness of VASS, studies addressing aspects closely related to amputee's functional performance when using VASS are strongly needed. In this study, we systematically evaluated and compared three prosthetic socket suspensions: 1) locking-pin; 2) suction; 3) VASS. It was hypothesized that VASS will improve knee proprioception and dynamic balance when compared to other suspensions.

METHODS

Participants

Unilateral transtibial amputees, who have amputations due to either trauma or PVD for more than a year without neuromuscular disorders and can walk independently (K level ≥ 2, 15 male and 1 female; mean (std); age: 63.4 (7.9) yrs; body mass: 85.5 (22.4) kg; body height: 1.77 (0.10) m), participated in the study. With one-way expulsion valve and/or vacuum pump, we were able to obtain two other types of suspension (i.e. suction and VASS) for five participants who were originally using locking-pin suspension. Participants were placed in three groups according to the suspension types used: 1) locking pin (n = 10); 2) suction (n = 9); 3) VASS (n = 7).

Knee position sense

A custom electrical goniometer was used to measure knee joint position. Knee position sense was tested with and without weight bearing across joint positions ranging from 5 to 25 degrees with 5 degrees of increment. The matching errors were calculated using root mean squared error (RMSE) over a window size of 100 samples.

Dynamic balance

Participants walked on a treadmill at their self-selected speed with a tri-axial accelerometer attached to the lower back for three 3-min walking sessions with break in between. Local dynamic stability (LDS) was estimated using Lyapunov exponents in mediolateral, anteroposterior and vertical directions. Data were processed in MATLAB (Mathworks, Inc. MA).

Statistics

One-way ANOVA with repeated measures was conducted with alpha level set at 0.05.

RESULTS

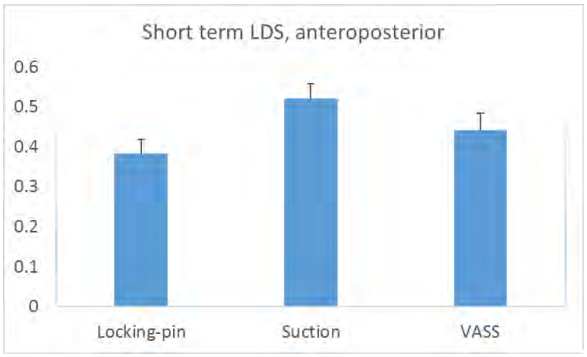

Figure 1. Short term LDS in anteroposterior direction.

The RMSEs (mean±SE) of knee joint sense are 2.02±0.57 deg, 2.20±0.60 deg and 2.02±0.68 deg for locking-pin, suction and VASS respectively and there is no statistical difference between suspensions (P=0.97). The RMSEs for knee joint sense are 2.63±0.44 deg and 1.53±0.35 deg for non-weight-bearing and weight-bearing respectively (P=0.004). RMSE for knee joint sense are 1.50±0.32 deg, 2.78±0.46 deg, 2.50±0.37 deg, 1.74±0.33 deg and 1.87±0.66 deg for target of 5, 10, 15, 20 and 25 degrees respectively (P= 0.004). The short term local dynamic stability (mean±SE) in the anteroposterior direction are 0.38±.04, 0.52±0.04 and 0.44±0.04 for locking-pin, suction and VASS respectively. The effect of suspension shows statistical significance (P=0.047) and the AP short-term LDS of locking-pin is significantly less than that of suction (P=0.036).

DISCUSSION

The outcome of this study indicates that prosthetic socket suspension does not influence knee joint sense and locking-pin is superior to other means particularly suction in dynamic stability. The study is limited by a relatively small sample size and the fact that some of the participants have not used other suspensions (i.e suction or VASS) before. Further study with larger sample size and suction/VASS suspension of original users is needed.

REFERENCES

1. Hilfiker R et al. *BMC Res Notes*; 6(1), 260, 2013
2. Clark FJ et al. *J Neurophysiol*; 42(3), 877-88, 1979
3. Board WJ et al. *Prosthet Orthot Int*;25(3), 202-9, 2001

ACKNOWLEDGEMENTS

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EMPOWERING PROSTHESIS WEARER'S SELF-MANAGEMENT ABILITIES THROUGH MOBILE TECHNOLOGY: A USABILITY & ACCEPTABILITY STUDY

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INTRODUCTION

The most common reason individuals with limb loss consult their prosthetist is due to lack of socket comfort.[1] Prosthetic socket fit is a fundamental factor in determining successful ambulation.[2] An appropriate fit between the socket and residual limb is necessary to optimally participate in vocational and recreational acitivities.[3] Achieving a comfortable fit requires that the wearer dynamically manage their socket fit conjointly with fluctuations in residual limb size, whether from volume and shape changes normally experienced throughout the day or secondary to long term changes to the residuum. Failure to manage a proper fit could result in preventable secondary complications: wound formation, residual limb pain, and musculoskeletal impairments.[4] Some of these complications, if not managed, can result in non-use of the prosthetic limb or even re-amputation.[5] Therefore, in order to maximize function and to prevent secondary complications associated with prosthesis wear, interventions designed to facilitate self-management of fit could benefit both prosthesis wearers, their caregivers, and treating prosthetists. Previous studies evaluated the face validity and acceptability of paper-based decision trees designed to guide a prosthesis wearer to achieving a comfortable socket fit. Based on feedback from that study, a mobile app was designed to facilitate self-management abilities in prosthesis wearers. This study compares the usability and acceptability of the interactive self-management mobile app against that of the previously studied paper-based decision trees in adult lower limb prosthesis wearers.

METHODS

Thirty participants were block randomized into either the paper-based decision tree (DT) group or a mobile app (APP) group. Participants were then asked to complete three unique trials of simulated problem solving using a scripted question-response structure with one researcher providing the responses to the participant's questions and a second researcher measuring usability. Following the three trials under the first condition, the participant crossed over and performed three trials under the remaining condition. Each trial was unique from the others so that the participant was unable to guess the correct response prior to performing the necessary question-response parlay. To maintain equivalency between trials, the number of steps required to complete each scenario was identical between each condition. For the DT condition, this involved navigating through the appropriate decision tree which was placed in a binder in front of the participant. For the APP condition, the participant navigated through each scenario using an interactive application on an iPad. Usability was measured by the participant's technical effectiveness and efficiency in each condition. Technical effectiveness is a measure of the number of errors committed during each trial, and efficiency is the amount of time to complete each trial. Acceptability was measured using likert-like questions and semi-structured interviews.

RESULTS

Thirty participants completed the study following obtaining informed consent. Seventy percent of the participants were male (21/30), the average age was 60.1 years (9.98SD), and the average years of experience using a prosthesis was 11.74 years (16.6 SD). A paired t-test was run comparing the mean time and errors between the two conditions. There was a significant difference between the amount of time taken to navigate the scenarios (DT=126.13s +/- 41.42s vs. APP=108.77s +/- 23.51s; p=.005) and the amount of errors (.6667+/-.81 vs. .2+/-.63; p<.001 (Figure 1)). Strong positive correlations were found between the age of the participants and the amount of time needed to complete the DT condition (r=.652; p<.001), as well as between the amount of time (r=.654; p<.001) and errors (r=.732; p<.001) between conditions.

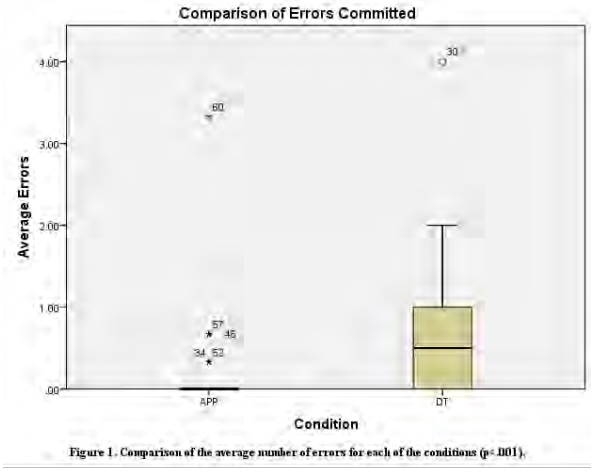

Figure 1. Comparison of the average number of errors for each of the conditions (p<.001).

DISCUSSION

Results demonstrate that the mobile app decision tree condition was significantly faster to navigate with less errors in comparison to the paper-based decision trees in paired t-test comparisons. Correlations demonstrated that the amount of time and errors were strongly associated between each condition, demonstrating consistency of the testing protocol between conditions. Age was correlated with an increased amount of time to complete the DT condition, not the APP condition which challenges the conventional bias that older adults prefer paper-based interventions over digital. Further analysis is required to evaluate the influence of educational level, age, and years of experience with a prosthesis on the outcomes of time and errors.

DISCLOSURES

The authors have no conflicts of interest to disclose.

REFERENCES

1.Hanspal RS, et al. *Disabil Rehabil.* 25(22):1278-1280, 2003.
2. Legro MW, et al. *J Rehabil Res Dev.* 36(3):155-163, 1999.
3. Klute GK, et al. *Arch Phys Med Rehabil.* 92(10):1570,2011.
4. Gailey R, et al. *J Rehabil Res Dev.* 45(1):15-29, 2008.
5. Dillingham TR, et al.*Arch Phys Med Rehabil.*86:480, 2005.

EVALUATION OF A NON-FLUID-BASED VARIABLE CADENCE CONTROLLER (VCC) TO CONTROL TRANSFEMORAL SWING-PHASE OVER A RANGE OF WALKING SPEEDS

INTRODUCTION AND PURPOSE

Conventional friction-based systems are not cadence responsive. They are set to function well at one walking speeds. Walking at a faster or slower speed may produce abnormal gait patterns and inefficient gait [1]. Hence, friction-based swing-phase control is typically reserved for low level ambulators (K1 and K2). For individuals capable of high-level ambulation (K3 and K4 mobility levels), hydraulic or pneumatic swing-phase control is commonly prescribed. These devices allow smooth gait at multiple speeds, but due to cost and maintenance these sophisticated systems are not accessible to many individuals around the world. They also may not be appropriate for certain applications, such as use in harsh environments. The purpose of this work has been to design and evaluate a novel variable cadence controller (VCC).

METHOD

The design of the VCC is based on a variable friction-spring system with optimized torque profiles to function over a range of walking speeds [2]. VCC performance was assessed through a combination of computational modeling (gait model) and empirical testing. A 7-segment gait model was developed in Matlab and SimMechanics. It was optimized using empirically based gait data of transfemoral amputees and able-bodied individuals, using a cost function. Four configurations of the swing-phase controller were modelled and simulated during gait. Performance evaluation was based on the ability of the controller to execute a step over three walking speeds, as well as to limit heel-rise and decrease terminal impact. A failed step was considered if the foot did not clear the ground, or if the knee did not extend in time for weight-bearing. The VCC was also evaluated with an individual with an above-knee amputation walking at multiple speeds on a treadmill.

RESULTS

Based on the modelling, a conventional spring system with constant friction (as typically used in knee joints) was able to provide control only at the slow speed. Performance was improved with variable friction, providing control at slow and medium walking speeds. Using the VCC allowed control over all three walking speeds. The VCC also reduced excessive swing-phase knee flexion achieving normal values (Figure 1). The VCC system limited terminal impact velocities even at fast walking speeds. From the single-subject walking trial, walking speeds at 0.9, 1.3, 1.6, 1.8 and 2.0 m/s were comfortably achieved, demonstrating high kinematic and spatiotemporal symmetry.

CONCLUSION

Using VCC shows promise for achieving swing-phase control across a range of functional walking speeds. Ongoing work aims to validate the results via further empirical testing involving an amputee population.

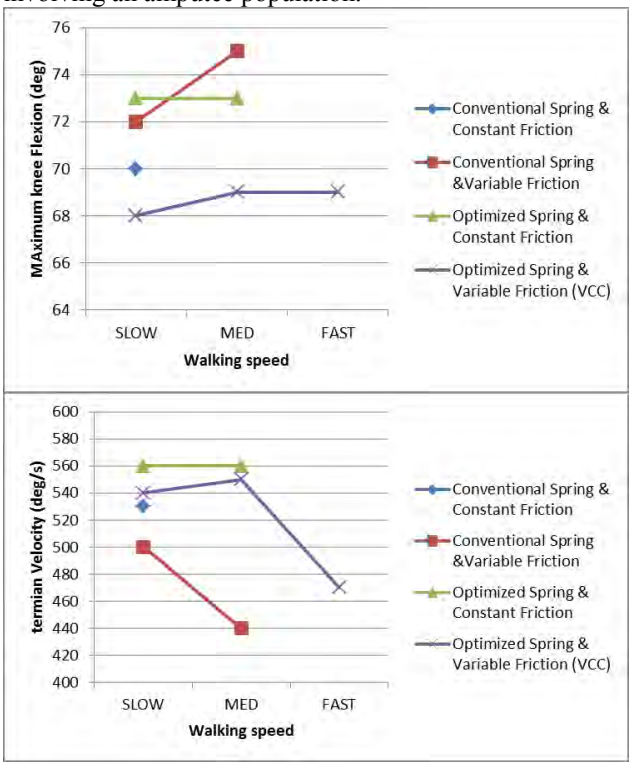

Figure 1. Computational model-generated maximum knee angles and terminal velocities for each walking speed. No data points are generated in case the controller was unsuccessful in allowing the completion of a full step. Walking speeds include slow at 1.04 m/s; medium at 1.11m/s; and fast at 1.37m/s. Dual spring Variable Friction refers to the VCC.

SIGNIFICANCE

Friction-based swing-phase control has traditionally been viewed to have performance limited to a single gait speed. This work demonstrates that it is possible to design and optimize friction-based control to function well at multiple walking speeds. Clinically, the VCC could significantly improve the performance of non-fluid-based prosthetic knee joints and provide an affordable option for many amputees around the world.

DISCLOSURE

J Andrysek is an employee if LegWorks Inc, the manufacturer of the VCC system

REFERENCES

1. Esposito et al., 2014, Gait Posture. 2014 Sep;40(4):640-6.
2. Furse A, 2011, IEEE Trans Biomed Eng. 2011 Aug;58(8)
3. Shandiz, 2013, Int. J. Adv. Robot. Syst.

Factors that influence acceptance and rejection of an upper limb prosthesis: A review of the literature.

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INTRODUCTION

Clinicians and health insurances are well aware of the fact that many patients with upper limb (UL) amputations reject their prosthesis in the mid- to long run (1). Factors that influence acceptance and rejection of an UL prosthesis are much less understood. If such factors and their impact were known, they could be leveraged to improve the acceptance of UL prostheses and the function and quality of life of persons with UL amputations.

METHOD

A search of the scientific literature was performed in the Medline, Embase, CINAHL, OTseeker, and PEDro databases as well as in the online library of the Journal of Prosthetics & Orthotics. Search terms were related to UL amputations and prosthetics, acceptance, use, rejection and abandonment of UL prosthesis. Identified references were evaluated for pertinence to the subject and analyzed.

RESULTS

Five pertinent publications were found. Malone et al. (3) suggested a “golden window” of 30 days after the amputation for the fitting of an (interim) UL prosthesis for occupational therapy. They found that all patients who received a prosthesis within this “golden window” were able to return to work, whereas only 15% of patients fitted after more than 30 days did so. In addition, patients fitted within the “golden window” did not present any striking preference for body-powered or myoelectric prostheses, irrespective of the first type of prosthesis fitted. They chose the prosthesis type objectively best suited for their everyday needs, whereas patients who were fitted later almost exclusively preferred myoelectric prostheses (3). Another study (2) found that definitive prosthesis fitting within 6 months of the amputation or 2 years after birth in congenital deformities increased the likelihood of prosthesis acceptance (odds ratio) by factor 16. The second biggest variable was the involvement of the patient in the selection of the type of prosthesis. Intense patient involvement in prosthesis selection increased the likelihood of acceptance by factor 8. Also, very young (<4 y), middle-aged (36-50 y), and older patients (>60 y) were 7 times more likely to accept an UL prosthesis than patients in different age groups. Patients with transradial amputations were more likely to accept a prosthesis than patients with more distal or proximal levels of limb absence (2).

DISCUSSION

Patients should be fitted a prosthesis for occupational therapy as soon as medically possible, ideally within 30 days after the amputation to prevent them from learning to manage their everyday lives with their sound hand alone. Definitive prosthesis fitting should occur within 6 months of the amputation or 2 years of birth in case of congenital deformities for the same reason. Patient involvement in prosthesis selection is a very important factor that improves prosthesis acceptance.

CONCLUSION

Ideally, patients with UL amputations should receive a prosthesis for occupational therapy within 30 days and undergo definitive prosthesis fitting within 6 months of the amputation. Patients involved in prosthesis selection are 8 times more likely to accept their UL prosthesis than those not involved in decision making.

REFERENCES

1. Carey SL, et al., J Rehabil Res Dev 2015; 52(3):247-262.
2. Bidiss EA, et al., Disabil Rehabil 2008; 3(4): 181-192
3. Malone JM, et al., J Rehabil Res Dev 1984; 21(1): 33-41.

DISCLOSURE

Andreas Kannenberg is a full-time employee of Otto Bock HealthCare LP, Austin, TX, a leading manufacturer of UL prosthetic components.

Which Functional Elements Stabilize the Residual Limb within Transfemoral Sockets in both Frontal and Sagittal Plane for Optimized Prosthetic Gait?

Kay Mitton1, Jai Kulkarni2, Kenneth William Dunn1
and Anthony Hoang Ung3

INTRODUCION

Different prosthetic socket techniques are available for the treatment of transfemoral amputees. Within this context, ischium containment sockets differ from other techniques in shape and functionality (1,2,3). The main difference is to be found in the proximal functional area that is responsible in different proportions for the force transmission between the residual limb and bony pelvis structures. Socket techniques without force transmission in the pelvic region are available as well (subischial sockets). Controversial opinions exist regarding the amount of load transfer and the importance of the proximal socket elements to stabilize the residual limb within the socket.

Within the scope of this biomechanical study, a study design has been developed to investigate force transmission principles by main functional elements of a transfemoral prosthetic socket. The study aims at further increasing the understanding of force transmission between residual limb and prosthetic socket in specific functional elements of the proximal socket portion.

METHODS

The sockets were segmented according to the main four functional elements (area of ischium containment, lateral wall, anterior wall, volume and control area) and implemented in a CFK frame to record the forces in these areas. Load sensors between frame and socket elements recorded three forces and their centres of pressure within a Cartesian coordinate system. The data were transferred via a mobile wireless LAN system to a central PC and triggered synchronically to a stationary gait analysis system (Kistler, Vicon).

Three different socket techniques (CAT-CAM, MAS, subischial socket) were measured each with 6 transfemoral amputees in the following situations: level walking and descending stairs and ramps. The sockets were installed on an identical prosthetic knee joint and foot type with the same patient individual prosthetic alignment.

RESULTS

The results suggest that the force transmission principles within the four main socket areas do not differ significantly between a CAT-CAM and MAS socket during different gait situations. With the ischium or ramus containment socket types, a significant degree of axial force is transferred by the medially located containment area. Furthermore, the data indicate that significant forces are acting in anterior-posterior and medio-lateral directions onto the containment elements as well. With the subischial socket that does not contact the pelvis, significant differences can be identified regarding the stabilization effects between residual limb and socket compared to both containment sockets. This is caused by the different positions of the total forces running through the entire sockets and the locally acting forces in the volume and control areas which is shaped more or less identically in all three socket techniques. Additionally reduced hip moments in the subischial socket indicate a reduced potential to transfer load when walking up the ramp. Less upper body side movement during stance phase of the prosthetic side can be identified when using an ischium or ramus containment socket.

DISCUSSION

In the literature, the force transmission between residual limb and the main functional areas of transfemoral sockets have been discussed exclusively based on theoretical models and fitting experiences (1,2,3). The method described in this comparative study allows objectifying which socket areas are involved in force transmission to what extent.

Based on these data it becomes obvious that the containment areas and the anterior walls are of high importance to stabilize the stump within the socket in both frontal and sagittal plane. The containment area also reduces the axial load on the volume and control area.

These biomechanical findings are represented by the forces acting in the four main functional socket elements, external sagittal hip moments measured during walking up a ramp and the upper body motion in the frontal plane.

REFERENCES

1. Sabolich J. *Clin Prosthet Orthot* 1985;9:15-26.
2

Functional Bracing for Treatment of Pediatric Diaphyseal Femoral Fractures: An Alternative to Spica Casting?

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Purpose: Closed Reduction and Spica casting (SC) is the traditional treatment of diaphyseal femoral fractures in pediatric patients ages 0 to 5 years. However, there are many disadvantages to SC. SC requires general anesthesia, is cumbersome for parents/patients, and difficult to clean and maintain. Additionally, a second cast application is at times necessary when there is progressive malalignment or significant soilage. We hypothesized that diaphyseal femur fractures in this age range could be more easily managed with immediate application of functional fracture bracing (FFB). FFB allows for consistent compression of the fractured limb, is more comfortable, easier to clean, and is more cost effective than SC.

Methods: Using case-control design, we compared the clinical, economic and functional outcomes of pediatric patients aged 0 to 5 years with displaced and non displaced femoral shaft fractures treated with FFB versus those treated with SC. We evaluated subjective clinical outcomes retrospectively using the Pediatric Outcomes Data Collection Instrument (PODCI) and objective clinical outcomes by assessing post-treatment radiographs in orthogonal planes for angular malalignment and shortening. We evaluated economic outcomes by comparing procedural and equipment costs. Statistical comparisons between groups were performed using the Wilcoxon Mann-Whitney test and Student's T-test.

Results: There were 41 patients and 43 patients in the FB and SC groups respectively. All patients had minimum of 2 years follow-up. The PODCI questionnaire revealed very high patient satisfaction with FBB. None of the patients had a limp or subjective leg length discrepancy at their most recent follow-up. All fractures went on to union with 6 weeks of immobilization. Comparison of fracture site angulation revealed significant correction of angulation between pre-treatment and most recent post-treatment orthogonal radiographs . There were no significant differences in magnitude of angular correction between groups ($p>0.05$). Economic comparison revealed that FB was significantly less costly overall compared with SC ($P<0.05$).FB eliminates the need for general anesthesia, surgical and anesthesia charges.

Conclusion: FFB is equally effective to SC in correction and maintenance of fracture alignment, time to union, and functional outcomes but is better tolerated by patients and their parents. Its open design improves hygiene, skin surveillance, and eases transport /lifting as it weighs substantially less than SC. The overall cost of FB is lower and can be applied immediately without need for general anesthesia and operating room time

Significance:This study suggests that FFB should be considered a viable alternative to SC in isolated pediatric femoral shaft fractures age 0-5.

FUNCTIONAL UTILITY OF WEARING A MYOELECTRIC UPPER EXTREMITY ORTHOSIS IN CHRONIC STROKE SURVIVORS WITH MODERATE HEMIPARESIS

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INTRODUCTION

Stroke remains a leading cause of long-term disability in the United States, often leading to motor impairment and consequent decline in functional independence. Upper extremity (UE) hemiparesis is especially common post-stroke and often leads to decreased independence with self-care activities of daily living (ADLs)[1]. Previous work demonstrated that using a portable myoelectric elbow-wrist-hand orthosis as a therapeutic adjunct to a multi-week rehabilitation regimen resulted in decreased UE motor impairment and increased function in stroke survivors with moderate UE hemiparesis.[2] The purpose of this study was to determine if wearing a portable, myoelectric elbow-wrist-hand orthosis immediately reduces motor impairment and increases functional ability in chronic stroke survivors with moderate UE hemiparesis.

METHODS

The current study was an observational cohort study set in an outpatient rehabilitation clinic. Participants included neurologically stable, chronic stroke (≥12 months) survivors exhibiting moderate UE hemiparesis (n=18). Participants underwent a total of 2 sessions; session 1 they were fitted and oriented to the myoelectric elbow-wrist-hand orthosis (Figure 1) and session 2 participants completed a battery of measures testing UE motor impairment and functional ability. After completing the battery of measures without the orthosis, participants then donned the myoelectric elbow-wrist-hand orthosis and were again tested on the same battery of measures. The primary outcome measure was the UE section of the Fugl-Meyer Assessment (FM; to assess motor impairment); secondary measures included a battery of functional tasks (to assess UE functional ability) and the Box and Block Test (BB; to assess gross manual dexterity).

Figure 1. MyoPro Motion-G Device[3]

RESULTS

Subjects exhibited significantly reduced UE impairment while wearing the myoelectric elbow-wrist-hand orthosis (FM: t=8.56, P<.001) and increased quality in performing all functional tasks while wearing the myoelectric elbow-wrist-hand orthosis, with 3 subtasks showing significant increases (feeding [grasp]: z=2.251, P=.024; feeding [elbow]: z=2.966, P=.003; drinking [grasp]: z=3.187, P=.001). Additionally, subjects showed significant decreases in time taken to grasp a cup (z=1.286, P=.016) and increased gross manual dexterity while wearing a myoelectric elbow-wrist-hand orthosis (BB test: z=3.42, P<.001).

DISCUSSION

This was the first study, to our knowledge, to compare the effects of a myoelectric UE orthosis versus no orthosis in UE hemiparesis. Results suggest that UE impairment, as measured by the Fugl-Meyer Assessment, is significantly reduced when donning a myoelectric elbow-wrist-hand orthosis, and these changes exceeded the Fugl-Meyer Impairment Scale's clinically important difference threshold. Further, utilization of a myoelectric elbow-wrist-hand orthosis significantly increased gross manual dexterity and performance of select functional tasks.

REFERENCES

1. Sveen U, et al. *Disabil Rehabil*; 21, 372-77, 1999.
2. Page SJ, et al. *Clin Rehabil*; 27, 494-503, 2013.
3. Peters H, et al. *Arch Phys Med Rehabil*; 2017.

DISCLOSURE

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Gait Training Interventions for Lower Extremity Amputees
A Systematic Review of the Literature

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INTRODUCTION There are 1.6M Americans with limb amputation(s) and ≈86% of these are lower limb amputations. Amputee gait impairments have been objectively documented in multiple domains including spatiotemporal, biomechanical and bioenergetic parameters. Gait parameters potentially altered in LE amputees include changes in magnitude and symmetry of forces and joint moments, event duration and others. These deviations may contribute to decreased balance and increased metabolic costs as well as more insidious, chronic issues including degenerative joint disease. Interventions to mitigate gait deviations and improve quality of life for Lower extremity amputees(LEAs) include prescribing the proper componentry and participating in physical therapy (PT) for gait training. This study's purpose was to systematically review the literature to determine the evidence strength supporting gait training interventions and to formulate empirical evidence statements(EESs) to guide practice and research related to therapeutic gait training for LEAs.

METHOD A multi-disciplinary team systematically reviewed 1.) Pubmed, 2.) CINAHL and 3.) Web of Science on Dec15, 2014 using the following date limits: 2000(Jan1)-2014(Dec14). One month after the initial search, the search was repeated. References were exported to EndNote reference management software. Duplicate references were eliminated. Remaining articles were sorted by type. Exclusion criteria were selected to eliminate manuscripts that did not include gait training for adults with LEA who used prostheses. Articles were assigned 2 reviewers who independently screened for eligibility and classified them as either: 1) pertinent, 2) not pertinent or 3) uncertain pertinence.

Methodologic quality was assessed using the American Academy of Orthotists & Prosthetists (AAOP) State-of-the-Science Evidence Report Guidelines. Internal and external validity of each study was rated. Each study was then given an overall quality of evidence rating of "high", "moderate", "low".

Key data were then extracted to describe studied subjects, interventions and their relative effect. Quality ratings were used to assign the confidence level for the developed EESs.

Based on publications' results, EESs were developed to describe study findings related to gait training interventions for LEAs. Reviewers rated the confidence level of each EES based on the quantity and quality of publications contributing to the statement and whether the contributing findings were confirmatory or conflicting.

Following screening and eligibility determination procedures, full-text articles were sorted by reviewers into sub-topical areas.

RESULTS 11,118 total manuscripts were identified. 18 articles met eligibility criteria spanning 2001-2014 publication years and divided into 2 topical areas: **1)** Overground Training (*n*=13) and 2) Treadmill Training (*n*=5). There were 11 experimental studies, 5 case study designs and 2 editorials. A total of 229 subjects were included. 145 LEAs served as experimental subjects (mean interquartile range[IQR]) age, height and mass were; 48.2(29.5)y, 1.7(0.04)m and 80.6(10.3)kg. In terms of amputation level, 57% had TFA, 21% had TTA, 21% were mixed lower extremity samples. Outcomes included biomechanical, spatiotemporal measures and bioenergetics outcomes, and clinimetric assessment. Ten studies had low, six had moderate and two studies had high internal validity. Conversely, 16 studies had high and two had moderate external validity. Eight EESs were synthesized within the two topical areas One was supported by a single study resulting in insufficient support. Four EESs had two to four studies supporting their synthesis (low confidence). One EES was supported by four studies(moderate confidence) and two were supported by sufficient evidence to provide high confidence. Four statements address overground gait training, one addressed treadmill gait training and three addressed both overground and treadmill gait training.

CONCLUSION Due to gait asymmetries, altered biomechanics and related secondary consequences associated with LEA, gait training is needed. Eight EESs were synthesized over two general areas of gait training therapy including overground and treadmill training. Overground training with verbal, other auditory, manual and psychological awareness are effective. Treadmill based training was also found to be effective as a supplement to overground training or independently and when augmented with visual feedback, body weight support or as part of a home exercise plan.

REFERENCES

Yang L et al. *Gait Posture* 2012;36:631-4.
Highsmith MJ, et al. *J Prosthet Orthot* 2010;22:26-30.
Sjodahl C et al. *Prosthet Orthot Int* 2002;26:101-12.
Darter BJ et al. *Phys Ther* 2011;91:1385-94.
Yiğiter K et al. *Prosthet Orthot Int* 2002;31:258-70.

IMPACT TEST FOR PROSTHETIC FEET

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INTRODUCTION

In combat, Service Members often find it necessary to jump down from elevated platforms, such as the cargo bed of a vehicle. For Service Members with lower limb amputations, if their prosthesis fails in combat, they become vulnerable to enemy action. At present, there is no accepted standard to simulate impact loading of prosthetic feet. The ISO 10328 test[1] forces are applied slowly (11-28s), but data from running prostheses[2] indicate impact loads occur much faster (0.04s). We developed an impact test system to investigate impact resilience of prosthetic feet. Testing has been performed on one specimen to validate the measurement variability, inter-rater variability, and impact velocity.

METHODS

The test system drops specimens vertically with the foot plantarflexed 20 degrees and mass equal to half of the user's body weight to simulate shared loading on both limbs. Laser lines project onto rulers indicating specimen height above the base. Ten measurements of the resting (statically loaded) height by one operator were used for calculating measurement variability. Eight measurements of the height at contact with the base (unloaded) were performed by three operators to calculate inter-rater variability. A specimen was dropped 0.1m. The height was increased by 0.1m until failure. Videos (120fps) were analyzed to determine impact velocity, which was used to calculate impact energy ($E = 0.5*m*v^2$). The impact energies were compared to the theoretical freefall impact energy (equal to the potential energy, m*g*h).

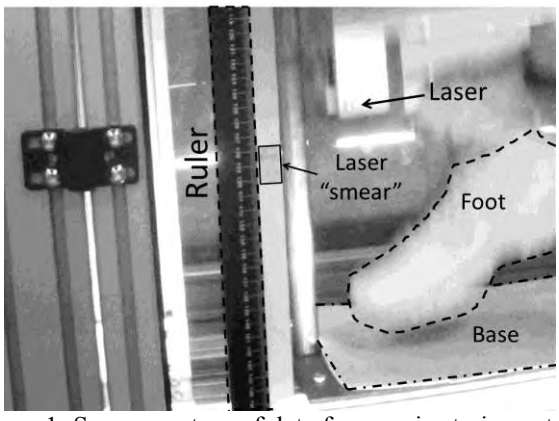

Figure 1: Screen capture of data frame prior to impact for 0.60m drop. The length of the laser "smear" and the exposure time were used to calculate impact velocity.

RESULTS

The measurement standard deviation was 0.06mm. The standard deviation between raters was 1.4mm. The specimen failed at a drop height of 0.6m. The difference between the calculated and theoretical impact energy was 4.7% (the mean of the absolute value of the differences).

CONCLUSION

The velocities in the frame prior to impact were on average within 2.3% of theoretical freefall (impact energy within 4.7%). A sensitivity analysis showed that varying the length of the "smear" band by 1mm resulted in a 7.5% change in impact energy. This suggests that the system is achieving freefall within the measurement error of ±1mm. For future analyses, the impact energy can be assumed to be equal to the potential energy of the drop. Measurement variability was below 1mm indicating repeatability within measurement error. Inter-rater variability was greater than 1mm. Future testing should be conducted by one rater for consistency.

SIGNIFICANCE

This impact test system accurately simulates freefall. It is suitable for testing prosthetic feet to determine impact resilience and may be useful in supporting decisions regarding prostheses for return-to-duty applications.

REFERENCES

1. International Organization for Standardization 10328:2016, Prosthetics – Structural testing of lower-limb prostheses – Requirements and test methods, 2016.
2. Jweeg MJ, et al. Int J Current Engineering and Tech; 5(1), 121-127, 2015.

DISCLOSURE

The authors have no conflict of interest to report.

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IMPROVEMENT IN FUNCTIONAL ELBOW MOVEMENT WITH A MYOELECTRIC ORTHOTIC DEVICE: A NOVEL APPLICATION OF A POST-CVA ASSISTIVE REHABILITATION ORTHOTIC DEVICE

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INTRODUCTION: Nerve grafting, nerve transfers and free functioning muscle transfers (FFMTs) have lead to improved functional outcomes in brachial plexus injury (BPI) patients. Reports have shown that 26% of nerve transfers and 39% of the FFMTs for elbow flexion achieve ≥ M4 elbow flexion strength[1]. However, there remains a substantial minority of patients with less favorable functional outcomes that need to be addressed further.

The MyoPro (Myomo Inc., Cambridge, MA, USA) is an FDA-cleared myoelectric elbow-wrist-hand orthosis that uses surface EMG signals from affected muscle groups to control a powered orthosis to assist with the movement of a paretic upper limb. This device was originally designed for the treatment of post-CVA upper extremity paresis, in patients who had incomplete recovery of muscle strength but preserved voluntary EMG signals. We describe the application of this orthosis for enhancement of elbow flexion and extension in patients with incomplete recovery from BPI with poor voluntary elbow movement.

METHODS: Two patients from a single-surgeon practice have been evaluated for the suitability of the myoelectric functional orthotic device. Both patients are 37 year-old men who were involved in motor vehicle accidents, 14 and 17 years ago, that resulted in left and right brachial plexus injuries. Patient 1 initially had brachial plexus reconstruction by nerve transfers and secondarily a free functioning muscle transfer for restoration of elbow flexion and finger extension. Patient 2 underwent brachial plexus exploration and neurolysis only. Both patients failed to regain voluntary elbow movement. Evaluation showed 0 –130 degree elbow passive range of motion in flail arms. Both patients had detectable EMG signals in the biceps or gracilis (FFMT), and triceps muscles. Both patients underwent 30 minutes of training with the device, which provides powered assistance for elbow flexion and extension via motors attached to the exterior of the orthosis. After the training, patients were asked to perform voluntary assisted elbow flexion and extension.

RESULTS: Both patients demonstrated immediate restoration of voluntary active elbow flexion and extension from 0 to 115 degrees using EMG control signals from the gracilis and triceps in Patient 1, and from the biceps and triceps muscles in Patient 2.

CONCLUSION: A myoelectric orthosis is a valuable option to improve the functional outcome in patients with BPI and poor return of voluntary elbow movement following reconstruction.

SIGNIFICANCE: Approximately 1% of multitrauma patients suffer from brachial plexus injuries[2]. A survey conducted among the brachial plexus surgeons revealed that elbow flexion and shoulder abduction are the two most important upper extremity functions to be restored following brachial plexus injuries[3]. Given the limited options available after definitive reconstruction, this device provides a valuable adjunctive therapy in patients with poor recovery of elbow function.

REFERENCES:

1. Maldonado AA, et al. Plast. Reconstr. Surg. 138(3): 438e-8e, 2016
2. Midha R, Neurosurgery 40(6): 1182-8, 1997
3. Belzberg AJ, et al. J. Neurosurg. 101(3): 365-76, 2004

Introducing the Prosthetic Homologue for Embodiment

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INTRODUCTION

Embodiment is the feeling that a prosthetic limb is truly their own [1]. The general understanding is embodiment is heavily dependent on whether the prosthetic device *looks like* the patient's missing anatomy [2]. To be clear: it's not just a matter of a prosthesis being life-like; it is a matter of the device looking *like their own*. We have dubbed this the **prosthetic homologue**.

The notion of the prosthetic homologue has two implications: 1) investment of resources in the attainment of ever-more homological prostheses, and 2) prostheses that are not homological will be criticized for their limited potential for embodiment.

But the concept of homology has never been formally tested. Here, we describe the first-ever test for prosthetic homology. This study was published recently in *Frontiers in Neurorobotics* [3].

METHODS

Thirty-two healthy volunteers were exposed to five silhouetted images of a hand; one image was of the patient's hand (without their knowledge; naivete was maintained with a physical blind; Figure 1AB) and the other four images were matched from a bank.

Each subject was shown the same set of 5 hands, in scrambled order, three times (Figure 1, Right); each of these three presentations was repeated once, for a total of six total exposures.

The instruction was as follows (abbreviated for space): "Please identify the hand that you find most aesthetically pleasing in each lineup. In particular, we want to know: if you had to receive a prosthetic hand, which hand would you most like your prosthesis to look like?"

Figure 1: Experimental setup of the prosthetic homologue study.

RESULTS

Subjects (13M/19F; 26 ± 11 years, range 19-53 years, all right-dominant) yielded a Brief Fear of Negative Evaluation Score (BFNES) of 33 ± 6 (range: 21 – 39, 0 = not at all fearful; 60 = maximally fearful).

Subjects showed preference for the homologue only 32% of the time (61 of 192 exposures); only 8 of 32 subjects (25%) showed preference for the homologue in more than half of the exposures (Figure 2A).

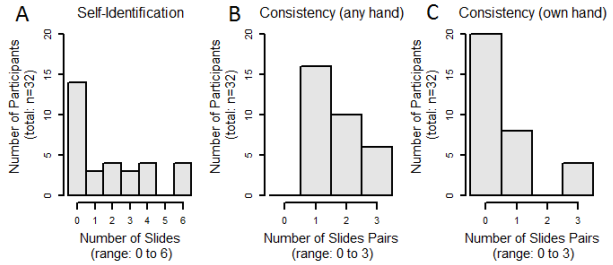

Figure 2: Results show inconsistent preference for the homologue

Furthermore, subjects were generally inconsistent about their preference, regardless of whether they showed preference for homologue (Figure 2B-C).

DISCUSSION

Here, we coined the concept of a prosthetic homologue, and provided a first-ever scientific inquiry into whether it is associated with a sense of embodiment. Our findings, while preliminary, indicate that the homologue is, indeed, not an essential design target.

At AOPA-Las Vegas, we seek to introduce the prosthetic homologue, discuss these findings and more, and also highlight strategies for testing the homologue both in face-to-face and virtual settings.

REFERENCES

1. Mulvey MR, *Neuromodulation*, 2012
2. Crawford CS. NYU Press, 2014
3. Dornfeld C, *Frontiers in Neurorobotics*, 2016

Limb Volume Stability in Response to Socket Suspension

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INTRODUCTION

There are several reported benefits of elevated vacuum suspension (EVS) including pistoning control[1,2], wound healing[3], increased proprioception, and volume management[4]. All of these benefits indicate EVS creates a more stable socket environment. This notion is supported by previous work quantifying physiological changes in the limb in response to elevated vacuum, where long-term improvements in blood perfusion, tissue oxygenation, and epidermal barrier function are believed to be due in part to socket interface stability[5]. The test procedures reported here were designed to investigate movement and volume stability of the socket interface.

Previously, the authors reported limb volume measurements during a rest period following activity. The results revealed differences between EVS and suction suspension. The purpose here is to report differences in limb volume stability over the course of the entire data collection (limb volume before activity compared to limb volume during post-activity rest periods).

METHODS

Participants: A total of 13 male and 2 female amputees participated in the study (8 transfemoral and 7 transtibial amputees). The average age was 49.4 years old. The causes of amputation were 9 traumatic, 4 cancer, 1 infection, and 1 vascular non-diabetic. Nine participants were existing elevated vacuum suspension prosthesis users and six were existing suction suspension prosthesis users.

Procedures: Each participant completed a total of three study visits (initial, one week follow-up, and eight week follow-up). Limb volume was collected using the Omega scanner before and after an intermittent walking task that lasted 15 minutes. Tracking markers were placed at known landmarks to enable systematic alignment and processing of the digital image for volume calculation. After the walking task was completed, participants doffed their prostheses and volume measurements of their residual limbs were collected immediately after doffing, 5 minutes out of the socket, and 15 minutes out of the socket. During the 15 minute post-activity period, participants were instructed to stay in one of three positions; 1) seated, 2) lying supine, 3) lying supine with residual limb elevated. The order in which subjects completed the positions was randomized by study visit.

Data Analysis: Limb volume was calculated by the Omega software after the limb model was positioned using the virtual tracking markers. The percent change in volume was calculated from the initial volume before activity to the limb volumes at the 5 and 15 minute rest volumes. A repeated measures ANOVA was used for statistical comparisons.

RESULTS

EVS better maintained limb volume in all rest positions. The most significant differences were found for the lying supine and lying supine with limb elevated rest positions.

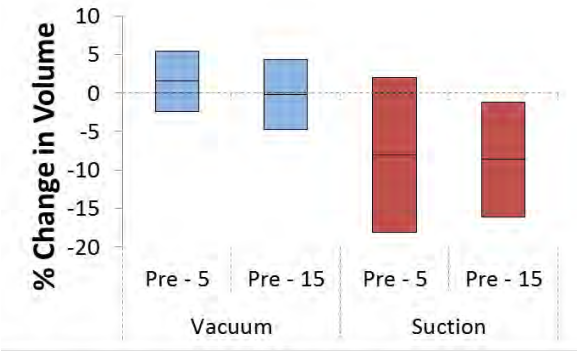

Figure 1. Percent change in limb volume before activity to 5 to 15 minutes after activity. Post-activity rest was completed with participants lying supine.

CONCLUSION

Limb volume changes were dependent on both the method of suspension and the rest position. Limb volume tended to increase when in a seated position and decrease in a lying down position following activity. Future work should expand the number of test participants included and also investigate the acute impact of EVS on limb volume change for new users of EVS.

SIGNIFICANCE

Prosthetists should consider how their patients are resting during a socket fitting as position was shown to change limb volume which could impact socket modification decisions. EVS suspension seemed to buffer differences in volume change among the various positions.

REFERENCES

1. Board W. *Pros. Ortho. Int.* 25, 202-209. 2001.
2. Gerschutz M. *J. Pros. Ortho.* 27, 161-165. 2015.
3. Traballesi M. *Eur J. Phys Rehab Med*. 48. 2012.
4. Goswami J. *Pros Ortho Int.* 27, 107-113. 2003.
5. Rink C. *JRRD.* In press.

DISCLOSURE

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Liner with Embedded Electrodes for Direct Control Prostheses

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INTRODUCTION

For individuals who use myoelectric upper limb prostheses that are controlled by skin-surface electromyogram (EMG) signals, the socket must fit the residual limb tightly to prevent loss of contact between the electrodes—typically mounted in the socket wall— and the skin. To prevent loss of signal, these sockets are made with a tight fit. However, this has a tendency to negatively impact the donning process. To address these challenges, several attempts have been made to include a gel liner into myoelectric socket interfaces[1-3]. Gel liners could enhance the use and function of upper limb myoelectric prostheses by offering superior cushioning and skin protection for improved comfort, ensuring consistent contact between the residual limb skin and electrodes, increasing the adjustability of the socket fit, and providing optimal prosthesis suspension via a distal locking mechanism.

The Rehabilitation Institute of Chicago developed a gel liner with integrated electrodes. This system was designed to work with pattern recognition control methodologies, which require a greater number of electrodes and require less specific electrode placement. Preliminary testing showed that the system maintained electrical signal quality after 8 weeks of at-home use (although electrical resistance did increase) and was preferred by the test participants over their existing systems. The purpose here is to report the efficacy of the liner with embedded electrodes for direct (conventional) control prostheses which require: (1) accurate placement of electrodes on muscle bellies and (2) the ability to consistently don the system. The test protocol here was design to evaluate these two factors.

METHODS

Donning Consistency: Two conical residual limb models were fabricated using the Omega Carver. Tapping screws were added to the model in defined positions to represent initial electrode location. Three participants then donned a small or medium sized liner on the corresponding residual limb model using one-hand and marked the position of the screw head on the outer liner fabric. A different color marker was used by each participant.

This protocol was repeated by one transradial amputee participant on his residual limb. Myo-sites were identified using the MyoBoy and foam targets were placed over those locations. A liner was then donned by the test participant and the positions of the foam pieces were recorded on the outer liner fabric with a marker.

Electrode Accuracy: Three electrode positions were chosen based on the marks left by the donning consistency test. These positions were transferred to a new liner using a grid mapping system. The new liner was then donned onto the residual limb model and the screw head positions recorded with a marker.

Data Analysis: For donning consistency, the total spread was calculated as the maximum distance between two marks of any color. Individual spreads was calculated as the maximum distance between two marks of the same color. Accuracy was measured as the maximum distance from the center of the target box to any mark.

RESULTS

Data shows a high consistency donning the liner and high accuracy of electrode placement.

		Small Liner, Anterior Side of Liner				Medium Liner, Anterior Side of Liner			
		Total Spread	MW Spread	CD Spread	AA Spread	Total Spread	MW Spread	CD Spread	AA Spread
Anterior Side of Liner	Distal 1	12	6	11	5	15	8	11	6
	Distal 2	15	5	14	6	15	9	10	8
	Distal 3	12	5	11	6	23	9	14	8
	Middle	12	5	10	6	18	8	8	8
	Proximal 1	12	6	10	8	15	5	9	11
	Proximal 2	12	5	11	7	15	7	8	10
	Proximal 3	10	5	9	6	17	6	12	10
Distal Side of Liner	Distal 1	10	6	10	6	15	8	16	5
	Distal 2	13	8	13	7	13	5	7	5
	Distal 3	13	5	5	6	25	7	11	5
	Middle	10	7	9	5	15	8	10	9
	Proximal 1	13	9	12	9	15	7	12	11
	Proximal 2	14	7	10	9	16	7	10	10
	Proximal 3	15	8	11	8	23	8	10	11
	Avg Total	12.4	6.2	10.4	6.7	17.1	7.3	10.6	8.4
	St Dev	1.6	1.4	2.1	1.3	3.7	1.3	2.4	2.3

Figure 1. Donning consistency results for the whole group and for individual participants.

CONCLUSION

Test participants were able to consistently don the liner in the same orientation. Greater variability was found among all users, suggesting the amputee user should always be the one to don the liner when positioning measurements are being made. A grid mapping system was able to accurately transfer electrode position.

SIGNIFICANCE

A liner with embedded electrodes may provide a clinically relevant socket interface option for myoelectric prosthesis users utilizing direct control. The results provide evidence that will help optimize the electrode positioning process to ensure accuracy and ultimately quality of signal.

REFERENCES

1. Salam Y. *JPO.* 6(4), 119-120. 1994.
2. Daly W. *JPO.* 12(3), 88-91. 2000.
3. Lipschutz R. *Patent.* 2011.

DISCLOSURE

Authors are employees of Ohio Willow Wood.

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None.

MAINTAINING UPRIGHT POSTURE: BALANCING MOMENTS AND PREVENTING FALLS

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INTRODUCTION & PURPOSE

Within a 1 year period, 35% of adults over the age of 65 will fall. The consequences include fractures, head trauma but most alarming is that falls are the leading cause of injury death. Postural control is obviously paramount to maintaining upright stance and therefore the prevention of falling. There are several systems functioning in the human body that contribute to the maintenance of upright posture. It is important for clinicians of musculoskeletal medicine to be cognisant of how these systems contribute so they recognize when patients are at risk of a fall and implement strategies to reduce the likelihood of a fall should a patient be at increased risk.

Objects are stable when the center of mass (COM) remains over the base of support. When the COM no longer resides over the base of support, a gravitational moment is created which will cause the patient to fall unless some type of strategy is implemented. To implement such strategies, several systems must be functional. Not only must they be functional, but they must have the ability to respond in a timely manner. The systems involved include the central nervous system for voluntary input, the visual system, the vestibular system and the somatosensory system. The somatosensory system in turn, has several subcomponents of control which include, pressure receptors in the foot, muscle spindle input, and joint afferents. The reason that the elderly fall, stems from the fact that these systems begin to function less than optimally due to cognitive impairment, neurological disorders and immobility due to osteoarthritic joints.

METHODS & RESULTS

To determine the input from the visual system, subjects are either blind-folded or placed in an environment referred to as a motion surround where images are projected on the wall signalling movement of the environment. The input from the muscle spindles and joint afferents is studied by placing the subject on a platform that maintains a constant joint position (sway-referencing). Cervical afferents are examined by rotating the subject while fixing the head to the torso. In addition the somatosensory contribution can be tested by utilizing subjects with peripheral neuropathies or utilizing anaesthesia. The vestibular system can be examined by utilizing subjects whose vestibular systems are impaired, by disrupting the vestibular system with galvanic stimulation or by studying the effect of zero gravity (astronauts) on stability. This presentation is a summary of the findings of various authors' contributions.

CONCLUSIONS & SIGNIFICANCE

Two musculoskeletal based interventions accessible to musculoskeletal clinicians will be discussed. They are designed to reduce postural sway and hence the likelihood of the patient becoming unstable. One involves muscle strengthening (active approach) while the second uses a more passive approach utilizing an ankle-foot orthotic (AFO) to stabilize the patient. The clinical advantages, disadvantages and research gaps for each approach are discussed.

REFERENCES

1. Brauer et al *Gerontol A Biol Sci Med Sci.* 55, M469-76, 2000.
2. Guerra Padilla et al *Neurologia*, 29, 423-32, 2014.
3. Inglis et al. *Exp Brain Res*. 101,159-64, 1994.
4. Kim et al *Clin Interv Aging* 2015 10, 1839-47. 2015.
5. Mergner T, et al *Exp Brain Res*. 85, 389-404. 1991.
6. Peterka RJ, Benolken MS. *Exp Brain Res*, 105,101-10, 1995.
7. Paloski et al. *Am J Otol*. 14, 9-17. 1993.
8. Warnica et al *Gait Posture* 39:1115-21, 2014.

DISCLOSURE

J. Kim Ross lectures for a company (OHI) that manufactures foot orthotic devices and AFO's.

On the (Im-)possibility to predict who may benefit from a microprocessor controlled prosthetic knee component

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Otto Bock HealthCare Vienna[1], Duderstadt[2]; Stat-Up Munic[3]
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INTRODUCTION

With the availability of microprocessor controlled prosthetic knee components in the mid 1990`s advanced function based on controlled knee flexion under load and swing control became available. Those components were presumed to preferentially suit more mobile amputees despite early evidence suggesting at least equal benefit to lower mobility grades [1]. Recent research confirms the latter [2,3,4]. Often, however, access to such technology is denied on clinical rationales with sometimes uninvestigated presumptions.

OBJECTIVE

We investigate an extended set of clinical variables on their potential to predict an individual's capability to utilize functional benefit provided by an advanced hydraulic microprocessor controlled exo-prosthetic knee component.

METHOD

Based on data from trial fittings with Genium (Ottobock Healthcare Products GmbH, Austria) gathered in Germany a retrospective cohort analysis is performed. Performance assessment categories included functional benefits [1], subjects perception and advanced maneuvers. Prosthetists and subjects assessments are noted in 5 point-Likert or dichotomized scales. An extensive set of clinical variables including age, mobility grade, etiology, body mass index (BMI), comorbidities, residual limb condition, socket type, previous fitting etc. is investigated via linear and logistic (uni- and multivariable) regression models. Effect size estimates and quality of the regression models allow an estimate of predictive power.

RESULTS

A cohort of 899 individuals, age 49.0±12.9ys; BMI 26.6±4.6; mobility grade classification MG2: 12.5%, MG3: 64.1%, MG4: 22.8%; etiology: 68.9% trauma, 15.4% tumor, 6.0% vascular disease; and predominantly male (83%) was investigated. Amputation level was transfemoral in 80.1% and knee-disarticulation in 18.9% of the subjects. Subjects were experienced prosthetic walkers having their first prosthesis since 21.2±15.6yrs. 78% had at least one comorbidity.

Most sensitive performance indicators per category were [# hits with p<0.05): variably gait speed (22), toileting (18) and stairs ascend (29). Effect estimates span up to 0.37 (mobility grade, p < 1E-26(!)) but regression models fail to reveal predictive power in any of the investigated variables nor their combination (univariable r2 <0.19, multivariable r2<=0.263). BMI failed to reach statistical significance.

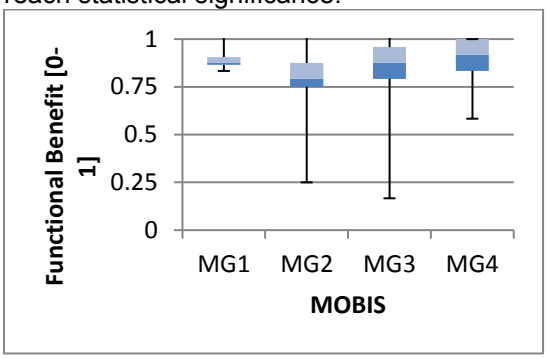

Figure 1. Compound measure of functional benefit depending on mobility grade rating. The effect of mobility grade is insufficient to predict individual response.

DISCUSSION & CONCLUSION

The statistical significance of the findings is remarkably high. While all clinical effects are plausible, none of the investigated variables (nor their combination) exhibit predictive power. This corresponds to earlier findings [3, 5, 6].

Based on the size of this sample we conclude that the investigated variables themselves may not be suitable to judge on an individual's potential to benefit from an advanced MPK and hence must be dismissed as both: predictors as well as indicators for denial [7].

REFERENCES

1. Wetz et al, 2005, Orthopäde 34:298-319
2. Kannenberg et al, 2014, JRRD 51(10)1469-1496
3. Hahn et al. 2015, JPO 27(3)86-95
4. Kaufman et al, 2016, AOPA, Proceedings
5. Wurdeman, 2016 AOPA, Proceedings
6. Wong et al. , 2012,AJPMR, 24(1)16-18
7. Hahn et al. 2016, Medicine 95(45)e5386

DISCLOSURE

Hahn and Lang are full-time employees of Otto Bock HealthCare. Stuckart is employed at Stat-up, a provider of provisional statistical analysis services.

On the use of health economic instruments to evaluate prosthetic services

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Background

Health technology assessment and health economic (HE) value proposition play increasingly important roles in a modern health care systems. Increasing pressure by demographic change forces specifically public health care to allocate resources where most value is being created. Next to an increase in level of clinical evidence, health economic arguments shall become increasingly vital. The recent inquiry of the AHRQ with respect to lower limb prosthetics are 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 flow costs and well valuated.

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

Method

Data were retrieved from five prosthetic workshops in Europe 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 81 subjects, 71% male, average age 45.3 +/- 17.3. Amputation levels were transtibial (28), transfemoral (35), knee disarticulated(5). Twelve subjects had double amputations. For one subject amputation level was not denoted. Etiologies were trauma (58%), tumor 11%, v.d. 6%, congenital 6%, others 11%, not stated 6%. Mobility ratings (MOBIS grading) were MG1: 2 subjects, MG2: 20 subjects, MG3: 50 subjects and MG 4: 9 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).

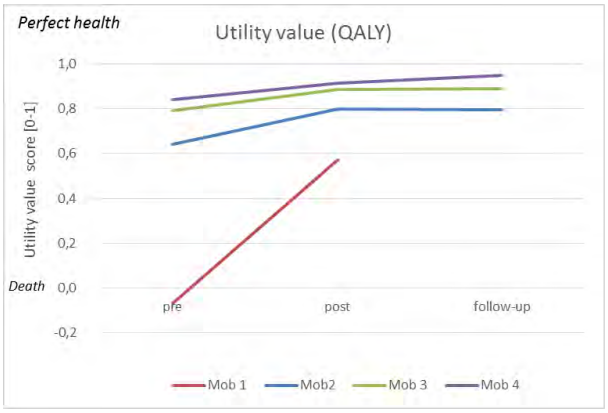

Fig. 1: Display of change of utility value stratified for different mobility grades (MOBIS). If the duration effectiveness of the intervention is set to unity, the number may directly be interpreted as Quality Adjusted Live Year (QALY)

Discussion and Conclusions

QALYs have been used with advanced hydraulic microprocessor-controlled prosthetic components for the quantification of the value added [1,2,3].

To our understanding this is the first time that this concept is extended to assessing P&O services. Strikingly, we find a very high sensitivity in all dimensions and the instrument qualifies for stratification. Absolute values are comparable to those derived in [1,2,3]. While in this analysis we omitted on the comparison of costs associated with the different health care systems it may be simple to induce that P&O services may be cost efficient. Further investigations will be required to fully explore the potential of the technique.

REFERENCES

1. Gerzeli et al, 2009, HEPAC 10(1)47-55
2. Cutti et al. 2016, POI epub
3. Brodtkorb et al, 2008, APMR 89(1)24-30

Disclosure

A.Hahn and P.Maciejasz are full time employees at Otto Bock

OSSEOINTEGRATED IMPLANTS IN PATIENTS WITH DIABETES MELLITUS: A CASE SERIES OF EIGHT PATIENTS

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INTRODUCTION

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. This is the first study reporting on the clinical outcomes of diabetic patients receiving an osseointegrated reconstruction.

METHODS

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

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.

DISCLOSURES

Dr. Al Muderis consults for and receives royalties from companies including: Osseointegration International Pty Ltd (Australia), Osseo-PL Inc (USA), Osseo-PL GmbH (Germany), AQ Implants GmbH (Germany) and Permedica S.P.A (Italy).

PERFORMANCE AND SATISFACTION WITH INTUITIVE MULTIFUNCTIONAL HAND PROSTHESIS CONTROL

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BACKGROUND

Pattern recognition-based control functions in a fundamentally different way than conventional, myoelectric control. Instead of relying on two manually chosen electrode sites to control a single degree of freedom, pattern recognition uses many electrodes and intuitive movement mapping to control several movements seamlessly[1].

The majority of previous pattern recognition studies have been performed on non-amputee subjects and only virtual arms had been controlled with pattern recognition systems instead of real prostheses[2]. Prolonged home-use of such devices is still little documented.

AIM

The aim of this feasibility study is to test 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.

METHODS

Transradial amputees fulfilling inclusion criteria and currently wearing prosthetic systems with CC, single opening/closing hand and active wrist rotation were enrolled in the study. To assure optimal control of the PR prosthesis, each participant underwent a structured learning process. Functional assessments were performed 4 times: 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). The functional assessment is comprised of performance-based (Modified Box and Blocks test (mB&B), Clothespin Relocation and Proportional Control Test) and self-reported tests (Disabilities of the Arm, Shoulder and Hand (DASH); project specific questions). 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 patients have been enrolled in the study and fitted with the PR devices. Data collected at baseline and 1st follow-up could be analyzed for all 6 participants, and 2nd follow-up for 4 participants. Users were mainly male (71%), mean age 44 years (± 13.4 years). Amputation etiology was trauma (100%). Prosthesis control experience varied widely between novices and decades of daily usage.

All participants were satisfyingly fitted with PR prosthesis within the first visit. The entire fitting and training process was rated as clear or slightly unclear with no or mild difficulty to follow the instructions (fitting process questionnaire mean score 1.7 ± 0.53; training process questionnaire mean score 1.2 ± 0.13).

The ability to control two degrees of freedom (hand open/close and wrist rotation), measured with clothespin test, was improved immediately after PR fitting and remained consistent after 1 month of PR home use (transporting the clothespins from vertical to horizontal bar showed 34% improvement and from horizontal to vertical bar 18% improvement, *Figure 1*). The time needed to transport 16 blocks in 4 rows with defined placement, measured with mB&B, was immediately after the fitting on average 27s (± 33.8s) prolonged and 9s (± 18.8s) after 1 month of PR home use when compared to the baseline (*Figure 1)*. Patients experienced on average mild difficulty and problems when controlling PR system (user´s project specific questionnaire mean score 1.7 ± 0.59). No difference was observed in DASH and the level of proportional control. 50% of participants would prefer PR over CC. Qualitatively observed, users who were already adept prosthesis users with CC gained disproportionally more from PR than technically less savvy users.

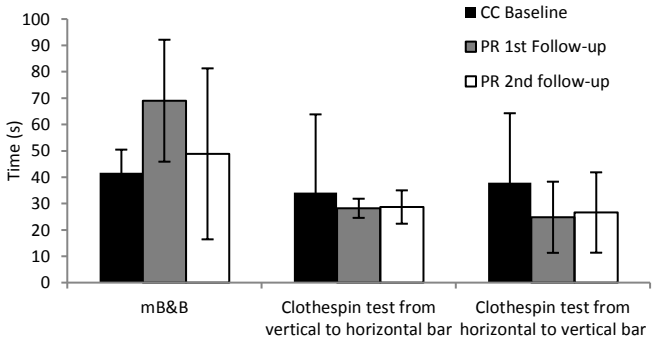

Figure1: Performance-based tests conducted at baseline with conventional control (CC), and at 1st and 2nd follow- up with pattern recognition control (PR).

DISCUSSION & CONCLUSION

In this study, feedback from certified prosthetists and users who had the possibility of testing the system at home for four weeks, have been be gathered. The improvements in unilateral gross manual dexterity and ability to control two degrees of freedom were observed with PR during the 1st and 2nd follow-up. 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.

REFERENCES

1. Young, Aaron et al. 2014 Journal of NeuroEngineering and Rehabilitation
2. Peerdeman, Bart et al. 2011 The Journal of Rehabilitation Research and Development

DISCLOSURE

Sebastian Amsuess, Ivana Sreckovic and Birgit Bischof are affiliated with Otto Bock Healthcare Products.

PREVALENCE OF FLAT FOOT/PES PLANNUS AMONG SCHOOL CHILDREN'S

BETWEEN 6 TO 10 YEARS

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BACKGROUND

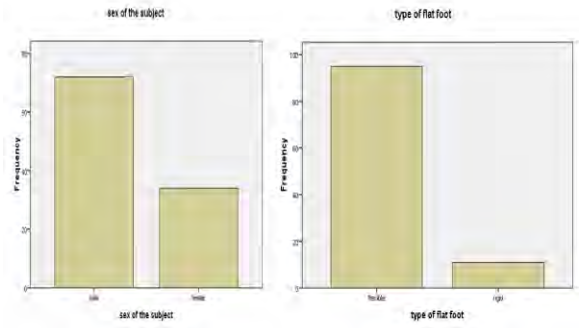
Flat feet is often a complex disorder in which MLA is collapsed/flatted or depressed sole of the foot comes in contact with ground. In flat feet the progressive weight bearing/stress produced calcaneal valgusity or flattened arches to drift or four feet abduction, pronated or everted foot Survey of 297 children at Ahmadabad, Utter perdesh India reveal that 40.32% of the children under 5-12 years, 15 % of children between 5-10 years, 15.48% of the children under the 10 years age suffered bilateral flat feet

METHOD

Our cross sectional study (prevalence survey) has been conducted on School children among 6-10 years (class one to class fifth) in six schools of the Rawalpindi/Islamabad. From 1st December 2011 to 1st march 2012(three months). ,the instruments used for data collection was questionnaire(unstructured)or Performa and the questionnaire mainly had three parts ,subjective history or bio data, objective history, examination .diagnosis of the flat foot was made on the basis of clinical examination of the foot (physical appearance of the foot) and special tests (arch on loading verses arch on unloading

RESULT

Our study determined the prevalence of the flat foot (age, gender, side involvement, and type). Our study included 714 children, male (512) and female (202).A specially designed Performa (subjective, objective history) is filled after doing physical examination and special tests for flat foot. The statistical analysis concluded that that the prevalence of flat foot in school children among 6 to 10 years (from class 1 to 5) is 14.8% (106) and more common in male child then female child and bilateral (76.4%) involvement of the flat foot is more than unilateral (23.4%).



The study showed that prevalence of flexible flat foot is ten times more than rigid flat foot having a ratio of 9:1 .all rigid flat foot cases are symptomatic and flexible flat foot cases are asymptomatic (showing no symptoms).the prevalence of flat foot is more in children's who are physically inactive .while physically active children have a very well developed medial longitudinal arch.

CONCLUTION

It is our conclusion that people/child who are living in different countries but having similar condition like environment, social, economical, life style. They have equal chance of developing flat foot or they have same % of the prevalence of the flat foot. Our study concluded that physical activity is directly proportional to the development of the medial longitudinal arch

Discussion

Our study of the literature environmental, social, economical, condition of the both countries ,(Pakistan and India) life style(physical activity level) , type of diet in both region are similar the nature of the children's in both region have resemblance that's the reason that our study shows resemblance with Ahmadabad survey. Our study shows a strong familial tendency for flexible flat foot. This has been shown in other studies proves that flexible flat foot is asymptomatic while rigid flat foot less common then flexible. And rigid form of flat foot is always symptomatic

REFERENCE VALUES FOR GAIT TEMPORAL AND LOADING SYMMETRY OF LOWER-LIMB AMPUTEES CAN HELP IN REFOCUSING REHABILITATION TARGETS

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INTRODUCTION

Temporal, loading and step length symmetry of gait are commonly considered as rehabilitation goals for lower-limb amputees. However, the literature does not clearly indicate that striving for maximum symmetry is really and always the best option for all patients. Focusing on temporal and loading symmetry, the aim of this work was to answer to two methodological (Q1-Q2) and four clinical (Q3-Q6) questions. Considering the former group, is there a correlation between:

1. Q1: step and stance temporal symmetry?
2. Q2: temporal symmetry and loading symmetry?

A positive answer will indicate that just one of the parameters must be measured. Considering the latter group:

1. Q3: how many AKAs and BKAs preserve the physiological three-rocker sequence?
2. Q4: are there different typical levels of temporal and loading symmetry depending on the level of amputation?
3. Q5: is it always true that amputees overload the affected side?
4. Q6: does the use of the C-leg improve temporal and loading symmetry?

METHODS

Sixty-three K3-K4 lower-limb amputees participated in the study after signing an informed consent: 12 mechanical knee users (AKAM, 46±10 y.o.), 26 C-leg users (AKAC, 48±12 y.o), 25 transtibial amputees (BKA, 47±14 y.o.). In addition, 10 able bodied subject were also included (CNT, 27±2 y.o.). All amputees had been successfully using their prostheses for at least 1 month at the time of testing.

We instructed each subject to walk along an 80m corridor at self-selected speed. For each gait cycle, the vertical ground reaction force (VGRF) and the instants of heel-strike (HS) and toe off (TO) were measured on each side through instrumented insoles (Pedar-X, Novel, D). *Sound vs affected side* indexes of symmetries were calculate for each step and stance times, and the median value was calculated among all gait cycles (>30). The existence of the two physiological VGRF peaks was verified for each gait cycle. We defined P1 as the VGRF peak at loading response, and P2 as the VGRF peak at terminal stance. A subject was classified as pertaining to subgroup:

- S1: if more that 50% of the VGRF patterns had a P1;
- S2: if more that 50% of the VGRF patterns had a P2;
- S12: if P1 and P2 were always detected.

For each subject of S1 and S12, we computed the symmetry of P1 between the *sound vs affected side* and we extracted the median value over the gait trial.

RESULTS

Results were as follows.

Q1: a statistically significant correlation between step and stance symmetry was found within each group and overall among subjects (r=0.96, CI 0.93-0.98, p<0.0001). Only stance symmetry will be considered hereinafter.

Q2: none of the groups presented a significant correlation between P1 and stance symmetry indexes. Therefore, both parameters have to be examined.

Q3: 58% of AKAM, 42% of AKAC, 88% of BKA and all CNT showed both P1 and P2.

Q4: with reference to Fig. 1, stance symmetry was statistically different among all groups and inversely related to the level of amputation. Mechanical knee users were more asymmetrical than C-leg users. Among P1 symmetry, ample variability exists, with amputees statistically different from CNT. Worst results were found in BKAs.

Q5: not all amputees overload the sound side (Fig. 1).

Q6: C-leg improves stance symmetry. Peak load asymmetry is reversed, with increased loading on the C-leg. This might be interpreted as increased confidence for the prosthetic side.

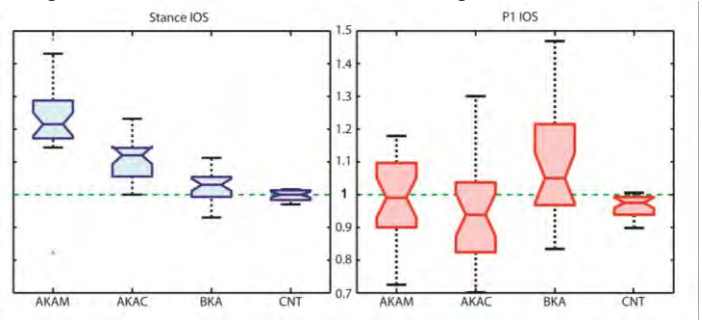

Figure 1 Stance time and P1 symmetry indexes

CONCLUSION

We can formulate four main clinical conclusions:

1) about 50% of AKAs show a compromised 3-rocker sequence, independently from the knee used. This can have an effect on energy expenditure;
2) not all amputees overload the sound side;
3) stance asymmetry is strictly related to the level of amputation and can be large for AKAM;
4) AKA have increased stance symmetry and load more the prosthetic side compared to AKAM. However, the inter-subject variability is high.

SIGNIFICANCE

All amputees examined were experienced and accommodated users. It does not seem reasonable to assume that symmetry should be perfect and the same for all levels of amputation and prosthetic component used. It could not be confirmed that all patients overload the sound side, but this was the case for most of BKA patients.

DISCLOURE

None.

RELATIVE INFLUENCE OF ORTHOTIC SUPPORT FEATURES WITHIN AN OPEN FRAME AFO VERSUS A TOTAL CONTACT AFO ON FUNCTION, ENDURANCE, AND ACTIVITY LEVEL IN PATIENTS WITH SPASTIC EQUINOVARUS SECONDARY TO CHRONIC STROKE

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PURPOSE

Most research investigating mechanical properties of AFOs has focused on sagittal plane characteristics.[1-3] However, patients suffering from neuromuscular disorders often have biomechanical deficits that result in tri-planar involvement. Traditionally, total contact orthoses are recommended to provide the highest level of support for the postural deficits associated with these conditions. Alternatively, open frame orthotic designs are sometimes used, offering a variety of benefits. The focus of this pilot study was to determine the relative influence of the orthotic support of open frame versus total contact AFOs on function, endurance, and activity level in subjects with spastic equinovarus secondary to chronic stroke. Specifically, whether a supramalleolar extension within an open frame AFO would be equally effective managing coronal postural deficits as compared to a total contact AFO with the same supramalleolar support geometry and additional support features.

METHOD

Subjects: Subjects included in this study were diagnosed with chronic stroke. All subjects had previously worn a lower extremity orthosis and were able to ambulate independently. Subjects had varying levels of unilateral neuromotor strength and/or range of motion deficits at the ankle and knee, including equinovarus ankle posture.

Apparatus: Orthoses fabricated for each subject included two custom laminated double upright AFOs. Multifunction ankle joints were used in both orthoses to allow for optimization of sagittal plane mechanics. One of the orthoses was a total contact design with a full shell and contoured footplate. The footplate included clinically relavent supportive elements to resist hindfoot varus. The second orthosis was an open frame AFO with a flat footplate. The two orthoses were identical in all aspects with the exception that modifications were made to eliminate all supportive elements from the footplate on the open frame AFO leaving only the supramalleolar extension and associated three-point force system to provide coronal support. Subjects were provided with and excluisvely wore New Balance model 813 shoes. StepWatch activity monitors were employed to measure activity over time.

Procedures: Subjects were casted and fit with a diagnostic check orthosis. Emphasis was placed on ensuring the appropriate supramalleolar extension geometry. The tested orthoses were fabricated with great care to isolate the effect of the supramalleolar extension. Subjects were fitted with both the total contact and open frame AFOs. StepWatches were used to measure use and activity level in two week intervals while wearing their own orthosis, the total contact AFO, and the open frame AFO. Outcome measures were also assessed including 10mWT, 6MWT, stride length, and a written questionnaire. The design of their own previously used orthosis was not controlled, but use and outcomes were measured with this orthosis as an additional point of comparison.

Data Analysis: Statistical analyses and comparisons to published clinimetric properties were performed, when applicable. Answers to the questionnaire as well as verbal feedback were used to understand the subjects' level of satisfaction with various aspects of the orthoses.

RESULTS

Visual observations and subjective feedback indicated that a similar level of postural support was achieved with the total contact and open frame AFO designs. There was an increase in walking velocity from the no orthosis to current orthosis condition and from the current orthosis to total contact orthosis condition. Stride length was increased with the total contact orthoses when compared to subjects' current orthoses. There was not a measurable difference for all subjects in the distance walked during the 6MWT between tested conditions. StepWatch data showed similar activity level while wearing the tested AFOs. However, combining stride length differences with the StepWatch data suggests an increase in walking efficiency with the total contact AFOs when compared to the subjects' own orthoses.

CONCLUSION

This pilot study suggests that the lateral supramalleolar supportive element within an open frame AFO design is an effective means of controlling varus ankle posture in hemiparetic stroke. However, additional research is required to determine whether severe equinovarus postural deficits can be effectively managed using open frame orthoses and whether the advantages of open frame orthotic designs are efficacious in the treatment of spastic stroke.

SIGNIFICANCE

Though there are significant functional benefits to the feature set of open frame orthotic designs, total contact designs are often used due to the prevailing opinion that the support of these orthoses is necessary to control the postural deficits of this patient population. With the knowledge of which support elements are necessary to the success of orthotic fitting, orthoses can be more optimally designed.

REFERENCES

1. Kobayashi T, et al. Gait Posture 37, 457-459, 2013.
2. Kobayashi T, et al. Clin Biomech 30, 775-780, 2015.
3. Singer ML, et al. Clin Biomech 29, 1077-1080, 2014.

DISCLOSURES

Beatrice Janka and Nicholas LeCursi are employees of Becker Orthopedic, Inc. Becker Orthopedic, Inc. manufactures the Triple Action™ ankle joint used in this study.

ACKNOLEDGEMENTS

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Report on Three Users' Function After One Year of Using Upper Extremity Myoelectric Custom Orthosis to Remediate Brachial Plexus Injury Paresis

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INTRODUCTION: This Case Series examines the experiences of three (3) end-users of an upper extremity (UE) custom myoelectric elbow-wrist-hand orthosis (EWHO) after the first year of use with the device. Only one myoelectric orthosis is available at the time of this study, the MyoPro. The EWHO utilizes the user's electromyographic (EMG) signal to operate a motor and facilitate motion through on-board computer systems. The myoelectric EWHO employs the EMG signals from the flexors and extensors of the elbow to flex and extend the elbow volitionally. The user must input and control the EMG signal in order for the orthosis to assist with the motion. The orthosis is not electrical stimulation nor passive mobility. These features of the device encourage high-repetition, functional tasks that could rehabilitate the dysfunctional arm better than current rehabilitation standards.

SUMMARY: This case series will describe, present, and discuss the experiences and outcomes of three male users who were fit with the EWHO following a brachial plexus. The users are ambulatory and use no assistive devices or lower extremity orthoses. One patient is a bilateral device user; the remaining two are unilateral users. At initial presentation in the orthotics and prosthetics (O&P) clinic, each user had limited active range of motion (ROM) and strength in the extremities. Active and Passive ROM metrics were collected at the initial evaluation, along with manual muscle testing (MMT) and functional ability. Each user has self-reported deficits in their ability to perform many functional activities due to their upper extremity impairment causing a loss of independence.

Each user was fit with the myoelectric EWHOs following a referral by his physician to a certified prosthetist-orthotist (CPO) who performed a full evaluation to determine candidacy. The orthoses were custom fabricated for the user from a mold and measurements of the UEs. The user worked with registered and licensed occupational therapists (OTs) trained in the myoelectric EWHOs to maximize his mastery of the orthoses and increase functional outcomes.

RESULTS: Prior to receiving the myoelectric EWHO, each user was unable to use his affected upper extremity for bilateral functional tasks due to limited AROM and severe weakness. Once the device was properly fit, the electrode sites on the bicep and triceps were selected, and an appropriate harness was constructed of transfer the weight of the device to the clavicle-scapula complex while controlling internal/external rotation of the shoulder and stabilization of the device on the arm. Each user demonstrated an ability to reliably operate the device and achieve gross dexterity tasks in the O&P clinic. We established appropriate modes to use both electrode myoelectric sites to operate the device in all 3 available modes: Bicep Mode, Triceps Mode, and Dual (Bicep/Triceps) Mode.

After fitting, each user met regularly with Occupational Therapists to train and practice with the device on strengthening exercises and functional tasks. The occupational therapists and patients were trained in proper adjustment of MyoPro programming. Adjusting the device functionality during the course of the recovery at subsequent appointments ensured more controllable operation of the EWHO and to encourage the user to continue to work hard to improve while operating the device. Each user achieved differing levels of rehabilitation, with the bilateral user graduating out of the devices, and the other two users meeting various levels of increased functional return. Passive, Active, MMT, and functional abilities were compared against earlier metrics to construct an impression of functional return.

SAFETY AND EFFECTIVENESS RESULTS FROM THE C-BRACE® RETROSPECTIVE REGISTRY

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INTRODUCTION

The C-Brace® is a microprocessor-controlled Stance and Swing Controlled Orthosis (SSCO). A retrospective registry was developed to gather safety and effectiveness data from patients that had been fitted with a C-Brace.

METHODS

Anticipated outcome measures at participating sites included Timed Up and Go (TUG), Fast Walking Speed (FWS), Berg Balance Scale (BBS), the Activities-specific Balance Confidence (ABC) Scale, and an Activity of Daily Living Questionnaire (ADLQ) consisting of 43 questions rating ADLs on importance (3-point scale) and ease (6-point scale) in eight separate categories.

RESULTS

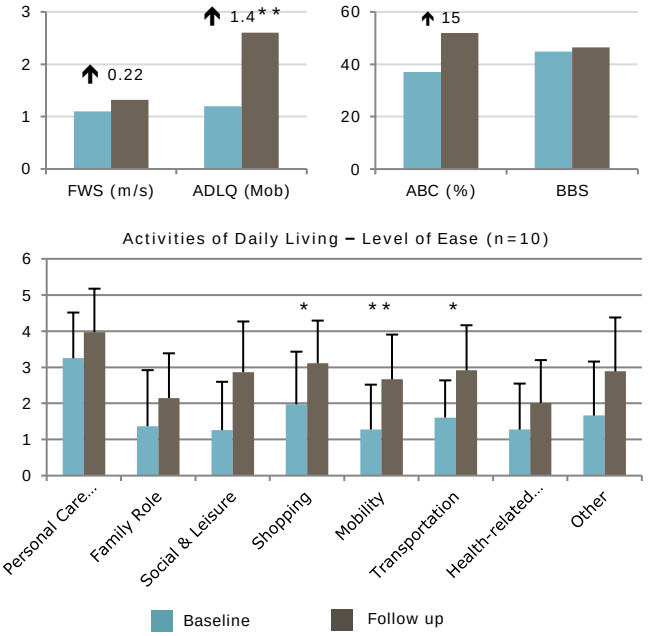
Data were collected from 19 subjects (5 female) fitted with a C-Brace at 14 clinics: mean age of 49.7 years and mean weight of 204 (125-272) lbs, 1 for bilateral fitting. The average follow-up duration after C-Brace fitting was 9.7 (0-27.8) months. 7 were incomplete SCI; other indications included post-polio, neuropathy and TBI. The average fall frequency for subjects prior to C-Brace fitting was 9 falls per month (ranging from 2 per year to 3 per day).

No Serious Adverse Events were reported related to the C-Brace. Only two falls were reported, both without serious injury (average 0.2 falls per month). Overall, 16 device-related adverse events were reported in 10 subjects, all mild in severity except one fall reported as moderate.

The baseline (B/L) and change (Chg) scores for each of four outcome measures are summarized in the table below.

Outcome	FWS m/s	BBS score	ADLQ (Mobility) score	ABC %
n	7	7	10	10
Avg B/L	1.1 ± 0.50	44.9 ± 7.5	1.2 ± 1.13	37 ± 24%
Avg Chg	0.22 ± 0.26	1.57 ± 0.98	1.4 ± 1.38	15 ± 23%
Med F/U	3 mos	3 mos	15 mos	15 mos

These results are also shown in the following graph along with the results for each of the eight categories of the ADL-Q.



** p<0.05, ** p<0.01, Wilcoxon Signed Ranks Test*

The mean changes in three of the ADL-Q subscores were statistically significant: Shopping, Mobility, and Transportation. At the individual level, clinically meaningful changes compared to baseline were observed in 10 of 12 subjects (83%) that had efficacy data at both baseline and follow-up. 5 of 7 (71%) of subjects had a clinically meaningful change in FWS.

CONCLUSION

Results from this retrospective registry revealed that the C-Brace can be used safely with a potential for dramatically reducing the frequency of falls. Furthermore, the majority of subjects demonstrated clinically meaningful improvements in outcome measures. FWS and ABC, in particular, appear to be sensitive outcome measures in the majority of subjects with implications for an ongoing prospective registry utilizing these outcome measures.

ACKNOWLEDGEMENTS

Funded by Ottobock. Special thanks to all participating sites for input and support for the C-Brace Retrospective Registry.

SELECTION AND ASSESSMENT OF A SET OF OUTCOME MEASURES FOR ELECTRONICALLY CONTROLLED KNEE USERS

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INTRODUCTION

Electronically controlled knees have the potential to improve the mobility and quality of life of transfemoral amputees if patients are involved in a tailored rehabilitation program [1]. To understand if the personalized care has been successful, it is essential to evaluate its outcome, both with functional tests and clinical questionnaires. Instruments for K3-K4 users should:

1) not suffer from ceiling effect;
2) have a smallest detectable change (SDD) between raters as low as possible;
3) be little or non-correlated, to ensure they are capturing different constructs;
4) be able to correctly classify subjects with different characteristics.

The aim of this work was to start answering these questions, considering a set of outcome measures, that were selected by 5 physical therapists during a 1-year internal course on evidence-based physical therapy: PLUS-M [2], AMP [3], L-TEST, 6 Minutes walking test (6MWT) [4], and 4-SQUARE [5].

METHODS

Since PLUS-M (12 questions) and AMP were developed in English, a back-translation approach was followed to produce an Italian version. Before study begun, both instruments were tested on a group of 5 pilot subjects and 5 physical therapists.

Then 11 male unilateral transfemoral amputees were recruited (mean age 45±7, weight 76±9, 6 smokers), after signing an informed consent: 4 after completing the transition from a mechanical to an electronic knee (group 1, G1), and 7 experienced electronic knee users (group 2, G2). All subjects completed all outcome measures once. Ten completed the functional tests twice within the next working day to minimize the within-patient variability. Repeated tests were administered by two different PTs.

PLUS-M and AMP scores were checked for ceiling effects. SDD (90%) was computed for all functional tests. Cross-correlation among instruments was calculated. Since the experience of subjects in G1 and G2 was known to be different, scores of G1 and G2 were statistically compared within each instrument to understand which outcome measure was able to highlight the dissimilarity.

RESULTS

The mean values was 50.7±5.7 for PLUS-M (ceiling: 71.4), and 43.7±1.2 for AMP (ceiling: 47). The SDD (including bias) was 0.6 pts, 2.9 seconds, 1.3 seconds and 62.0 meters for AMP, L-TEST, 4-SQUARE and 6MWT, respectively.

Table 1 reports the correlation matrix among outcomes.

The rank-sum test was close to statistical significance only for PLUS-M (p=0.07), while the p-values for AMP, L-TEST, 4-SQUARE and 6MWT were 0.98, 0.32, 0.79 and 1, respectively.

	PLUS-M	AMP	L-TEST	4_SQUARE	6MWT
PLUS-M	1,00				
AMP	0,03	1,00			
L-TEST	-0,38	-0,42	1,00		
4_SQUARE	-0,24	-0,34	0,53	1,00	
6MWT	0,29	0,04	-0,60	-0,75	1,00

Figure 1 – Correlation matrix among outcome scores.

CONCLUSION

PLUS-M and AMP did not show any ceiling effect, but for AMP all subjects scored between 42 and 45. The AMP had an almost null SDD, smaller than what reported in [6]. L-test SDD was also smaller than the value reported in [7], while 6MWT SDD was higher [6]. No SDD reference values was found for 4-SQUARE. The analysis of correlation suggests that PLUS-M and AMP address different constructs: both outcomes should be administered. The correlation between 6MWT and AMP could not be confirmed. 6MWT, L-TEST and 4-SQUARE were most correlated. PLUS-M results for G1 and G2 were close to statistical significance.

SIGNIFICANCE

Results suggest that PLUS-M and AMP do not suffer from ceiling effects, AMP is reliable between rater, and the two instruments measure different constructs. 6MWT seems a good addition too, based on the low correlation with AMP; however, this conclusion is different from the literature. All results will need confirmations on a wider group of patients.

REFERENCES

1. Cutti et al, Prosthet Orthot Int. 2016
2. Hafner et al, Arch Phys Med Rehab, 2017
3. Gailey et al, Arch Phys Med Rehab, 2002
4. BACPAR toolkit
5. Whitney et al, Arch Phys Med Rehab, 2007
6. Resnik et al, Physical Therapy, 2011
7. Deathe et al, Physical Therapy, 2005

DISCLOURE

None.

SIXTY YEARS OF ACTIVE PROSTHESIS USE: A SELF-REPORT CASE STUDY WITH RECOMMENDATIONS

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INTRODUCTION

According to information posted by the Amputee Coalition (n.d.), there are approximately 2,000,000 Americans who have experienced the loss of a limb or congenital limb difference and another 28,000,000 Americans who are at risk for amputation. These numbers are expected to double by the year 2050, primarily as a result of the effects of diabetes and trauma due to violence. The ratio of individuals with upper limb loss to individuals with lower limb loss is 1:4. Among the population with upper limb loss, the most common involves partial amputation of one or more digits, with loss of one upper extremity as the next most common (60% at the trans-radial level). In addition, approximately 4 out of every 10,000 babies (or approximately 1,500 babies) per year are born in the United States with upper limb reductions (Amputee Coalition, n.d.). Zeigler-Graham et al. (2008) reported there are approximately 2,000 Americans who experience new upper limb amputations at, or proximal to, the wrist every year. Many individuals who experience acquired limb loss report that they were given little to no information from their medical professionals.

Individuals who experience unilateral upper limb loss or congenital difference would likely be obvious candidates to experience secondary conditions related to overuse of the sound upper limb. Little evidence pertaining to this topic has been published until recently. Jones and Davidson (1999) investigated the presence of conditions affecting the function of the sound arm among individuals with unilateral upper limb loss and Gambrell (2008) conducted a review of the literature noting the consequences and importance of prevention of overuse syndrome. Recently, Sheehan and Gondo (2014) reported on the impact of limb loss in the United States, stating that the number of individuals experiencing limb loss is expected to double by 2050, and secondary conditions appear include disparities that affect physical health as well as mental health because there is no active medical surveillance. They emphasize that "those with limb loss in America have been forgotten in the health care system" (p. 9).

METHODS

This report is a reflective single subject case study of an individual with congenital limb difference and chronicles prosthesis use from the age of 14 months through the age of 61 years. Social issues, overuse symptoms, adaptive strategies and assistive devices are chronicled through developmental milestones and stages of childhood and adulthood. These are substantiated through medical documentation, personal journals, and photographs.

DISCUSSION

While much evidence has been published about individuals with acquired upper limb loss, little has been documented about the aging individual with congenital limb difference. Murray (2005, 2009) used interviews with prosthesis-users to discover common experiences and themes that are important to the population. Murray's research (2009) suggested that the valued personal identities and the self- management of patient's ability status should be a priority for the health professionals involved in prosthesis-users medical care and personal development.

CONCLUSION

This presentation will offer insight to the experiences of an individual over six decades of active and diverse prosthesis use and incorporates the compelling perspective of the individual as a consumer of prosthetic technology, clinician and contributor to the population and the industry.

REFERENCES

Gambrell, C. R. (2008). Overuse syndrome and the unilateral upper limb amputee: Consequences and prevention. *Journal of Prosthetics and Orthotics, 20*(3), 126-132. http://dx.doi.org/10.1097/JPO.0b013e31817ecb16

Jones L. E., Davidson J. H. (1999). Save that arm: a study of problems in the remaining arm of unilateral upper limb amputees *Prosthetics and Orthotics International*. 23, 55-58. http//dx.doi.org/10.3109/030936499090

Murray, C.D. (2005). The social meanings of prosthesis use.

Journal of Health Psychology, 10, 425-441. http//dx.doi.org/10.1177/1359105305051431716 11

Murray C.D. (2009). Being like everybody else: the personal meanings of being a prosthesis user. *Disability and Rehabilitation*, *31*, 573-581. http//dx.doi.org/10.1080/0963828080224029 Sheehan, T. P., & Gondo, G. C. (2014). Impact of limb loss in the United States. *Physical Medicine and Rehabilitation Clinics of North America*, *25*(1), 9-28. http://dx.doi.org/10.1016/j.pmr.2013.09.007

SURVEY OF U.S. PRACTITIONERS ON THE VALIDITY OF THE MEDICARE FUNCTIONAL CLASSIFICATION LEVEL SYSTEM AND UTILITY OF CLINICAL OUTCOME MEASURES FOR AIDING K-LEVEL ASSIGNMENT

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INTRODUCTION

The Medicare Functional Classification Level (MFCL or K-level) system is an index for classifying the functional mobility and rehabilitation potential of individuals with lower-limb loss[1, 2]. K-level assignment often relies on subjective information, and the level of content validity of the K-level system has been questioned[3]. Outcome measures have the potential to bring objectivity and consistency to the commonly subjective and imprecise method of K-level assignment. The purpose of this study is to characterize the opinion of the prosthetic clinical care community on the K-level assignment process, including limitations and practicalities involved with the integration of outcome measures (OMs) into the clinical practice framework.

METHODS

A survey consisting of 19 multiple-choice, Likert Scale, and open-ended questions was administered online via SurveyMonkey (Palo Alto, CA) and advertised through the US-based professional orthotics and prosthetics emailing list, OandP-L. The survey consisted of questions regarding professional opinion on the K-level system and the use of clinically-relevant outcome measures for K-level assignment. Data were analyzed only for U.S. practitioners.

RESULTS

Data were collected from 236 respondents, 213 of which practiced in the US. Forty-seven percent of respondents indicated that they were the sole determinant in the K-level assignment process, and forty-two percent reported the process as a collaboration with other healthcare professionals. Sixty-nine percent of respondents reported using some form of standardized OMs to assist in K-level assignment (see Figure 1 for type breakdown). Sixty-seven percent of respondents did not believe the K-level system is sufficient to accurately assign a level of rehabilitation potential, with 75% agreeing that incorporating OMs into clinical practice would enhance objectivity of the K-level assignment process.

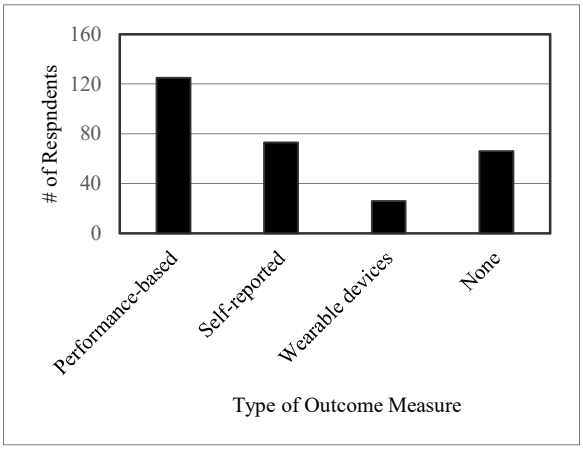

Figure 1. Form of OM used to assist with K-level assignment (213 Respondents).

DISCUSSION

The results suggest that most prosthetics practitioners are either the sole determinant of a patient's K-level or involved in the K-level assignment at some level, and a majority agreed that the K-level system is insufficient to accurately assign a level of rehabilitation potential due to its limitations. To address these issues, many practitioners are using OMs to assess various aspects of patient mobility and rehabilitation potential, and minimize the subjectivity of the assignment process.

REFERENCES

1. Gailey RS, et al. *Arch Phys Med Rehabil* 2002;83(5):613-27.
2. Administration UHF. Healthcare Common Procedure Coding System. In: Services HaH, editor. Washington D.C.; 2001.
3. Gailey RS. *J Prosthet Orthot* 2006;18(6):P51-P60.

DISCLOSURE

None

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THE CLINICAL APPLICATION OF PATTERN RECOGNITION CONTROL IN UPPER LIMB PROSTHETICS: A TWO-YEAR RETROSPECTIVE

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INTRODUCTION

Weight, comfort, and control complexity have all been indicated in reason for abandonment of a myoelectric prosthesis[1].

Traditional myoelectric control has been around since the late 1940's. Although the control circuits have evolved and become more advanced over time, the basic principle of using a minimum EMG threshold voltage to send a control signal to the components of a prosthesis has remained the same. Pattern recognition myoelectric control has been shown to provide equal if not superior prosthetic control as compared to tradition two site myoelectric control[2].

The recent introduction of a commercially available pattern recognition control system for myoelectric prostheses, the COAPT Complete Control (Coapt LLC, Chicago, IL), provides a new method of controlling externally powered prostheses through myoelectric control. The COAPT system includes a calibration button that the user can access at any time, without a computer, to record up to 5 different calibrations.

Presented here is a series of case studies describing the successes and challenges that were experienced, as well as the innovative solutions that were developed, during the real-world clinical application of this technology over the course of a two-year period.

These case presentations demonstrate that pattern recognition control has the potential to expanded the patient population that can benefit from myoelectric control, who only a few years ago, would not have been considered a candidate.

METHODS

This is an observational series of case study based on patient and prosthetist experience during the prototype, delivery and continued treatment of patients with transradial, transhumeral, and shoulder disarticulation amputations all fit with the COAPT Complete Control pattern recognition system.

Over the course of two years a total of 13 patients were fit with pattern recognition technology. Three females and ten males were fit. Five patients had a transradial amputation level, seven patients had a transhumeral level amputation, and one patient had a shoulder disarticulation level amputation. One of the patients with a transhumeral level amputation also uses a body powered transradial prosthesis on his contralateral side. One of the patients with a transradial presentation had a congenital limb difference.

RESULTS

Two of the four patients in the transradial group discontinued use of PR. One discontinued use due to general non-compliance, the other discontinued use due to the extra bulk in the prosthesis created by the additional COAPT components.

All the patients with transhumeral level amputations continue to utilize their PR systems except for the patient with bilateral amputations. This patient was a long-time user of body-powered technology and decided to abandon any attempts at using external powered prostheses.

The one patient with the shoulder disarticulation was initially successful with utilization of the PR technology, but due to health complications secondary to a brachial plexus injury necessitated that the external powered prosthesis be abandoned in favour of a lighter weight custom silicone restoration.

Initially all patients could consistently control their prostheses with increased accuracy over the course of their post-delivery occupational therapy.

All patients initially subjectively reported being satisfied with the fit, function, and comfort of their prostheses.

All patients actively utilize the calibration feature of the COAPT system daily when they don the prosthesis for optimal control. Everyone reported that this feature was very important to them.

DISCUSSION

During initial clinical evaluation, all patients were tested with a Myoboy to determine if they were a candidate for surface EMG prosthetic control. Not all the patients were able to produce discrete usable signals to control a prosthesis with multiple degrees of freedom. All patients were then tested using the COAPT system to evaluate their ability to utilize pattern recognition control. In all cases, it was initially observed and perceived by the patient that their ability to control a prosthesis with multiple degrees of freedom was improved with the use of pattern recognition. Because of this clinical observation, all the patients were delivered a definitive external powered prosthesis using the COAPT pattern recognition control. Everyone expressed an initial high level of satisfaction with their delivered prostheses.

Although several of the patients ultimately discontinued use of their prostheses with the COAPT system, none discontinued use because of dissatisfaction with the system. All who discontinued use expressed that they were very satisfied with the technology and would recommend that others try it. Nine out of the 13 patients continue to utilize the pattern recognition system. This equates to a 69% acceptance rate of the externally powered prostheses.

CONCLUSION

These case studies demonstrate that the pattern recognition technology available from COAPT can be utilized in externally powered prostheses for patients with all levels of upper limb differences. In some cases, had the patient only been myotested for conventional EMG control, they would have been contraindicated due to poor signal strength or inability to produce discrete signals. Anecdotally this suggests that it is important to continually reassess patients as new prosthetic technology is commercially available.

These cases also demonstrate the importance and benefit of integrating features into the prostheses that make the patient feel more in control of the device.

REFERENCES

[1] E. Biddis, et al. *Prosthet Orthot Int*. vol. 31 (3), pp. 236-257, 2007.
[2] S. Wurth, et al. *J. of NeuroEngineering and Rehabilitation* 11:91, 2014

The first 500 of the POQOL-100

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INTRODUCTION

The Prosthetics & Orthotics Quality of Life (POQOL) is a new outcomes measure under development by a team of clinician-investigators. The POQOL currently contains one-hundred quality of life items extracted from 17 extant validated QOL measures including SF-36, WHOQOL-BREF, PEQ, QUEST, TAPES, BRACE-Q, WOMAC, VASFA, and the EUROQOL; some of these questionnaires are general QOL surveys, some are specific to prosthetics or orthotics, and some are unrelated to P&O, but were adapted to P&O application.

Our line of inquiry here is: among these 100 QOL items, which are most commonly asked by clinicians and in what circumstance?

METHODS

Twenty-three certified clinicians provided information related to the 100 POQOL items: for each item, was this question asked during your patient encounter; (YES/NO). Additionally, for each patient encounter, supporting information was provided. To the extent possible, clinicians engaged in this study represent a geographically diverse, and diversely specialized cadre. Clinical case management softwares, e.g. Janus, Opie, Futura, etc., were tracked.

All activities described here were performed with Institutional Review Board approval.

RESULTS

Descriptive Statistics

Our data pool contained majority orthotics visits (n=440, 88%) and majority lower-limb orthotics (n=332, 66.4%); the majority of patients were male (n=290, 58%). The patient population was of mixed familiarity to the clinicians (first encounter: n=160, 32%; known > 5 years: n=32; 6.4%), were of mixed etiology (congenital: n=158, 31.6%; traumatic: n=123, 24.6%, and systemic: n=220, 44%), and were a range of ages (most frequent age category: 60-75 years: n=164, 32.8%; least represented category: 18-30 years: n=10, 2%; categories ranged from 0-6 years to 75+ years).

POQOL Frequencies

In the first 500 administrations of the POQOL, every QOL item was asked at least 1ce. Twenty-five (25%) items were asked <10% of the time, however 9 items (9%) were asked >40% of the time (Figure).

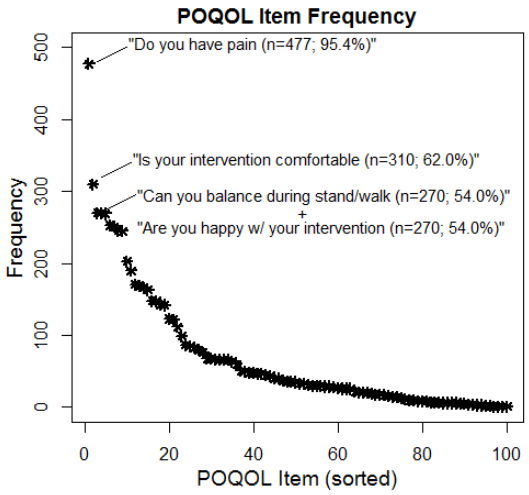

Figure: QOL item frequencies, sorted.

Space limitations prevent a break-out by visit type, i.e. which questions were asked in which setting, but these results will be explicitly provided during the platform presentation.

DISCUSSION

We present an update to the first ever study of QOL items asked by clinicians "in the raw." We propose that a refined POQOL (say, a POQOL-10) or sub-POQOLs (e.g. POQOL-Prosthetics or POQOL-Orthotics) could be obtained with adequate sample. Future extensions of this work will assess which QOL items do patients want to be asked. We believe that this level of open inquiry into the native QOL tendencies in both clinicians and patients will help refine clinical practice and scientific inquiry.

THE MICRO-PROCESSOR CONTROLLED ORTHOSIS:

WHAT IS THE IMPACT TO THE USER,

VERSUS THE STANCE CONTROL ORTHOSIS AND CONVENTIONAL LOCKED KAFO?

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INTRODUCTION

The current standard orthosis for people with severe quadriceps weakness is the "locked" knee-ankle-foot-orthosis (KAFO); it is relatively inexpensive and available but causes abnormal gait patterns contributing to chronic pain, slower gait, decreased mobility and a high physiological energy cost. The state of the art Stance Control Orthoses (SCO) allows users to flex the knee during the swing phase to improve gait patterns, but is still limited by the lack of controlled knee flexion or extension. A micro-processor controlled orthosis (MPO) could provide more control during the swing and stance phases allowing for increased speed, efficiency and safety in walking on uneven terrain, stairs and self-correction during a stumble.

PURPOSE

The purpose of the study is to evaluate the potential of the microprocessor controlled orthosis (MPO) to improve the functional mobility and quality of life in individuals with lower extremity impairments as compared to the SCO and conventional KAFO.

METHOD

20 individuals using a KAFO were randomized to either SCO or MPO. Following an instructional acclimation period of one month, participants were evaluated on device use in their home for another month. Following which, participants crossed-over to the other device group (SCO or MPO) and received a month of acclimation followed by home trial. Standard patient reported and performance-based measures of function and metabolic cost during ADLs and walking were assessed. In addition, advanced wearable sensors, GPS tracking and activity recognition techniques were applied to quantify device use at home, community mobility and quality of life.

RESULTS

Results of reported falls and balance testing demonstrate a lower number of falls using the MPO versus the SCO and KAFO and a significant difference in balance testing of the MPO versus the SCO and KAFO, exceeding the minimal detectable change of 5 points. Not all participants became proficient in the use of all the features available with the MPO during the relatively brief take-home period, in particular the stance flexion dampening for descending ramps and stairs. Those who did utilize this feature demonstrated a significantly increased score on the Stair Assessment Index and increased speed and safety in managing stairs and ramps. In addition, the energy cost of walking is not significantly different between devices when measured at fast velocity on a 6 minute walk test, but the distance and speed are significantly improved using the MPO versus the SCO and conventional KAFO. Furthermore, the community mobility and step count measured with wearable sensors and GPS was higher in the MPO users compared to SCO and KAFO.

DISCUSSION

The reduction in falls during use of the MPO indicates improved safety at home and in the community. The improved scores on the Stair Assessment Index using the MPO demonstrates improved proficiency which may lead to increased safety on stairs and ramps. The increased walking speed and distance by users of the MPO versus the SCO during a 6 minute walk test with equivalent oxygen cost shows the ability for the user of the MPO to improve cardiovascular conditioning and the potential for general health benefits. Although these results are from a small sample of orthotic users, the MPO does show potential to improve the functional mobility in the clinic and community for the user of a KAFO. These benefits may contribute to improved health and quality of life. However, not all users enjoyed the benefits of an MPO. Further sub-group analysis is required to identify optimal users vs. non optimal users.

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THE PROVISION OF PROSTHETIC LIMBS THROUGH VOCATIONAL REHABILITATION ENABLES PEOPLE WITH AMPUTATION TO ACHIEVE SUCCESSFUL EMPLOYMENT

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INTRODUCTION

Research that demonstrates the restorative effect of using a prosthesis to improve the lives of people with amputation is lacking. This is due, in part, because prosthetic research is typically limited by small sample sizes [1] and the fragmented US Healthcare system makes it difficult to get a consolidated database that can tie a pathology with an intervention and an outcome.

The RSA-911 database contains data on individuals with disabilities that utilize vocational rehabilitation (VR) services in the entire United States. This database contains information about the individuals' disability (e.g. if they have an amputation), and the VR services provided. The services provided also include how much funding was devoted toward assistive technology (that includes a prostheses). Most importantly, the databased contains their employment status, wages, and public support for both **pre and post** VR services. Thus, the information in the RSA-911 database could enable research designs that can better quantify the effect of a VR service (i.e. receiving a prosthesis) on an outcome (employment) with a large number of people with amputation.

The purpose of this research was to define the effect of receiving a prosthesis through Vocational Rehabilitation services on employment outcomes. The hypothesis being that people with amputation that receive funding for prosthetic care through VR services will be more likely to get a job that makes more than minimum wage and decrease the amount of public assistance they are receiving. A secondary hypothesis is that people receiving a prosthesis through VR would earn higher wages at the closing of VR services than people that did not. This information could then be used to demonstrate how prosthetic prescription can have a positive effect on people living with amputation.

METHODS

The Rehabilitation Service Administration Case Service Report (RSA-911 database) was filtered to include only individuals that had amputation listed as the primary impairment and whose vocational rehabilitation case was closed within 2014. The analysis was limited to only 2014 because the database was changed for 2014 and offered more information than previous years. People were said to have received a prosthesis when the database listed those individuals received assistive technology through VR services, that service was provided by an outside vendor (e.g. a prosthetist), and at least $4000 (i.e. the cost of a basic transtibial or transradial prosthesis) were spent on the assistive technology.

The receipt of other VR services or subject demographics that were shown to predict an individual with amputation's ability to gain employment were included in the analysis [2]. Those included, On-the-job training, On-the-job support, diagnosis, maintenance, job placement assistance, the presence of a comorbidity, having funding for Healthcare.

The primary outcome measures were; 1) successful outcome as defined as gaining employment with wages higher than minimum wage, and either no change or a reduction in funding from other public sources (etc. food stamps, welfare, etc.), and 2) their hourly wage at close of VR services.

A forward logistic regression model was used to analyze the effect of a prosthesis while accounting for the effects of other VR services on a successful outcome. A Mann-Whitney U test was used to determine if wages were significantly different ($p \leq 0.05$) between groups.

RESULTS

2243 cases of people with amputation were identified. 64.6% of the 99 that likely received a prosthesis through VR services achieved a successful outcome compared to the 33.2% of the 2144 that did not receive funding for a prosthesis. Having a prosthesis paid for by VR was a significant predictor of success ($p < 0.001$) and had an odds ratio of 4.97 (%95 CI of 3.18 – 7.75). When employment was achieved, the Mann-Whitney U test showed a significant difference in wages between prosthetic treatments ($U = 25038$, $p = 0.005$) with median wages per hour of $13.44 for the group that likely received a prosthesis and $11.51 for the group that did not receive a prosthesis.

DISCUSSION

These data demonstrate that when VR services provide funding for a prosthesis, that individual is 4.97 times more likely to gain employment at higher than minimum wage while reducing the burden on the welfare system than people that did not get a prosthesis through VR services.

Provision of prosthetic limbs through third party payers (like VR) has a positive effect of people living with amputation and the original funding source (i.e. federal and state governments) and should be continued. When a prosthesis was likely provided by VR, the person was more likely to be employed, employed making more money, and this resulted in a reduction in the amount of public support they are receiving. All of these results are very positive and all would help the person reintegrate and contribute to their local communities.

REFERENCES

1. Kuiken, et al. *JAMA*; 301, 619-28, 2009.
2. Childers et al. *AAOP Annual Meeting,* Orlando, FL, USA, 2016.

ACKNOWLEDGMENTS

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THE RISK OF MAJOR CARDIOVASCULAR EVENTS FOR ADULTS WITH ABOVE KNEE AMPUTATIONS

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INTRODUCTION

It is well-known that the risk of cardiac disease is increased for those with lower-limb amputations likely as a result of the etiology of the amputation [1]. Cardiac disease leads to increased disability amongst those with lower limb amputations [1-3]. Those with traumatic amputations have been found to have a risk of cardiac death that is 1.6 times higher than non-amputee controls [4].

The purpose of this study was to use a longitudinal population-based dataset to examine the association between AKA status and the risk of experiencing a major cardiac event for those undergoing either dysvascular or traumatic amputations. The association of receiving a prosthesis with the risk of experiencing a major cardiac event was also examined.

METHODS

Study Population and Cost Data: All individuals with AKA (N 162), i.e. knee disarticulation and transfemoral amputation, residing in Olmsted County, MN, between 1987 and 2014 were identified via administrative data and subsequent chart reviews. Each individual was matched on age, sex, and residency length with 10 individuals without an AKA. Major cardiac events (MI, acute ischemic heart disease, cardiac arrest, and cardiac interventions to include CABG, angioplasty, and stenting) were identified using ICD-9/10, HICDA, and Berkson diagnosis codes.

Data Analysis: A competing risk Cox proportional hazard model was used to estimate the relative likelihood of an individual with an AKA experiencing a major cardiac event in a given time period as compared to the matched controls [5]. The cohort was divided by amputation etiology: dysvascular vs trauma/cancer. Additional analysis was performed on only AKA to look at the relationship between prosthesis receipt and major cardiac events

RESULTS

Dysvascular AKA, N=107: Having a dysvascular AKA was associated with an approximately four-fold increase in experiencing a cardiac event both prior to and after 2.5 years of undergoing an amputation (HR 3.78, 95%CI: 3.07 – 4.49, HR 4.17, 95%CI: 3.46 – 4.86). There was also an increased risk for non-cardiac mortality both prior to and after 2.5 years (HR 6.27, 95%CI: 6.11 – 6.58; HR 3.03, 95%CI: 2.60– 3.46)

AKA due to trauma or cancer, N=55: Those with an AKA had no significant increase in experiencing a cardiac event within 10 years or beyond 10 years relative to the controls (HR 1.30, 95%CI: 0.30 – 5.85; HR 1.60, 95%CI: 0.67– 3.80). Additionally, adjusted non-cardiac mortality risks did not appear to differ from the controls (HR 1.94, 95%CI: 0.54 – 6.91; HR 1.45, 95%CI: 0.72– 2.93).

AKA (Dysvascular and Trauma/Cancer) with prosthesis, N=72: Those receiving a prosthesis had almost an 80% reduction in risk of death (HR 0.23, 95%CI: 0.13 – 0.39). There was no difference in risk of experiencing a cardiac event for those with or without a prosthesis (HR 0.72, 95%CI: 0.52 – 1.11) particularly in the 5 years following an amputation . (Figure 1)

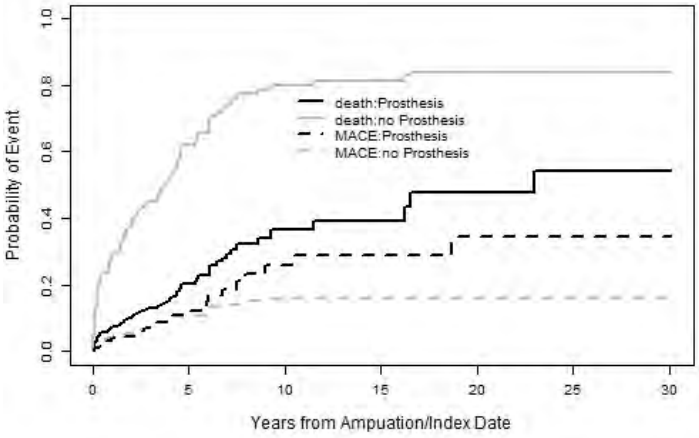

Figure 1. Predicted probabilities of experiencing a cardiac event or non-cardiac death for AKAs with and without a prosthesis

DISCUSSION

The high risk of initial mortality stemming from an amputation event may preclude many amputees from CVD progression. Etiology of the amputation is also an important factor: cardiac events appear to be more likely amongst patients with a dysvascular AKA. Providing a prosthesis does not appear to be associated with a reduced risk of a major cardiac event following amputation. The correlation between prosthesis receipt and reduced risk of death is likely due to the fact that one has to live for a certain length of time following an amputation to receive a prosthesis. This longitudinal population-based study of cardiac events in those with AKA compared to non-AKA controls compliments the findings of prior research looking at the military population [4].

REFERENCES

1. Kaptein S, G.J., Dijkstra PU, Disabil Rehabil, 2017. 27: p. 1-9..
2. Ma VY, C.L., Carruthers KJ., Arch Phys Med Rehabil., 95(5): p. 986-995, 2014.
3. Aulivola B, et al. Arch Surg., 139(4): p. 395-9, 2004
4. Naschitz JE, L.R., QJM.,101(4):p 251-9, 2008.
5. Wolkewitz M, et al. Critical Care. 12:R44, 2008

DISCLOSURE

The authors have no conflicts of interest to disclose.

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THE ROLE OF EXERCISE TESTING IN PROSTHETIC REHABILITATION: A SYSTEMATIC LITERATURE REVIEW

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INTRODUCTION

The topic of functional classification for individuals with amputation as it relates to prosthetic candidacy and component eligibility has recently become one of great debate. The current industry standard, the K-level, is defined by the CMS and limits prosthetic users to certain categories of components based on a number of criteria.[1] Since many private insurances and other payers typically align their policies with Medicare guidelines, this verbiage becomes crucial for the majority of amputees across the country seeking prosthetic rehabilitation.

The recent proposed changes to the verbiage in the Local Coverage Determination policy defining k-level criteria have brought it to the forefront of the prosthetic community's collective consciousness. The American Orthotics and Prosthetics Association recently funded a systematic review project to seek out alternative means of defining prosthetic candidacy. An outcome of this tasking was to create a clinical practice guideline to serve as a basis for determination of prosthetic candidacy.

One such alternative or augment to the current K-level system would be exercise testing. Exercise testing is a noninvasive procedure that provides diagnostic and prognostic information and evaluates an individual's capacity for dynamic exercise which has translation to ambulatory and functional capability.[2] The results of this testing have been reported in the amputee population, however the modalities used and extrapolation of the data varies greatly in the literature.[3] Before any type of clinical recommendation regarding the role of exercise testing in prosthetic rehabilitation can be made the contents of the literature must be aggregated and analyzed. The purpose of this systematic review was to aggregate and evaluate available literature regarding the use of exercise testing in the amputee population and to use those results to formulate a clinical practice guideline.

METHODS

Database searches of Medline, Cochrane, Web of Science, and Google Scholar were completed. Primary search terms included: "amputee, limb loss, prosthetic, exercise, stress, ergometer, cycle, and test." Articles were screened for inclusion by two independent reviewers using a set of predetermined inclusion/exclusion criteria. Articles were assessed for quality and scored using the United Kingdom National Service Framework for Long-Term Conditions tool.[4]

RESULTS

In total, 4,123 articles were identified in the search of which 26 were included. Of these, 12 works directly described exercise testing in the amputee population and 14 provided normative data for amputees which is used in the clinical practice guideline for benchmark development. Nineteen of the articles were scored as high, five as moderate and two as low, quality.

From these results, evidence statements were formulated and research evidence grades assigned. Statements with a grade of A or B were included in the practice guideline:

(1) Single-leg cycle ergometry is a valid and reliable assessment of pre-operative and post-operative cardiovascular function in those expecting imminent or with history of lower extremity amputation.
(2) Combined upper extremity and intact lower extremity ergometry is a valid assessment of post-operative cardiovascular function in individuals with history of lower extremity amputation.
(3) Upper extremity ergometry is a valid assessment of post-operative cardiovascular function in individuals with history of lower extremity amputation when other options are not feasible or available.
(4) Ability to sustain an exercise intensity of $\geq 50\% VO^2_{max}$ can be regarded as a guideline value for the level of fitness required to successful prosthetic ambulation in elderly amputees.
(5) Ability to balance on the intact limb should be considered for prosthetic prescription when exercise testing benchmarks are not or cannot be met.

A clinical practice guideline was formulated proposing exercise testing results as an alternative or adjunct to the K-level criteria for functional level determination. Benchmark values for VO^2_{max}, watt output, and oxygen consumption were established for use in the proposed guideline.

DISCUSSION

A systematic review and evaluation of literature regarding exercise testing in the amputee population was executed using a valid, international assessment tool. Results of the assessment were used to formulate a proposed clinical treatment guideline. The guideline was designed to be integrated into a larger set of guidelines for prosthetic rehabilitation and amputee care. If accepted and implemented, the proposed guideline could improve access prosthetics and higher level componentry for potential prosthetic users in the United States.

DISCLOSURE

The authors declare no conflicts of interest. The findings are those of the authors and do not constitute the opinions of the U.S. Department of Defense, Veterans Affairs, the University of South Florida, or Orthotics and Prosthetics Centers, Inc.

REFERENCES

1. Gailey et al. *Arch Phys Med Rehabil*. 2002; 83(5): 613-27.
2. Fletcher et al. Circulation. 2001; 104(14): 1694-1740.
3. Chin et al. Arch Phys Med Rehabil. 2006; 85: 992-6.
4. Sansam et al. J Rehabil Med. 2009; 41: 593-603.

VARIABLE RESISTANCE ORTHOTIC KNEE

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INTRODUCTION

As an enhancement to the Ottawalk-Speed hydraulic joint [1], which controls knee collapse by mechanically stopping flexion at a pre-set angular velocity, a modified Endolite Elan prosthetic ankle's hydraulic control value was integrated into the design to provide microprocessor controlled variable resistance. The resulting orthotic knee joint is low profile and enables safe mobility across multiple surfaces and activities. This new Ottawalk-Variable Speed (OWVS) design addresses size and modularity limitations of other microprocessor controlled stance control knee angle foot orthoses. This paper presents a novel 3D printed hydraulic control unit that takes advantage of new additive manufacturing capabilities.

Figure 1: OWVS mechanical components.

METHODS

A new OWVS prototype design takes advantage of additive manufacturing (3D printing) to reduce size and weight and accommodate new sensors for device control. Revised electronics accommodate the additional sensors, provide Bluetooth-based and on-board control for switching between resistance settings, and can incorporate more advanced sensor fusion models to enhance device control (i.e., better gait phase identification across multiple conditions).

Bench testing was performed to verify load bearing capabilities of the new microprocessor-controlled valve assembly. Testing was conducted on a Lloyds materials test machine (LR10K PLUS) using the following protocol:

- Hydraulic piston rod was attached to the machine load cell via the thread on the end of the piston rod
- Piston rod extended out of the hydraulic housing to provide 27mm between the housing and piston rod trunnion
- Hydraulic housing was supported by the machine's base
- The hydraulic resistance valve was set to the fully closed position to achieve the highest hydraulic resistance
- The test machine was set to run to load limit
- A 10N preload was applied
- The compression load was applied at a rate of 50N/s

Two trials were performed, with maximum loads of 1000 N or 4500 N. When applied to the OWVS joint, these loads related to 25 Nm knee moments for 1000 N and 100 Nm for 4500 N, at a 45 degree knee angle with the joint in a locked setting.

RESULTS

The load test results are displayed in Table 1. The load was ramped up to maximum and then sustained for 10 seconds. The assembly successfully resisted the loads without fluid leakage or mechanical failure.

Compression load limit (N)	Maximum Displacement (mm)
1000	2.03
4500	9.65

Table 1: Compression load test results.

DISCUSSION

The new control valve assembly for the Ottawalk-Variable Speed design was able to successfully resist high loads, and thereby large knee moments that could be experienced during a stumble during descent (i.e., large acceleration onto the SCKAFO). While maximum displacement was low at walking loads, piston rod displacement could be improved with better hydraulic fluid filling procedures that remove air from within the system and ensure complete filling of the assembly.

This new additive manufactured design resulted in a 14.7% lighter and 18.2% shorter device, with no increase in profile thickness. Smaller and lighter components are essential for improving end-user compliance with this class of orthosis.

The improved control valve assembly should enhance overall microprocessor controlled SCKAFO design, enabling variable resistance to allow people to safely negotiate different terrain types with a device that fits beneath the person's clothing.

REFERENCES

1. Lemaire ED, et al. *J Rehabil Res Dev*; 50(1), 43-52, 2013.

DISCLOSURE

Lemaire, Herbert-Copley, and Duke developed this version of the hydraulic orthotic joint. Duke is employed by The Blatchford Group.

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VIABILITY OF PRESCRIBING INCREASES IN PHYSICAL ACTIVITY IN LOWER LIMB AMPUTEES

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INTRODUCTION

Physical activity (PA) is known to have many positive effects on human health. Regular PA not only improves physical health, but also psychological and social health, which all are important factors in the amputee rehabilitation process[1]

Individuals with disabilities, including those with lower limb loss, generally display lower levels of daily activity than non-disabled peers, amassing in many cases less than about 5,000 steps per day. By a commonly used definition, a step count of less than 5,000 steps per day signifies the threshold to sedentary behavior, which is known to be detrimental to health including increased risk of chronic disease[2].

Recording daily step counts has recently increased in acceptance as a method of outcome assessment used by researchers and healthcare professionals, proving to be clinically relevant for the use of prescribing exercise and classifying activity levels [3]. Accordingly, intervention studies have been conducted with different populations, including people with lower limb loss [4], in an effort to investigate the effects of prescribed PA increases on a number of health outcomes.

The effectiveness of such interventions in clinical application depends on patients' compliance. The aim of this study was to investigate to what extent people with lower limb loss will adhere to the increases in PA as prescribed.

METHOD

Participants: Users of trans-tibial prostheses were recruited and assessed for willingness to participate in an increased step count intervention. They were excluded if their daily step counts, as recorded during the first week of the protocol was above 12,500.

Study Design: This pilot study was a secondary analysis of data recorded in a repeated measures design analyzing how increasing PA affects pain levels in prosthesis users.

Data Collection: Participants were provided with a pedometer and instructed to wear it for one week performing activities as normal. For the subsequent intervention week, participants were asked to increase their step counts by 60% over their individual average daily step count by meeting (or exceeding) a respective target number. They were able to track their progress using the display on their step counters.

Data Analysis: Individual step count data were quantified with regard to absolute and relative increases following the prescription. Effect sizes were calculated for the purpose of informing subsequent larger-scale studies. Secondary analyses included bivariate correlation between level of adherence to the prescription and factors such as initial PA level, age, and prosthesis experience.

RESULTS

Data of five subjects are presented here. Participants represented a wide range of demographics, including ages from 24 to 70 years, two male and three female, and a wide range of starting activity levels. Individual step count increases ranged between 1,253 and 1,866 (Figure 1). Relative

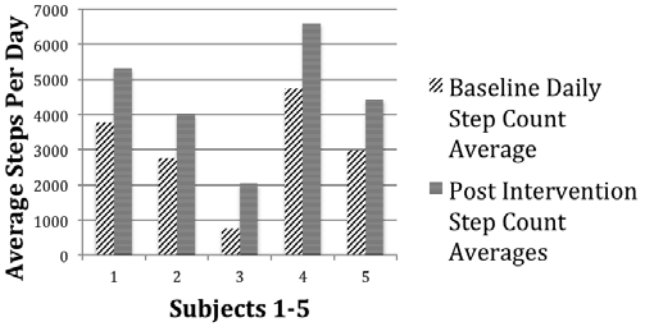

Figure 1: Increases in Average Step count from week one (baseline week) to week two (intervention week).

increases ranged from 39% to 166%, albeit in the latter case from a very low baseline. The mean relative increase across the sample was 68% with a Standard Deviation (SD) of 55%. Without the outlier at 166% increase, the mean was 44% (SD = 4.5%). Initial activity level and relative increase are slightly negatively correlated ($R^2 = 0.27$). Without the outlier, this correlation coefficient increased to $R^2 = 0.46$.

DISCUSSION

Our results indicate that step count increases of about 40% are feasibly attainable by users of trans-tibial prostheses. The majority of our sample did miss the prescribed rate of step count increase by about 1/3 of the target value. This was a fairly consistent finding, irrespective of the prescribed absolute increase (if one outlier is ignored). This may suggest that target step rate increases in future studies be exaggerated by that amount, in order to arrive at the desired outcomes. The observed slight trend that lower initial PA levels are correlated with better adherence to the prescribed intervention may be considered in that context as well.

While the small sample size of this study prohibits conclusive findings, the generated pilot data can be the basis for more extensive protocols in the future.

CONCLUSION

Prescribing PA increases may not be adhered to fully by people with lower limb prostheses, which should be considered when determining individual such prescriptions.

CLINICAL APPLICATIONS

This research can be used to begin the search for amputee-specific guidelines for PA in order to help improve physical, psychological, and social well-being.

REFERENCES

1. Da Silva, et al., Prosthet Orthot Int. 34 (4), 432-8. 2011.
2. Tudor-Locke, et al., Int J Behav Nutr Phys Act. 8, 80. 2011.
3. Tudor-Locke, et al., Med Sci Spo Exerc, 40, 537-43. 2008.
4. Heskett, et al., Proc. of the AAOP Annual Meeting, 2017

Which Functional Elements Stabilize the Residual Limb within Transfemoral Sockets in both Frontal and Sagittal Plane for Optimized Prosthetic Gait?

INTRODUCION

Different prosthetic socket techniques are available for the treatment of transfemoral amputees. Within this context, ischium containment sockets differ from other techniques in shape and functionality (1,2,3). The main difference is to be found in the proximal functional area that is responsible in different proportions for the force transmission between the residual limb and bony pelvis structures. Socket techniques without force transmission in the pelvic region are available as well (subischial sockets). Controversial opinions exist regarding the amount of load transfer and the importance of the proximal socket elements to stabilize the residual limb within the socket.

Within the scope of this biomechanical study, a study design has been developed to investigate force transmission principles by main functional elements of a transfemoral prosthetic socket. The study aims at further increasing the understanding of force transmission between residual limb and prosthetic socket in specific functional elements of the proximal socket portion.

METHODS

The sockets were segmented according to the main four functional elements (area of ischium containment, lateral wall, anterior wall, volume and control area) and implemented in a CFK frame to record the forces in these areas. Load sensors between frame and socket elements recorded three forces and their centres of pressure within a Cartesian coordinate system. The data were transferred via a mobile wireless LAN system to a central PC and triggered synchronically to a stationary gait analysis system (Kistler, Vicon).

Three different socket techniques (CAT-CAM, MAS, subischial socket) were measured each with 6 transfemoral amputees in the following situations: level walking and descending stairs and ramps. The sockets were installed on an identical prosthetic knee joint and foot type with the same patient individual prosthetic alignment.

RESULTS

The results suggest that the force transmission principles within the four main socket areas do not differ significantly between a CAT-CAM and MAS socket during different gait situations. With the ischium or ramus containment socket types, a significant degree of axial force is transferred by the medially located containment area. Furthermore, the data indicate that significant forces are acting in anterior-posterior and medio-lateral directions onto the containment elements as well. With the subischial socket that does not contact the pelvis, significant differences can be identified regarding the stabilization effects between residual limb and socket compared to both containment sockets. This is caused by the different positions of the total forces running through the entire sockets and the locally acting forces in the volume and control areas which is shaped more or less identically in all three socket techniques. Additionally reduced hip moments in the subischial socket indicate a reduced potential to transfer load when walking up the ramp. Less upper body side movement during stance phase of the prosthetic side can be identified when using an ischium or ramus containment socket.

DISCUSSION

In the literature, the force transmission between residual limb and the main functional areas of transfemoral sockets have been discussed exclusively based on theoretical models and fitting experiences (1,2,3). The method described in this comparative study allows objectifying which socket areas are involved in force transmission to what extent.

Based on these data it becomes obvious that the containment areas and the anterior walls are of high importance to stabilize the stump within the socket in both frontal and sagittal plane. The containment area also reduces the axial load on the volume and control area.

These biomechanical findings are represented by the forces acting in the four main functional socket elements, external sagittal hip moments measured during walking up a ramp and the upper body motion in the frontal plane.

REFERENCES

1. Sabolich J. *Clin Prosthet Orthot* 1985;9:15-26.
2

WHY DO AMPUTEES PREFER ENERGY STORAGE AND RETURN FEET? CLUES FROM THE ANALYSIS OF STEP LENGTH ASYMMETRY AND MARGIN OF STABILITY

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INTRODUCTION

Energy storing and return (ESAR) prosthetic feet have long been prescribed to reduce the energy cost of walking. Increasing evidence, however, exists that energy cost is only marginally effected by ESAR feet [1]. The question why amputees do largely prefer ESAR feet, therefore, remain largely unexplained from the biomechanical standpoint. Clearly, the question is not merely academic, because a better understanding of the underlying reasons can help classifying the multitude of existing prosthetic feet in a more rational way, and hence improve product selection [2].

Likely other benefits exist. Two potential advantages might be found in a positive effect of ESAR feet on gait symmetry and gait stability. Previously Hak et al (2014) [3] demonstrated that a reduced push off with the prosthetic foot could result in reduced back margins of stability and hence a larger risk of disturbed progression during walking. Amputees seem to reduce this risk by shortening step length of the intact leg, resulting in a functional step length *asymmetry* in the gait pattern.

We hypothesize that an ESAR foot might enhance push off power and enhance the backward margin of stability allowing a more stable and symmetrical gait pattern, when compared to a SACH foot in transtibial amputees.

METHODS

15 participants with a unilateral, traumatic, transtibial amputation were included in this study. All subjects were experienced with walking with their ESAR foot, which was a Variflex (Ossur) for all subjects. Participants firstly walked in the gait laboratory with their ESAR foot. Then they were fit with a SACH foot that was aligned by an experienced prosthetist. After using the SACH for 24 hours, they returned to the gait laboratory for the second test. All gait trials were performed at a speed of 1.2 m/s. An optoelectronic motion analysis system (Vicon, Oxford United Kingdom) and a set of two force plates (Kistler; Winterthur, Switzerland) were used to record gait kinematics and kinetics from which ankle push off work, step length and center of mass velocity (vcom) could be derived [4]. Backward margin of stability (MoS_{BW}) was calculated according to [3]. The MoS_{BW} represents the predicted position of the centre of mass relative to the base of support after toe off. A positive value indicates that the center of mass will pass the base of support during single support, hence progression is preserved and a backward fall is prevented.

RESULTS

With the ESAR foot participants generated more push off work at the ankle (0.11 ± 0.03 J kg−1) than with the SACH foot (0.05 ± 0.02 J kg−1, $p < 0.001$). This coincided with an increase in center of mass velocity and a reduction in step length asymmetry. Intact step length was 0.05 ± 0.04 smaller than prosthetic step length with SACH and only 0.01 ± 0.04 m smaller with ESAR foot ($p<0.05$). The reduction of step length asymmetry was reached while backward margin of stability was preserved (Fig 1).

CONCLUSION

The ESAR foot enhances ankle push off power, thereby increasing center of mass velocity in double support. This allows to walk with a more symmetric step length without reducing backward margin of stability.

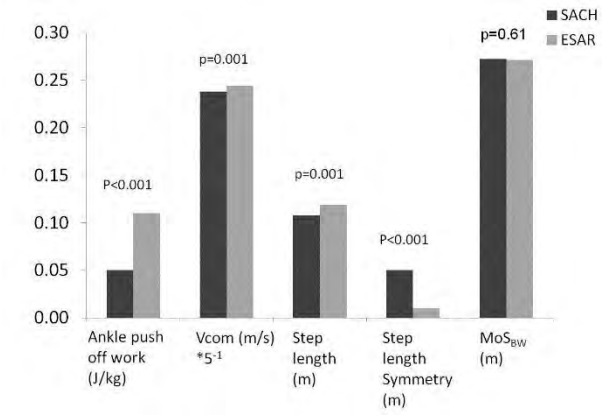

Figure 1. Differences in gait parameters between walking with a SACH (dark bars) and an ESAR (light bars) foot

SIGNIFICANCE

This effect of the ESAR foot on gait stability and asymmetry might explain the preference of lower limb amputees to use ESAR feet despite their limited benefits on gait economy.

REFERENCES

1. Hofstad C et al, Cochrane Database Syst Rev, 2004, (1):CD003978
2. Hafner et al, Clin Biomech, 2002, 17(5):325-44
3. Hak L et al. Phys Ther.2014, 94(10):1480-8.
4. Wezenberg D, et al. JRRD. 2014, 51(10), 1579-1590.

DISCLOURE

None.

A biomechanical comparison of an ESAR foot, a tradition heel height foot and a new heel height foot

Findings of a case study with 2 users

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INTRODUCTION

This abstract presents results from a pilot study on a new heel height adjustable prosthetic foot. The new foot is compared to an ESAR foot [Pro-Flex LP] and a foot that is heel height adjustable [Elation]. The results show improvement over Elation and resemblance with the Pro-Flex LP. The increased dynamics of this new heel height adjustable foot show that dynamics do not need to be compromised in a heel height adjustable prosthesis.

METHODS

This pilot study was performed with two unilateral female amputees. The testing was split into two sessions, where initially users were aligned by qualified CPOs with all 3 prosthetic feet and acclimation time of 10-30 minutes was allowed for. In second session kinematic and kinetic data was collected with a 3D motion capture system (Vicon Motion Systems Ltd., UK). Users walked a 10m walkway with two embedded force plates (Kistler, Switzerland) at self-selected walking speed 10 times during which data was collected by the Vicon system. Kinematic data was collected during level walking. Data was processed in Nexus (Vicon Motion Systems LTd.) using the traditional inverse dynamic (ID)[1] method data was analysed.
Subjects weight was 45kg and 76kg, ages 41 and 46. Both subjects were K3 trans-femoral amputees (one using Total Knee 2100(Össur), other Rheo Knee XC (Össur)). The results present trends and indications.

RESULTS

The most interesting results in this pilot study were the ankle range of motion (ROM), and peak ankle power during pre-swing.

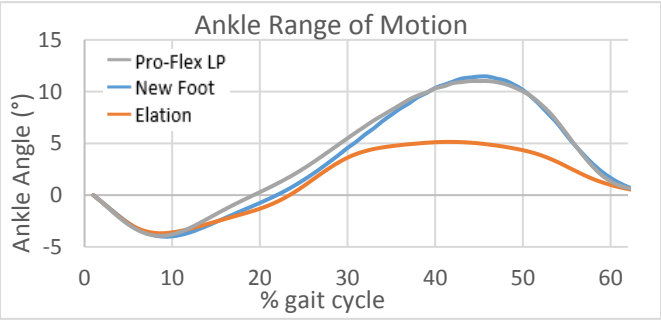

Figure1. Ankle Range of Motion Prosthetic Side – average of one user

The ankle ROM (figure 1) for the Pro-Flex LP and new foot was similar, both in terms of plantar flexion (PF) and dorsiflexion (DF). Elation had less ROM in the ankle for both users. Interestingly Elation mainly has less DF when compared with the other two feet.

The lower DF in Elation is visible as well in the lower peak ankle power at pre swing (figure2).

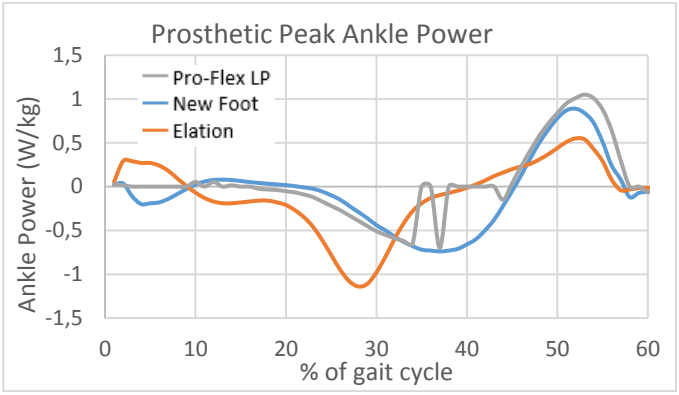

Figure2. Ankle Power Prosthetic Side – average of one user

CONCLUSION

This pilot study indicates that the new foot improves the functionality of heel height adjustable feet from Elation to Pro-Flex LP. Main changes are the increased range in dorsiflexion and ankle power.
This pilot based on two users will need to be performed with more users to attain more conclusive data. Never the less the improvements seen with the two users above are exciting for the new foot. Also interesting would be to perform a study where measured would be how the Elation and the new foot perform in different heel heights.

REFERENCE

[1] Guillaume et al.; 2006, Journal of Biomechanics

DISCLOSURE

J.A. Nijman is a full time employee of Össur ehf and this research was conducted as a part of his employment

A PILOT INVESTIGATION OF THE SOCKET STRENGTH OF 3D PRINTED SOCKETS

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PURPOSE

As 3D printing gains exposure, patients are beginning to ask if 3D printing technology is right for them. As Prosthetists, we use several manufacturing method to provide our patients with safe, reliable treatments. However, currently there is no clinical standard for evaluating the strength of sockets. We applied the ISO 10328 Structural testing of Lower Limb Prostheses standard to evaluate the static socket strengths of transtibial sockets made using conventional and 3D printing technologies[1].

METHODS

Building on previous studies on conventional sockets, we first evaluated socket attachment strength, applying the ISO standard for static testing using two conditions (the instant of maximum loading occurring at early and late stance phases of walking), for three different loading levels (weight > 60 kg, > 80 kg and > 100 kg), for two types of total surface bearing sockets (cushion and locking) and three fabrication materials (Thermoplastic, laminated composites and 3D printed PLA) [1,2]. Twelve identical sockets were fabricated out of each material – six attached to a 5R1 block and six to a Fillauer's Cylindrical Lock - and were attached to an Ottobock pyramid, pylon and tube clamp. A plaster mold was converted to a 3D print file using a Vorum Spectra Scanner and Additive O&P. Testing was done using a custom made jig within a Tinius Olsen Universal Machine, with a urethane limb providing load proximally. All setups went through a proof test and an ultimate strength test, before applying force to failure (visible deformation/yielding occurred).

RESULTS

Materials were compared based on ultimate strength, strength-to-weight ratios and failure modes. All sockets setups of same type and material could withstand higher forces at early stance than late stance. All sockets made for cushion liners passed the ISO standards. For forces applied at early stance, laminated sockets withstood 12-13,000 N before cracking up the posterior wall, thermoplastic sockets withstood 11-12,000 N before yielding and the 3D printed sockets withstood 5-7,000 N before cracking circumferentially. For forces applied at late stance, 8/9 pylons broke before any of the sockets were affected. For those with distal locks, all passed the standards for maximum loading at early stance. However none of these setups passed the standard for terminal stance – the thermoplastic sockets yielded around the lock, the locks mechanisms broke in the laminated sockets, and the 3D printed sockets broke circumferentially around the lock.

CONCLUSION

This study demonstrates a successful protocol while highlighting concerns about components breaking below the standard. It provides initial evidence of 3D printed sockets being appropriate for use with cushion liners, but raises concerns of using thermoplastic or 3D printed sockets with distal locks. Also, while conventional sockets yield or crack, 3D printed sockets break catastrophically. Future studies must address if various techniques can alter breaking methods and provide patients with higher safety.

SIGNIFICANCE

This study is one of the first evaluations of the strength of 3D printed sockets and their appropriateness in the field of prosthetics. It is critical that we evaluate the strength of the sockets before putting them on our patients. From here, we can delve deeper into the evaluation of these sockets.

REFERENCES

1. ISO10328:2006(E) Prosthetics — Structural testing of Lower Limb Prostheses — Requirements and Test Methods, Geneva Switzerland, 2006.
2. Graebner RH & Current TA. *J Prosthet Orthot; 19, 67-74, 2007.*

ACKNOWLEDGEMENTS

Thank you to David Moe for ongoing support, Barber Prosthetics Clinic for providing funding and expertise, and BCIT for the use of the testing machines. Thank you to Additive O&P for the 3D printed socket design and OttoBock and OrtoPed for materials and componentry.

Additive Manufacturing and Changing Body Images in the Prosthetics Industry

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Introduction

This paper argues that the introduction of 3D printing to the field of prosthetics entails more than a new production technology. As historical accounts of the industrialization of prosthetics suggest[1], new modes of manufacturing are tied to changes in the cultural body images the field is organized around. The paper employs a sociological perspective to map these changes for the current digitalization of the industry. Drawing on preliminary data from Germany and the US, it points out existing tensions, along which such changes are likely to occur. The findings are organized along three lines: (1) mass production, customization, mass customization, (2) patient, customer, prosumer, (3) disability, normality, enhancement.

Methods

The data was produced through an array of qualitative methods. These include interviews, group discussions, ethnographic observation and document analysis as well as participatory methods like makeathons (figure 1). Data analysis followed an iterative approach, in which theory and empirical findings continuously shaped each other. Particular attention was given to discussing preliminary results with selected practitioners from the fields of prosthetics and additive manufacturing, to ensure plausibility and inform further lines of inquiry.

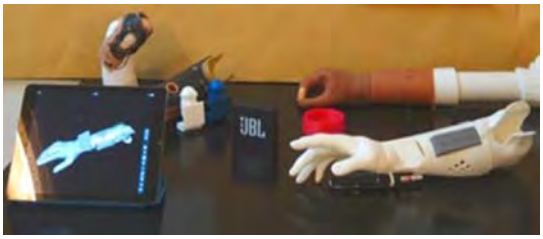

Fig.1. Results of Makeathon in Munich, Germany

Results

In contrast to conservative views held by many practitioners in the field, additive manufacturing does have the potential to lead to a significant reorganization of the field. Changes begin to cluster around three prevalent tensions. First, the tension between industrially produced standardized components and hand crafted customized components might be upset by digitally enabled mass customization. This leads to changes in which markets are considered profitable and which people are served. Second, the tension between views of people as patients to be healed and customers to sell products to results in structural underserving of certain groups. These might leverage online based open source communities and decentralized production to produce their own devices. Third, the traditional idea of normalizing disabled bodies, so deeply ingrained in the field of prosthetics, is called into question by external players drawing on cultural imaginaries of enhanced bodies as epitomized in the figures of cyborgs or superheroes.

Conclusion

The paper concludes by cautioning against simplistic technological determinism. The introduction of new technologies such as 3D printing does not lead to any of the changes suggested above in an off itself. Rather, if such transformations will occur and what shape they might take hinges on the way new technologies are designed, disseminated and adopted. A sociological perspective draws attention to the importance of cultural and regulatory contexts, as well as the central role of people in shaping the impact of new technologies. Hence, the paper ends by advising all stakeholders to consider their agency in the matter, instead of falling back to overly optimistic or pessimistic versions of technological determinism.

Significance

Additive manufacturing has been a topic of much debate within the field of prosthetics and orthotics. This paper fills a gap by systematizing different trends in different sections of the industry. Its sociological perspective enables a more holistic view of the impact of additive manufacturing on prosthetics and sets it apart from purely technical considerations of the problem.

References

1: Herschbach, Lisa (1997): Prosthetic Reconstructions. Making the Industry, Re-Making the Body, Modelling the Nation.

ARE ALL FEMURS CREATED EQUAL? THE BASIS FOR FEMORAL COMPONENT DESIGN OF THE OSSEOINTEGRATION IMPLANT

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INTRODUCTION

Osseointegration is a comparatively new technology that allows direct skeletal attachment of a prosthesis to a transfemoral or transtibial amputation. Between November 2010 and December 2016 198 patients with transfemoral amputation were fitted with the Osseointegration device by a single Australian surgeon. Several design iterations evolved during these years due to the realization that biologic fixation of the implant requires primary stability by optimum fit in the entire femur. The shape of the femoral canal is much more variable, in fact, than most contemporary designs of the femoral components would suggest or can accommodate. The anatomy of the femur must be known precisely in order to accommodate all of these variations.

METHODS

All 197 patients underwent a 3D CT scan of the operative femur. Measurements were collected for all patients: bow angle, femoral length from tip of greater trochanter to the distal end of the femur and from the lesser trochanter to the distal end of the femur. Measurements of the canal diameter at the lesser trochanter, middle of the residual femur and the distal femur.

RESULTS

The average canal diameter varied 5.5mm at the level of the lesser trochanter and 2.9mm at the middle of the femur. The average bow angel varied 2.0 degrees. There was also a large variation in canal diameter and bow angle between the male and female patients.

DISCUSSION

This study indicates that a single implant design is unsuitable for all transfemoral amputees. Furthermore, patients diagnosed with osteoporosis may need additional fixation into the femoral head. Those patients with a long residual femur will need to have a long implant with a bow to match the bow of the femur. More accommodating designs will be required that will enable proximal and distal fitting of the prosthesis in the femoral canal.

REFERENCES:

1. The morphology of the proximal femur. A three-dimensional radiographic analysis.
2. Rubin PJ, Leyvraz PF, Aubaniac JN. J Bone Joint Surg Br 1992 Jan; 74(1): 28-32.
3. The anatomic basis of femoral component design. Nobel PC, Alexander JW, Lindahl LJ, Yew DT, Granberry WM, Tullos HS. Clin Orthop Relat Res 1998 Oct; (235): 148-65
4. Anthropometric measurements of the human distal femur: a study of the adult Malay population. Hussain F, Abdul Kadir MR, Julkifly AH, Sa'at A, Hossain G. Biomed Res Int 2013
5. Anthropometric measurements to design best-fit femoral stem for the Indian population. Rawai BR, Ribeiro R, Bhatnagar N. Indian J Orthop 2012 Jan-Feb; 46 (1): 46-53.

DISCLOSURES:

Dr. Al Muderis consults for and receives royalties from companies including: Osseointegration International Pty Ltd (Australia), Osseo-PL Inc (USA), Osseo-PL GmbH (Germany), AQ Implants GmbH (Germany) and Permedica S.P.A (Italy).

BACK PAIN AND SPINE OSTEOARTHRITIS IN ADULTS WITH ABOVE KNEE AMPUTATIONS

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INTRODUCTION

Low back pain (LBP) affects 50-80% of those who undergo lower extremity amputation[1-3] compared to an estimated 27.5% of the adult U.S. population[4] and can have a greater impact on quality of life than phantom limb pain.[1] Risk factors for LBP unique to amputees include altered gait mechanics , postural changes , poor prosthetic fit, amputation level, multiple comorbidities, and presence of phantom or residual limb pain.[5,6]

Osteoarthritis (OA) is the leading cause of disability, most common indication for joint replacement, and is among the top five causes for both hospitalizations and outpatient visits in the U.S[7,8]. There is an increased prevalence of symptomatic hip and knee OA amongst elderly traumatic amputees.[9] To our knowledge, no studies have specifically evaluated spine OA in a population over an extended period of time. The purpose of this study was to evaluate both the prevalence of LBP and time to development of spine OA in adults with above knee amputation (AKA) compared to matched individuals without AKA in order to identify a potential cause for increased healthcare utilization amongst the AKA population. We also evaluated effect of prosthesis use on development of OA.

METHODS

Study Population and Cost Data: 162 individuals with AKA residing in Olmsted County, MN, between 1987 and 2013 were identified using resources available through the Rochester Epidemiology Project. They were matched (1:10 ratio) with non-AKA adults on age, sex, and duration of residency in Olmsted County. Diagnoses of spine OA and the symptom of back pain were identified using Berkson, Hicda, and ICD-9/10 diagnostic codes. Use of prosthesis was obtained through review of medical records.

Data Analysis: A competing risk Cox regression model was used to evaluate time to development of OA due to the high mortality rates among amputees. LBP prevalence was analyzed descriptively. The amputees were divided into two cohorts by etiology, dysvascular disease vs. trauma/cancer, for analysis of OA and mortality. Effect of prosthesis was evaluated amongst all individuals with AKA, not divided by etiology.

RESULTS

Dysvascular AKA, N=107: Risk of OA significantly increased with age (HR 1.03 ± 0.004; p< 0.001), insignificantly increased with AKA within 2.5 years of index date (date of amputation) (HR 1.07 ± 0.47, p=0.877) and decreased after 2.5 years (HR 0.908 ± 0.39, p= .804). There was significantly increased risk of death with AKA at and after 2.5 years of index date (HR 5.03 ± 0.16; p <0.001; HR 1.89 ± 0.20, p=0.0012 respectively).

AKA due to trauma or cancer, N=55: Risk of OA significantly increased with age (HR 1.03 ± 0.005; p< 0.001), insignificantly increased with AKA within 10 years of index date (HR 1.29 ± 0.38, p=0.4927) and decreased after 10 years (HR 0.44 ± 0.72, p= .257). There was significantly increased risk of death at 10 years of index date (HR 2.46 ± 0.32; p =0.005;) but insignificantly increased risk after 10 years HR 2.38 ± 0.62, p=0.1606). 11% of dysvascular AKA had OA and 6.5% had back pain without OA compared to 24% of controls with OA and 17% with back pain without OA.

AKA (Dysvascular and Trauma/Cancer) with prosthesis, N=72:
All amputees that survive five years after amputation and that have a prosthesis were significantly more likely to develop spine OA, (HR 9.47 ± 1.06, p = 0.033).

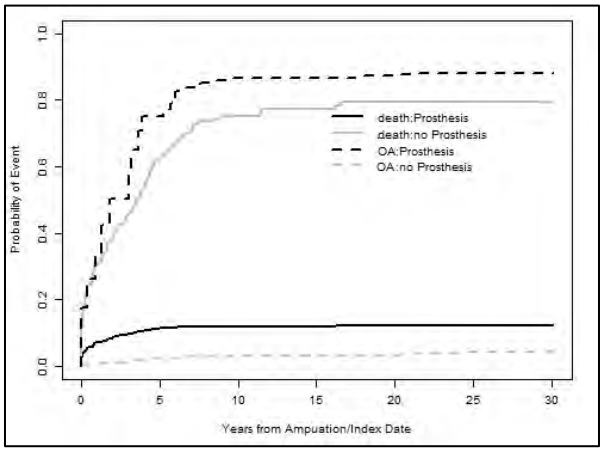

Figure 1: Effect of prosthesis on OA development amongst individuals with AKA, all etiologies combined

DISCUSSION

This unique, population-based study suggests that the early high risk of mortality amongst AKA patients precludes development of a multifactorial degenerative disease that is most common amongst the elderly. However, it is likely that gait and posture abnormalities secondary to prosthesis use contribute to development of OA in surviving amputees with prostheses.

DISCLOSURE

The authors have no conflicts of interest to disclose.

ACKNOWLEDGMENTS

Partial funding provided by the American Orthotic and Prosthetic Association. This study also used resources from the Rochester Epidemiology Project (NIH AG034676).

REFERENCES

1. Smith, D.G. et al. *Clin Orthop Relat Res.*, 1999(361): p. 29-38.
2. Kulkarni, J. et al. *Clin Rehabil.*, 2005. 19(1): p. 81-6.
3. Friel, K. et al. *Journal of Rehabilitation Research and Development,* 2005. 42(2): p. 155-166.
4. *Severe headache or migraine, low back pain, and neck pain among adults aged 18 and over, by selected characteristics: United States, selected years 1997–2012.*, CDC/NCHS, National Health Interview Survey: Atlanta, GA.
5. Morgenroth, D.C. et al. *Am J Phys Med Rehabil*., 2010. 89(8): p. 635-43.
6. Devan, H. et al. *PM R*, 2017. 15(17): p. 30175-2.
7. *National Ambulatory Medical Care Survey: 2013 State and National Summary Tables* 2013, U.S. Department of Health and Human Services ·
8. CDC, 2015. *Chronic Diseases: The Leading Causes of Death and Disability in the United States*. U.S. Department of Health and Human Services
9. Norvell, D.C. et al. *Archives of PM&R*, 2005. 86(3): p. 487-493.

Title: Brain Computer Interface Control of a Prosthetic Knee in Trans Femoral Amputee

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Objective: The purpose of this study was to establish the feasibility of manipulating a prosthetic knee with a brain-computer interface (BCI) system in a transfemoral amputee.

Design: A transfemoral amputee subject was trained to activate a knee-unlocking switch through mental imaging of the movement of his lower extremity. Surface scalp electrodes transmitted brain wave data to a software program that was keyed to activate the switch when the event-related desynchronization (ERD) in electroencephalography (EEG) reached a certain threshold. After achieving more than 90 percent reliability for switch activation, the subject then progressed to activating the knee-unlocking switch on a prosthesis that turned on a motor and unlocked a prosthetic knee.

Setting: The project took place in the prosthetic department of Veterans Administration hospital.

Patient: The study consisted of a single subject with a transfemoral amputation with adequate cognition and physical capacity to engage in the study.

Methods: The subject walked up and down parallel bars and unlocked the knee for swing phase and for sitting down.

Main Outcome Measurements: The success of knee unlocking through this system was measured. Additionally the subject filled out a questionnaire on his experiences.

Challenging Everyday Gait Situations Performed with Various Microprocessor-Controlled Prosthetic Knee Joints: do their Safety Potentials Differ?

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INTRODUCION

Microprocessor-controlled knee joints can offer significant biomechanical advantages [1,2,3] in many everyday situations. However, there are considerable differences in the knee joint function performances. The reason can be found in the different concepts for control of motion resistance. Besides good stance and swing phase control strategies for walking on level ground with a nearly natural gait pattern [1,2], the joint characteristics regarding safety levels to prevent an uncontrolled knee flexion under load are of the highest importance. Only reliable and sophisticated control concepts allow the user to safely walk on various surfaces. This includes situations like alternating walking on stairs and ramps. There are also significant differences in the safety potential of joints to prevent falls after stumbling [2].

METHODS

Three prosthetic knee joints (A, B, C) with different microprocessor-controlled concepts for resistance generation for flexion and extension movements were biomechanically investigated with seven transfemoral amputees (MG 3-4). Kinetic and kinematic measurements were taken during walking with small steps, walking backwards, walking up and down a ramp (10°), alternating walking down stairs [2] as well as a test scenario for detecting safety potential after stumbling during the prosthetic side swing phase [1]. Measurement technology consisted of two force plates (Kistler,9287A, CH) connected to an optoelectronic 12 camera system (Vicon, Nexus, GB).

RESULTS

Switching from a high to a low flexion resistance during walking with small steps takes place with B in approx. 99%, with A in approx. 83% and with C in approx. 75% of all recorded steps. Maximum knee flexion angle during swing phase when walking with small steps and walking up or down a ramp with A is increased by 6-7%. A high initial yielding resistance with B makes it more difficult to initiate yielding movement when walking down stairs and ramps. In the same situation the increase of the external sagittal moment with A is the highest. Also the maximum value of this moment is highest with A (A: 1,05 Nm/kg, C: 0,90 Nm/kg, B: 0,76 Nm/kg). Reaching the extension stop at the end of swing phase when walking down stairs is continuously achieved with A. B and C partially stay in a non-reproducible and varying flexed position of 3° (B) or 4° (C). Only with A a non-switching to the low swing phase flexion resistance could be observed, with C sporadically under prosthetic load and with B during walking backwards on the prosthetic side. With B this led to occasional falls. Stepping on a flexed prosthesis after external triggered tripping of the prosthetic side foot leads with B from a knee flexion angle >30° to falls; with C of 40°. However, with knee flexion up to 50° no fall was observed with A.

DISCUSSION

The tests performed in this study design that emulate daily gait situations demonstrate safety relevant difference between the knee joint concepts investigated. Swing phase characteristics that lead to higher ground clearance and to exact foot positioning are of high importance. This is critical especially when walking down stairs as safe foot positioning can only be achieved after reaching reliable and reproducible extension stop. Also load bearing capacity, created by internal flexion resistances, is higher with A when walking down stairs and ramps due to stronger resistance progression. With B an initial high flexion resistance delays the initial flexion phase of the joint which should happen quite rapidly. With B the load bearing capacity is comparably low with increased flexion. Loading of the flexed prosthesis after simulated snagging the foot on the floor does not directly lead to a fall with A even with a large flexion angle. With B and C however falls were registered with smaller flexion angles. This indicates a significant higher load bearing capacity of A. The default-swing concept of B apparently shows advantages when walking with small steps, but appears to be safety-critical when walking backwards. Therefore the overall safety potential for avoiding a fall seems distinctly higher with A as with B and C.

REFERENCES

1. Highsmith M. J. et al. Technol Innov 2014;15:369-375.
2. Bellmann M. et al. Arch Phys Med Rehab 2012;93:541-549.
3. Thiele J. et al. J Biomed Tech 2014;59:65-77.

DISCLOSURE

All authors are fulltime employees of Otto Bock.

Clinical Trials of newly designed AORI Foot Abduction Brace and its comparison with Dennis Brown Splint

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INTRODUCTION OR PURPOSE

Clubfoot is the most common congenital deformity in babies. 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, plantigrade foot with good mobility and without surgery. The management/treatment of idiopathic congenital clubfoot is serial gentle manipulations to stretch the contractures of the ankle, after serial casting, splinting, or strapping is started to maintain the correction.

Now a days Ponseti technique is common practicing technique followed by the effective orthotic intervention (bracing schedule). The Ponseti method is safe and effective treatment for congenital idiopathic clubfoot, and radically decreases the need for extensive corrective surgery.

METHODS

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 whereas 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 4 years study from 1st April 2011 to 30 March 2015.

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 21% 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.

CONCLUSION

AORI foot abduction brace is light in weight and having dynamic effects for Dorsi-flexion while D.B splint is relatively heavy and was poor to maintain Dorsi-flexion at ankle joint, which ultimately leads to the relapse of the abduction and then equinus. There is chance of skin damage in AORI FAB if not properly fitted especially on heel part. Superficial skin damage (bruise etc) were noticed in most of the patients using DB Splint. In AORI FAB too much tightening of Velcro straps may cause the edema of the distal part of the foot. Our clinical trials of the AORI FAB shows very good results in maintenance of the corrected C.T.E.V as Marcunde described in Ponseti Management manual that relapse occurs in more than 80% of cases, where relapse occurs only 6% in compliant families and there is more family compliance of AORI FAB at low cost.

SIGNIFICANCE

The designed involves no leather work and provides fixed dorsiflexion and abduction as per requirement. The material of the brace is recyclable (Polypropylene) and can be fabricated at industrial level and is easy to assemble in few minutes. On the other hand it very be very cost effective and light in weight. Picture is given bellow as figure 1.

REFERENCES

1.Pryor GA, Villar RN, Ronen A, Scott PM. Seasonal variation in the incidence of congenital talipes equinovarus. JBJS 1991 73B (4): 632-634

2.Falks S, Luther B. Changing paradigm for the treatment of clubfoot. Orthopaedic Nursing 2005 24(1): 25-30.

3.Ponseti IV. Treatment of congenital clubfoot: Current concepts review. J Bone Joint Surg Am.1992;74:448–54.

Herzenberg JE, Radler C, Bor N. Ponseti versus kite methods of casting for idiopathic clubfoot. J Pediatr Orthop. 2002;22:517–21.

DISCLOSURE

Short sampled, non-randomized clinical trials. There is industry related issue involved.

ACKNOWLEDGMENTS

Thanks to My dear fellow Rehan Ali Malik for his kind support and help in fabrication of the device.

Figure 1. AORI Foot Abduction Brace.

CORRELATING CLOSURE TIGHTNESS TO SUSPENSION WITH AN ADJUSTABLE SOCKET

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INTRODUCTION

Adjustable socket are becoming more prevalent. Case studies have shown to improve clinical outcomes.[1,2] Yet there are few rigorous studies generated from a biomechanical gate lab. This study aims at understanding fundamental of adjustable sockets.

METHODS

A test subject performed various gait tests on a six-axis, treadmill and stairs. Both setups had embedded force plates. An infrared reflective motion capturing system was used to track the subject during the tests. The subject was a transfemoral amputee and wearing an Infinite Socket. He performed the test with tightness settings of self-selected, loose, and tight. For the loose and tight sets the closure system was set to 12 mm less and more than the self-selected setting respectively. The speed of the treadmill was 1.7 miles per hour. This speed was self-selected speed as a normal walking rate.

RESULTS

The appropriate markers were selected to observe the relative movement between the body and the socket. The distance between these two marker was calculated from the magnitude of the connecting vector. Using the self-selected tightness setting as a baseline, the loose setting displayed a greater amount of movement with respect to the body (pistoning), while the tight setting displayed a reduced amount of movement.

Markers on the body were used to evaluate the lateral body movement. The magnitude of the lateral movement was correlated to the tightness of the closure system.

The histogram below shows the distance between marker located on the trochanter (body) and the lateral strut (socket). The lower and upper peak of the bimodal distribution represents the stance and swing phase respectively.

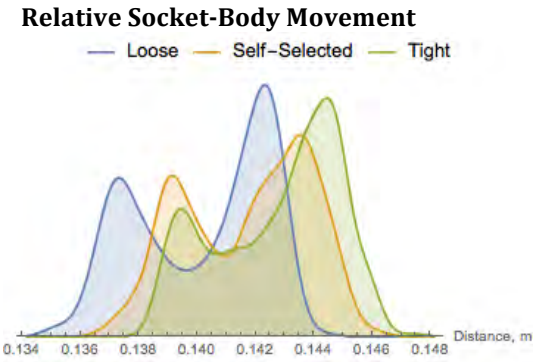

Figure 1. Histogram of the distance between the markers placed on the trochanter and the lateral socket strut.

DISCUSSION

The level of tightness on the closure system had multiple effects on how the patient interacted with the socket. The tightness effected how deep the patient sank into the socket. Also, the standard deviation of the data was greatest for the loose socket and least for the tight socket. This shows that there was the most relative movement between the body and socket when the socket was loose, and least amount of movement when the socket was tight. Last the lateral movement of the socket was correlated to the socket tightness. The presentation will discuss these results and more in greater detail.

REFERENCES

[1] Mitton K, et al. *Prosthet Orthot Int;* 2016.
[2] Kahle JT, et al. *Technol Innov*. 18, 175-183, 2016.

DISCLOSURE

The authors Williams, Das, and Hurley are employees of LIM Innovations.

ACKNOWLEDGEMENTS

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Differential function of mechanical prosthetic knees: An overview based on technical and biomechanical considerations.

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INTRODUCTION

The selection of mechanical, non-MP controlled prosthetic knees (NMPK) for an individual is primarily based on the prosthetist´s experience and/or insurance coverage of the patient, but not substantiated by clinical evidence (1). Therefore, this paper aims at finding more objective criteria for the selection of mechanical prosthetic knees.

METHOD

A search of the scientific literature was performed in the Medline, CINAHL, OTseeker, and PEDro databases as well as in the online library of the Journal of Prosthetics & Orthotics. Search terms were related to mechanical prosthetic knees. In addition, English and German language prosthetic textbooks as well as the personal library of the author were reviewed.

RESULTS

Most of the references found were primarily technical and/or biomechanical. Many classifications of NMPKs did not prove useful to guide selection of a knee type for an individual patient. A systematic review of studies with NMPKs was unable to give any useful guidance for knee selection either (2). A German language publication suggested a classification of knees based on their ability to allow for flexion during weight-bearing (3). Knees have been classified to allow for no knee flexion (locked knees, friction brake [safety] knees, 4-bar knees), limited knee flexion (multiaxial knees with >5 axes), and unlimited knee flexion (hydraulic stance control knees) during weight-bearing. Knees that do not allow for flexion during weight-bearing basically support walking on level surfaces only. Locked knees may be fitted in patients only who are not able to make sure that an unlocked knee is safe (fully extended) prior to heel strike of the next step. Friction brake knees are suitable for subjects who can make sure the prosthesis is extended (safe) prior to heel strike, but still require great stability during the stance phase of gait. More dynamic walkers may benefit from a 4-bar knee that allows for a more physiologic knee flexion at terminal stance and shortening of the calf during swing for increased toe clearance. Knees that allow for limited flexion during weight-bearing (multiaxial knees) support stance flexion for shock absorption and, depending on the amount of knee flexion, ambulation on slightly uneven terrain and shallow slopes. Knees that allow for unlimited flexion during weight-bearing (hydraulic stance control knees) allow for ambulation on all kinds of terrains, but require very good muscle strength and coordination to control them as mechanical knees are generally characterized by an inverse relationship between stance stability and functional support: The more stable a knee, the fewer functions it supports and vice versa.

DISCUSSION

Clinical studies with NMPKs that could give useful guidance for knee selection for individual patients are lacking, but technical and biomechanical considerations may help improve knee selection criteria for the physical condition and needs of individual patients.

CONCLUSION

Mechanical prosthetic knees may be classified based on their ability to allow for flexion during weight-bearing, and technical and biomechanical considerations allow for improving knee selection criteria.

REFERENCES

1. van der Linde H, et al. Prosthet Orthot Int 2003; 27:170-178.
2. van der Linde H, et al., J Res Rehabil Dev 2004; 41(4):55-70.
3. Blumentritt S, Orthopädietechnik 2004; 55(6): 508-521.

DISCLOSURE

Andreas Kannenberg is a full-time employee of Otto Bock HealthCare LP, Austin, TX, a leading manufacturer of prosthetic components.

Dynamic response/energy storing AFO

To define the use of a carbon composite posterior leaf spring to create energy return. Thus the ability of an AFO to return a patients' posterior calf group function in stance and ambulation.

Review of the biomechanics of gait, focusing on the normal function of the gastrocnemius and soleus muscle group, as they relate to standing balance and gait propulsion. Subsequent review of pathological gait as it relates to the weakness/absence of plantar flexion strength and/or related valgus or varus deformities in ankle positioning.

With this establish the baseline, a scale is presented to correlate the measure of the patient's weakness and deformity to the measurable amount of dynamic force required to return the patient to normal biomechanical gait pattern. Secondarily we will review the proper timing and application of the force against the patient, to be effective at returning the patient to functional stance and ambulation.

Videos are utilized to show the evaluation techniques in determining the patients pathological condition as well as to show the application of the force and it's effectiveness and returning the patient to a near normal biomechanical gate pattern.

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Energy Storing Partial Foot Prosthesis

To define the need for a tibial tubercle height prosthesis to produce energy storing function in a partial foot prosthesis.
Review of the levels of partial foot amputation's and the common deformity and deviations that arise. Review of normal gait biomechanics as they relate to the partial foot amputees deviations.
The practitioner will be presented with a measure to develop an amount of resistance force to replace or supplement extended lever arm of the prosthetic foot.
A comprehensive review of the indications and contraindications for this type of application to be successful.

Presented by:

Noel J. Chladek, CO nchladek@aol.com

GROSS MOTOR SKILLS CHANGES OF CHILDREN WITH DEVELOPMENTAL DELAY, BENIGN HYPOTONIA AND SIGNIFICANT PRONATION WEARING SURESTEP SMOS

Megan Smith
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INTRODUCTION

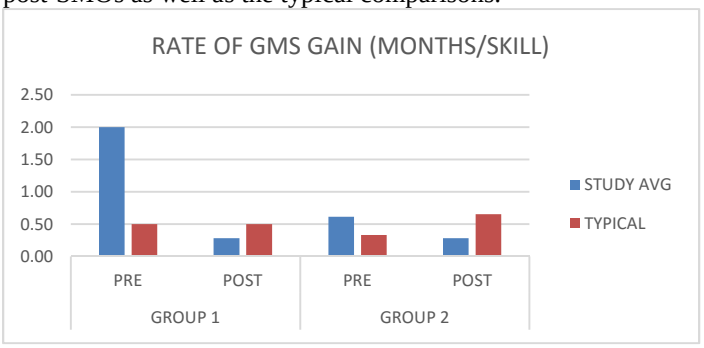
The purpose of this study was to analyze the changes in gross motor skills of children with developmental delay, hypotonia and significant pronation who wore SureStep SMOs over a 16 week period. This study compared the rate of change of gross motor skill level of the participants relative to their same-age peers. SureStep SMOs are indicated for children with developmental delay, hypotonia and pronation[1]. The Peabody Developmental Motor Scale 2 (PDMS-2)[2] was used to assess gross motor skill level. The PDMS is a norm-based test designed to evaluate a child's skill level relative to same-age peers[3]. It has been evaluated for reliability and validity[4] and can be used as a 'global measure of change in motor development'[5]. This abstract is an update from an abstract presented in 2013 that included only four children.

METHODS

Twenty seven children were recruited for this study. Five children had an underlying diagnosis such as Down syndrome and did not qualify due to non-benign hypotonia. Four children started the study but did not follow through with data collection. Eighteen children (11 males) participated in this study. Each child presented with developmental delay, benign hypotonia and significant pronation upon weight bearing. The participants were separated into two groups based on gross motor skill level. The first group was pulling to stand and cruising when they were evaluated. The second group was taking independent steps. There were 11 participants in Group 1 (PTS) and 7 participants in Group 2 (Walk). Mean age at initial testing was 15.8 ± 2.1 months and 18.6 ± 2.1 months respectively. Each child was evaluated and fitted for Surestep SMOs by an ABC Certified Orthotist (CO). Video was taken and the PDMS-2 test was given every 2 weeks for 16 weeks. Item numbers tested included items from the Locomotion and Object Manipulation subsets. Skills included crawling, standing, walking, squatting, stairs, and kicking. Parent reported data was collected for items that had been mastered prior to the initial evaluation. Data for the participants was compared to the developmental normal, per the PDMS-2, to evaluate the rate of change of gross motor skills for both groups and to compare the participant's skill level to their same-age peers.

RESULTS

Average age of pull to stand was 13.5 ± 2.2 and 13.4 ± 1.5 for Group 1 and 2 respectively. Average age for independent walking was 17.9 ± 2.1 and 18.1 ± 2.0. Compared to typical, the rate of change for Group 1 was 4 times slower than typical prior to receiving SMOs and was almost 2 times faster than typical after receiving SMOs. The rate of change for Group 2 was almost 2 times slower than typical prior to receiving SMOs and was over 2 times faster than typical after receiving SMOs. The rate of change of gross motor skills gain was the same for both groups (0.28 ± 0.1). Figure 1 shows the rate of change, or slope of the trend-lines, for each group pre- and post-SMOs as well as the typical comparisons.



Figures 1. Comparison of the rates of gross motor skill gains of study participants to typical developing children pre and post receiving SMOs.

DISCUSSION

This study suggests that the Surestep SMOs improve gross motor skills and aid children with developmental delay by helping them attain the same gross motor level as their peers. The data would suggest that these children master gross motor skills at a faster rate than their peers once they receive Surestep SMOs. Rate of skill acquirement increased for all participants after reaching SMOs when compared to pre-SMO rates as well as typical rates, suggesting that the SMOs do not slow children down and actually help them gain skills faster than typically developing children. The participants in Group 2 who had a pre-SMO rate ratio close to 1.0 actually had some of the fastest post-SMO rates, suggesting that even if a child is gaining skills close to a typical rate but are significantly pronated and delayed, they will benefit from Surestep SMOs. The study participants represent children that are normally "stuck" on one or more gross motor skills and are having issues progressing due to their foot and ankle alignment and stability along with a lack of proper postural control development. It is important that we evaluate and provide Surestep SMOs to children with developmental delay, hypotonia and pronation as soon as they start to pull to stand so that they can gain gross motor skills, postural control and be on track with their peers.

REFERENCES

1. SureStep: Dynamic Stabilizing System: http://www.surestep.net/about.html
2. Folio MR, Fewell RR. Peabody Developmental Motor Scales and Activity Cards. 1983.
3. Wiart L, Darrah J. *Developmental Medicine & Child Neurology*; 43, 279-285, 2001.
4. Palisano R. *Physical Therapy*; 66, 1714-1719, 1986.
5. Palisano RJ, et.al. *Physical Therapy*; 75, 939-948.

DISCLOSURES

The author is an employee for Surestep; however, she did not evaluate, measure or fit the orthoses.

HIGH EFFICIENCY PYLON USING CFRP GRID STIFFENED STRUCTURE

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ABSTRACT

Nowadays, commercially types of pylon are made from stainless steel, aluminum, titanium or composites materials as carbon fiber reinforced polymer (CFRP). It is notorious that the CFRP pylon brought mechanical performance associated with lightness compared to pylons metals. In this paper, the main objective was developing a CRFP grid stiffened pylon, i.e., a pylon composed by a shell structure (skin) and supported by a lattice pattern. This type of CFRP structure proposed in this work differs from commercial due high structural efficiency. Considering technical requirements of ISO 10328 standard as boundary conditions for Finite Element Analysis (FEA) was possible to validate the first pylon design. After that, grid stiffened pylon was manufactured in filament winding machine and tested in a universal testing machine to ensure the technical requirements of ISO 10328 standard. Numerical and experimental results showed that this type of structure has all the technical requirements to be manufactured and marketed as pylon for transtibial amputees. Beside this, CFRP grid stiffened pylon has shown a greater structural efficiency and lightness compared to commercially CFRP pylons.

IMPACT OF GENIUM MICROPROCESSOR CONTROLLED KNEE ON AMBULATION, MOBILITY, ACTIVITIES OF DAILY LIVING AND QUALITY OF LIFE OF ACTIVE TRANSFEMORAL AMPUTEES: A SYSTEMATIC REVIEW

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INTRODUCTION

In 2011 a new advanced hydraulic microprocessor controlled knee (MPK) Genium was introduced in the market. New sensors, algorithms and technical solutions enable the knee to offer a range of new functions to lower limb amputees. The objective of this review was to evaluate the effect of the knee on ambulation, mobility, activities of daily living and quality of life in active transfemoral amputees.

METHODS

The systematic review was conducted according to the Prisma Guidelines and recommendations of the State-of-Science Evidence Report Guidelines of the American Academy of Orthotists & Prosthetists. Three reviewers conducted the quality assessment independently.

RESULTS

Twelve articles were identified as appropriate and included in the review. They report of transfemoral amputees (MFCL-3 and 4) transitioning from C-Leg to Genium (or comparable device X2). In terms of quality, all included articles scored 'high' for external validity, while internal validity varied with most articles rated as 'high' and 'medium'. Eight articles focused on ambulation, in particular on level walking, stairs and ramps[1-9]. In addition to reporting results of motion analysis, several clinical tests have also been conducted. During level walking, improved toe clearance and reduced speed-dependency of maximum knee flexion angle are reported in the swing phase [3]. A more physiological gait pattern is also reported during stance phase where larger knee flexion angle was measured[1]. New stair ascent function resulted in 70-80 percent of the subjects being able to ascend stairs reciprocally[1,2,8]. This resulted in more physiological hip and knee movement on the prosthetic and sound side[1,4]. Gait analysis on ramps showed increased maximum knee flexion angle and foot clearance similar to those measured on sound side[2,5,8]. New standing function resulted in significantly more loading on the prosthetic side during standing on ramps[3]. Two articles addressed the effect of Genium on mobility[10-11]. Four square step test and Amputee Mobility Predictor results significantly improved with Genium use. Effect of Genium on activities of daily living was reported in three articles[6,11,12]. A validated, performance-based outcome Short form Continuous Scale - Physical Functional Performance (CS-PFP10) was significantly improved, particularly in the subcategories of endurance, balance and upper-body flexibility[11]. Perceived safety and difficulty when performing forty-five meaningful activities of daily living showed clinical relevant results for Genium[6,12]. Two articles evaluated the effect of Genium on quality of life[6,10]. Significant improvement was measured on Prosthetic Evaluation Questionnaire evaluating prosthesis-related quality of life[10].

DISCUSSION

The results suggest increased efficacy of Genium in comparison to C-Leg in the areas of ambulation, mobility, activities of daily living and quality life.

REFERENCES

1. Aldridge Whitehead JM, et al. *Clin Orthop* Relat Res; 472, 3093-3101, 2014.
2. Bell EM, et al. *Clin Biomech*; 33, 26-31, 2016.
3. Bellmann M, et al. *Arch Phys Med Rehab*; 93, 541-549, 2012.
4. Bellmann M, et al. *Biomed Tech*; 57, 435-444, 2012.
5. Lura DJ et al. *Clin Biomech*; 30, 175-181, 2015.
6. Highsmith MJ, et al. *Technol Innov*; 18, 139-150, 2016.
7. Highsmith MJ, et al. *Technol Innov*; 18, 151-157, 2016.
8. Highsmith MJ, et al. *Technol Innov*; 15, 359-368, 2014.
9. Hahn A, et al. *Medicine*; 95(45), e5386, 2016.
10. Highsmith MJ, et al. *Technol Innov*; 15, 369-375, 2014.
11. Highsmith MJ, et al. *JRRD;* 53, 753-766, 2016.
12. Kannenberg et al. *JPO*; 25, 110-117, 2013.

DISCLOSURE

Milana Mileusnic, Lena Rettinger and Andreas Hahn are affiliated with Otto Bock Healthcare Products. Authors are solely responsible for the contents of this report.

IMPLICATIONS OF PROSTHETIC HAND DESIGN AND CONTEXTUAL SOCIAL INTERACTION ON COGNITIVE EMBODIMENT

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INTRODUCTION AND DISCUSSION

A number of recent advances in upper limb prosthetics such as multiarticular prosthetic hand design, input/control, haptic feedback, proprioceptive awareness, therapeutic techniques, and socket design promise to provide patients with improved comfort and function. Together these improvements may be working as complements to increase the sense of prosthetic embodiment or "projected kinesthesia." This sense is also referred to as phenomenological osmosis where an instrument melts into the sense of being. [1] Clinically many therapists and prosthetists have noted when the patient becomes so confident with the controls and feed back that the prosthesis seems more fully integrated in the functionality of the prosthesis. This sense of oneness with the prosthesis may also have a dual relationship with the social context of the patient in that that patient is able to demonstrate greater competency with the prosthesis so it is accepted while the social group also provides support for this acceptance.[2] Upper limb prosthetic users have been known be pulled into acceptance or rejection by the prevailing attitudes of the social system. Since the face and hand are neurosynaptically linked directly to the brain the hand serves as a form of social communication.[2] This historical need for outward cosmetic appearance may be significant as to why patients desire multiarticular hand designs to a greater degree as opposed to more functional devices despite their advantages in durability and function.

COMPLEMENTARY RESEARCH & DEVELOPMENT

One finds this commonality of approaching prosthetic embodiment from a number of avenues of research and prosthetic design. The most apparent has been the changes to hand design specifically with small and powerful brushless motors that enable individual finger positioning. Although the fingers are not yet individually controlled, various modes can be programmed. Patients have difficulty remembering the controls. Surveyed prosthetic specialists estimated that 86% patients have shown that they only use 2 modes of the up to 14-34 available.[2] However, these fingers allow certain finger combination that serve to communicate with others socially. Also they approach the qualitative expectation of the patient for finger movement. Other designs place a design emphasis on speed and grip force. [3] The human hand can move as fast as 4000 mm/s but typically moves at 310 mm/s with up to 22-24 lbs of force but typically requires only 5 lbs of force 1500 times a day.[2] Coupled with wrist motion to place finger and thumb position within the work envelope, this provides the user with the physiologic movement they require.[3] Researchers in neuroscience have used combinations or individual visual, proprioceptive, and haptic feedback loops increase the prosthetic users engagement of the prosthesis.[4] This can be demonstrated in a variety of ways including the "rubber hand illusion" which stimulates visual and haptic feedback resulting in the brain adopting a prosthetic hand albeit with a 40-50ms.[4] More tool-like terminal devices may interrupt the somatotopic mirror neuron that seeks symmetry and integration of the devices.[5] This may be why some congenitally limb deficient patients choose do not choose use prosthetic hands since the prosthesis itself seems foreign and they are not seeking physiologic emulation. Often these are worn to satisfy the social context. In terms of control sequential and simultaneous movements utilizing pattern recognition are possible that do not the delay the movement using implantable electrodes and TMR surgery.[6] The patient begins to use more intuitive control schemes rather than isolating the control for each movement.[6] The phantom limb now utilized to increase the awareness and connection to the cognitive controls. Historically phantom attenuated due to loss of connection with the cognitive interaction.[6] With pattern recognition this interaction is integral in patient training and stimulates this connection to the prosthesis. Since the thumb alone constitutes roughly 25% of the cerebral cortex due to evolutionary developments the hand directly drives cognitive performance.[2] The use of more intimate fitting silicone devices that allow a greater amount of dynamic flexibility and coupling with the limb increase the proprioception presented with the residuum. Mechanical stimulation of the proprioceptors in tendons of the elbow can stimulate these proprioceptors to mimic kinesthestheic pathways.[3] All of these advances demand similar growth in therapy and training to optimize function.

RESULTS

Many simultaneous advancements are approaching this nebulous sense of embodiment. Along with technologic and surgical developments designs are now able to address not only the functional, but the sociological needs of the patient. Prosthetists need to continually consider these how these innovations may be optimized to create not just a more eloquent tool, but a fully integrated device that is acceptable within the larger sociological context.

REFERENCES

1) Murray, C., Psychoprosthetics, 2008.
2) Stark, G., AAOP,AOPA, 2013, 2014, 2015
3) Kannenberg, A., Cutti, A, SCULPT, 2014
4) Marasco, P, MEC, 2014
5) Cusak, W., Frontiers in Neuroscience, 2012.
6) Kuiken, T., Marasco, P. PNAS, 2007.

Is 3D Printing O&P devices Disruptive?

Jeff Erenstone, CPO

By definition, additive manufacturing (commonly known as 3D printing) is a classic example of a disruptive innovation, which is a term coined by the economist Clayton M. Christensen. However, a disruptive innovation doesn't need to disrupt the patient care provided by trained, professional Prosthetists and Orthotists; instead, it can augment it. 3D printing is a tool and it is important to separate the tools from the devices makes, and from the people who are using it. Especially because the manufacturing of a prosthesis or orthosis is only a small part of the care that is provided by an Orthotic and Prosthetic practice.

This lecture will explain the current benefits of 3D printing to the O&P field and give examples of how clinicians around the world are currently utilizing it. The lecture will provide background, terminology, explanation of processes and overviews of clinical cases that currently utilize this technology in the field.

LOWER LIMB PROSTHETIC OUTCOME MEASURES: A TWO-YEAR RETROSPECTIVE CHART REVIEW

Russ Lundstrom, MS[1]; Scott Sabolich, CP, LP[2]; Andreas Kannenberg, MD, PhD[1]

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INTRODUCTION

Outcome measures can provide valuable insights to help improve patient care in prosthetics. Additionally, these measures can help justify advanced technologies to third-party payers and other stakeholders. However, standardized outcome measures are still underutilized in prosthetics clinics. This study is a retrospective review of outcome measure data collected over a period of two years from patients with lower-limb loss at two prosthetic clinics.

METHODS

Outcome measures routinely administered since the beginning of 2015 at both clinic sites included the following: Timed Up and Go (TUG), Fast Walking Speed (FWS), Self-selected Walking Speed (SSWS), the Amputee Mobility Predictor (AMP), the Prosthetic Limb User Survey of Mobility (PLUS-M), and the PROMIS-29 v2.0, an instrument designed to measure health outcomes in 7 domains, Depression, Anxiety, Physical Function, Pain Interference, Fatigue, Sleep Disturbance, and Ability to Participate in Social Roles and Activities. Outcomes were assessed at baseline at least once prior to definitive prosthetic fitting and at follow up visits with a few weeks after the fitting (Initial assessment), 6 months post-fitting, and annually after that.

RESULTS

Outcomes data were collected from a total of 1172 lower limb subjects, 94 bilateral, average 56.1 years (range 3 to 97).

Row Label	Number of Subjects
TT Prosthesis	643
TF Prosthesis	287
TT Replacement Socket	148
TF Replacement Socket	107
Partial Foot	27
Syme	19
Knee Disarticulation Prosthesis	17
Replacement Foot	12
Hip Disarticulation Prosthesis	8
Foot	6
Toe(s)	4
TT Replacement Prosthesis	1
Supplies	1
TT Replacement Foot	1
TF Replacement Prosthesis	1
Grand Total	**1282***

*Some subjects were in more than one category.

The number of lower limb subjects with both baseline and follow-up data by outcome measure are given in the table below.

Outcome	Subjects with Outcome Data	Subjects with Baseline & Follow up Data
FWS	535	118
SSWS	597	134
AMP	817	216
PLUS-M	768	74
Promis-29	813	85
TUG	524	108

Analysis of the data is ongoing and results will be presented showing the mean improvements for each outcomes by K-level and amputation level. Initial analysis revealed the following: (1) K3 and K4 subjects showed greater improvements in walking speed, (2) K1 and K2 showed greater improvements in AMP and PLUS-M scores and (3) transfemoral amputees showed greater improvements in physical function as measured by the PROMIS 29 instrument.

CONCLUSION

Routine outcome measurements in a prosthetic clinic is feasible and can provide valuable information that is useful for improving patient care and for justifying the use of technology to third party payers. This data may also provide important insights for the industry regarding the types of clinical improvements that can be demonstrated with prosthetic fittings.

ACKNOWLEDGEMENTS

Data analysis support by Ottobock.

MATERIAL ANALYSIS OF PROSTHETIC SOCKETS AND COMPARISON TO CLINICAL OUTCOMES

Garrett Hurley, CPO, Jesse Williams, PhD, Jon Smith, CPO
LIM Innovations, San Francisco, CA

INTRODUCTION

Materials within prosthetic sockets are anecdotally associated with outcomes and patient satisfaction. However, little research has been done to understand, validate, and quantify the significances and clinical relevancy of socket materials. Many prosthetist hold strong options as to what materials get the best results but few of those opinions are supported with empirical evidence.

Regardless of differences in option, prosthetist should be prepared to justify their reimbursement for sockets and materials used with quantifiable data and results. This study aims to quantify properties of materials in prosthetic sockets and associate results with clinical outcomes.

METHOD

This is an unblinded clinical study with 75 transfemoral amputee participants.

Material properties of a dynamic modular socket design and vacuum-formed thermoset prosthetic sockets were measured and associated with outcome measures and Hanspal Socket Comfort Scores (SCS).

Measurements of durometer, modulus of elasticity, tensile modulus, and flexural modulus were tested for the dynamic modular socket design and vacuum-formed thermoset prosthetic sockets (with and without flexible inner liners). Materials tested include; thermoset plastic, thermoplastic, thermoplastic fiber composites, 3D printed plastic, urethane foams, and various textiles. Participant satisfaction was evaluated by users reporting Hanspal Socket Comfort Scores (SCS) at intervals after patients were fit.

RESULTS

Material testing for dynamic modular sockets showed greater variation in flexural modulus and other material properties than that of vacuum-formed thermoset prosthetic sockets. Patient reported Hanspal Socket Comfort Scores doubled on average (μ = 101%, n = 75, $p<0.0001$) with the dynamic modular socket system as compared to vacuum-formed thermoset prosthetic sockets.

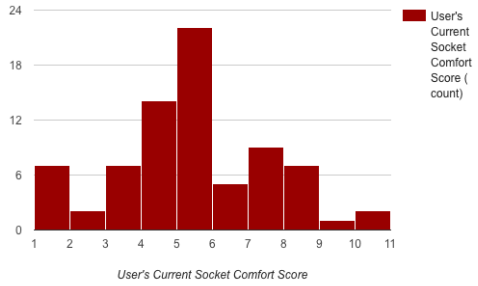

Figure 1: Average SCS results with vacuum-formed sockets (cohort of 75 participants)

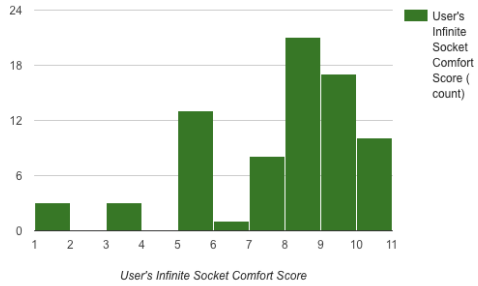

Figure 2: Average SCS results with a dynamic modular socket (same cohort of 75 participants as in Figure 1)

DISCUSSION

Dynamic modular prosthetic sockets have been designed and engineered with materials that mimic and complement residual limb anatomy with an objective to provide improved comfort and function. The results of this study suggest that prosthetic sockets with materials that better mimic human anatomy can offer improved prosthetic outcomes over sockets with more rigid materials.

Research directed to gain a better understand of the relationship between socket materials and clinical outcomes is continuing. This research may be helpful in justification of billing and reimbursement relating to socket materials.

REFERENCES

1 Mitton K, et al. Prosthet Orthot Int; 2016.
2. Kahle JT, et al. Technol Innov. 18, 175-183, 2016.
3. Van de Weg, et al. Prosthetics Orthot Int; 2005.

DISCLOSURE

Authors are employees of LIM Innovations.

NOTIFICATIONS

This study was funded by LIM Innovations.

McGann Client Feedback Form: Update And Development Of Self-Advocacy

Individuals who present with upper limb loss or congenital difference experience challenges that impact physical and psychosocial functions. Many of these individuals utilize prosthetic technology to provide or restore some of the upper limb function. As no single technology is currently available to replicate the diverse functions of the human hand, upper limb prostheses come in many forms to serve many purposes from passive assistance to complex manipulative capabilities for bimanual tasks. Today's innovative prosthetic technologies can help to restore the consumer's independent function at home, at work and in the community and improve their perceived quality of life. Existing client satisfaction tools often appear inadequate; and the information is typically requested late in the process, hampering functional outcomes and hindering the opportunity to rectify dissatisfaction. In addition to the limitations in physical function, are the impacts of prosthetic wear on self-esteem and how one performs social roles and conducts social functions. All of this can result in rejection and/or abandonment of the prosthesis. The problem is multi-dimensional and ultimately impacts all who use or might potentially use prosthetic technology.

As healthcare professionals and providers, it is incumbent upon us to provide client- centered care. The consumer demands it, the healthcare industry requires it and our professional ethics mandate it. Scaffa, Reitz and Pizzi (2010) call us to "understand the determinants of health, such as lifestyles and living conditions, so that these can be maintained or improved". The authors cite the meaning of health as defined by the World Health Organization (WHO) to be the "complete state of physical, mental and social wellbeing, and not just the absence of disease or infirmity". Patient satisfaction has long been a buzzword and in the prosthetic industry; it includes satisfaction with service delivery as well as with technology.

Hill et al. {2009) conducted a systematic review of assessment tools relevant to this population and prosthesis use. Their findings included barriers to communication culturally, linguistically and with lack of common terminology across professions. They cited the need to implement a unified collaborative approach to improve communication between all stakeholders including the clients, clinicians and researchers (Hill et al., 2009). This viewpoint also coincides with the strategic directions of the National Prevention Strategy {2011) that include empowering people and eliminating health disparities.

The International Classification of Functioning, Disability and Health (ICF) was designed to serve several purposes such as to provide such common language and reach across the multiple health care disciplines and to provide a structure for advocacy for individuals with disabilities (WHO, 2001). The ICF model provides a framework of inter-relatedness of the health condition, environmental and personal factors to the components of body functions and structures, activities and participation. Hill et al. {2009) note that according to the ICF definitions, prostheses are perceived as assistive devices and designated as environmental factors. The disparity for individuals who utilize prosthetic technology is that for many, the prosthesis serves as an extension of the user's body. While it may serve as a tool to access bimanual functional tasks, it also becomes a replacement for the absent body structure/body function. According to Hill et al. {2009), this unfortunate classification stifles the voice of this population and ignores the experience of the prosthesis user.

Within the prosthetic industry there has been much queried about the use of the technology, how individuals perceive the technology, why they use it and how it is incorporated into the schema of the person. Few researchers have tackled and reported on the evidence as cogently as Craig Murray in his studies of 2005 and 2009. In the earlier study he explored the factors toward adjustment and social meanings surrounding the use of prostheses and particularly sought the perceptions by limb users themselves. Several themes emerged including actual prosthesis use and social rituals, the perceptions of social isolation and the reactions of others, whether to conceal or disclose the limb difference and the social implications of each, and feelings/experiences relative to social and intimate relationships. Factors that influence adjustment and successful rehabilitation included early prosthetic fitting, prosthetic satisfaction and the need for individual expression (Murray, 2005). Satisfaction with the prosthesis is associated with increased self-esteem, increased social integration and absence of emotional challenges. The need for individual self-expression includes social expression, 'person-first' societal acceptance and personalizing the appearance of the prosthesis to what is perceived as aesthetically pleasing to the wearer. It is this work that served as the impetus for the development of a platform to raise the voices of the consumers and to heighten the hearing of the practitioners.

Clinicians at Handspring (based in NY with additional clinics in FL, CO, and UT) use a client-centered collaborative approach with occupational therapy and prosthetic services. They recognize the need to obtain client feedback in a systematic way that would empower the individuals and allow provision of technology that wearers of upper limb prostheses would like and would use. They collaborated with clients to create a document that uses common language and offers a feedback loop during all phases of the prescriptive prosthetic process, initiating use of the information during the pre-prosthetic phase and extending it through follow-up after delivery of the definitive technology. The form addresses specific elements of prosthesis use cited as important by the clients such as comfort of the socket, aesthetics, ease to don/doff, tolerance to weight, length, socket and harness as appropriate; control systems, reliability, pain and functionality of the technologies. The user grades each item using a 3-point color-coded system that is easy to use by children and adults. Any item that the client rates in the red column is immediately addressed during that visit; items in the yellow column are addressed subsequently. By enacting emergent practitioner response to remediate the identified problem(s), the client experiences that his/her voice has been 'heard', that their perceptions are important and that they as individuals are important. What first began as a client-centered feedback form to improve prosthetic satisfaction, acceptance and use has additionally and more importantly become a tool to empower the population of individuals who have experienced upper limb loss to speak and to be heard.

Murray (2005 and 2009) cites the importance of consumer perceptions, input and self- advocacy to the design of prosthetic technologies. He speaks of the social meanings of prosthesis use and the value of this as it relates to user satisfaction and integration to the community. By actively engaging the client and extracting personal feedback, as well as input from the family and/or case manager, the prosthesis user is able to influence his/her care. Relationships between prosthetic satisfaction, self-perception of ability and function emerge as important facets of the rehabilitation process. As clients use their voices to note the problems they experience and the functions they enjoy, they appear to develop self-advocacy skills and to be more confident in their observations and reporting. Functional abilities appear to improve and the personal perception of 'disability' appears to diminish. This speaks to population health relating to occupational justice as the clients appear to be more "ability-aware". The opportunity to provide meaningful feedback that is heard and is acted upon acts as a change agent to impact the individual consumer, the collaborative team and ultimately the care. It proves Reilly's statement that "man through the use of his hands as they are energized by mind and will, can influence the state of his own health" (Scaffa et al., 2010).

References

Hill, W., Kyberd, P., Hermansson L.H., Hubbard S., Stavdahl 0., Swanson S., Cooper M.F. (2009). Upper limb prosthetic outcomes measures (ULPOM): a working group and their findings. *Journal of Prosthetics and Orthotics,* 21(4), 69-82. http:ljdx.doi:10.1097/JPO .OB013E3181ae970b

Murray, C.D. (2005). The social meanings of prosthesis use. *Journal of Health Psychology,* 10,425-441. http:ljdx.doi.org/10.1177/1359105305051431

Murray, C.D. (2009). Being like everybody else: the personal meanings of being a prosthesis user. *Disability and Rehabilitation, 31,* 573-581. http://dx.doi.org/10.1080/09638280802240290

Scaffa, M.E., Reitz, S.M., & Pizzi, M. {2010). *Occupational therapy in the promotion of health and Wellness.* Philadelphia, PA: F.A. Davis.

OSSEOINTEGRATED IMPLANTS FOR LOWER LIMB AMPUTEES: EVALUATION OF BONE MINERAL DENSITY

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INTRODUCTION

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. 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.

METHODS

This is a prospective study of 33 patients, consisting of 24 males and 9 females, aged 22-77 (mean = 51.0 ± -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

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.

DISCLOSURES

Dr. Al Muderis consults for and receives royalties from companies including: Osseointegration International Pty Ltd (Australia), Osseo-PL Inc (USA), Osseo-PL GmbH (Germany), AQ Implants GmbH (Germany) and Permedica S.P.A (Italy).

OSSEOINTEGRATED IMPLANTS FOR TRANS FEMORAL AMPUTEES: RADIOGRAPHIC EVALUATION OF BONE REMODELING

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INTRODUCTION:
Osseointegration is a novel method to overcome persistent socket prosthetic issues in amputees by anchoring a transcutaneous implant directly onto the skeletal residuum. Although similar technologies have been widely applied in the area of hip and knee arthroplasty, little evidence exists in the literature reporting the bone remodeling effects of osseointegrated implants. Stress shielding results in the reduction of bone density due to the implant removing the stress that is usually exerted on the bone, which greatly reduces implant stability. This paper investigates the bone remodeling effect and quantifies it in two of the most common osseointegration implants.

METHODS:
This is a prospective study of 50 patients with trans-femoral amputations, consisting of 35 males and 15 females, aged 20-73 (mean 48.2) years at surgery, with minimum two-year follow-up. Two implants, the Integral Leg Prosthesis (ILP) and Osseointegrated Prosthetic Limb (OPL), with differences in tapering, coating and bone ingrowth regions were examined. Radiographs were taken at 6 months, 1 year, 2 years and 5 years post-surgery. The surrounding bone was defined using inverse Gruen zones and graded into 5 levels of bone growth or resorption.

RESULTS:
Results obtained at 1 and 2 year follow-ups were compared to the 6-month follow-up values as a baseline. Significant bone growth near the proximal zones of the implant was observed on patients with the ILP implant. This was accompanied by significant resorption towards the distal end indicating the occurrence of stress shielding. The OLP implant demonstrated much more uniform bone density throughout the length of the implant.

DISCUSSION:
Overall, the patterns of bone remodeling after osseointegration showed similarities to those seen on hip stems with a press-fit design. Of the two osseointegration implants examined in this paper, the OLP implant exhibited less stress shielding effects and is expected to provide better long-term stability.

DISCLOSURES:
Dr. Al Muderis consults for and receives royalties from companies including: Osseointegration International Pty Ltd (Australia), Osseo-PL Inc (USA), Osseo-PL GmbH (Germany), AQ Implants GmbH (Germany) and Permedica S.P.A (Italy).

OSSEOINTEGRATED IMPLANTS IN PATIENTS WITH PERIPHERAL VASCULAR DISEASE

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INTRODUCTION

Osseointegration is an alternative treatment for amputees who have inability or difficulty in wearing socket prostheses. Although the majority of limb amputations are due to vascular disease, they represent perceived contraindications for osseointegration surgery. For the first time, this case series reports the outcomes of osseointegrated reconstruction in patients with limb amputation due to peripheral vascular disease in Australia and the Netherlands.

METHODS

This is a multi-centre case series with 12-month post-operative follow-up in patients with trans-tibial amputation and a history of peripheral vascular disease, who have received osseointegration implants during 2014–2015. Clinical and functional outcomes assessed included pain, prosthesis 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

Five trans-tibial amputees (aged 56–84 years) were included in this case series. All patients were pain-free and using the osseointegrated prosthesis at 12-months post-operation. The mobility of all patients improved at follow-up. Notably, three of the five patients were wheelchair-bound prior to osseointegration surgery, but all were able to walk again and perform daily activities. One patient experienced pain at the stoma site due to progressive peripheral vascular disease, which was treated successfully using balloon dilatation. Two patients experienced a single episode of superficial soft-tissue infection treated with oral antibiotics.

DISCUSSION

Patients with limb amputations and a history of peripheral vascular disease have been traditionally excluded from prosthetic reconstruction. An osseointegrated implant may be considered as a feasible alternative to the conventional socket prosthesis for these patients. The osseointegrated prosthesis may provide such patients with immense benefits, including improved function, mobility, quality of life, and even survival. Further evidence is required to confirm the possibility of implementing osseointegration surgery as the standard of care for these patients.

DISCLOSURES

Dr. Al Muderis consults for and receives royalties from companies including: Osseointegration International Pty Ltd (Australia), Osseo-PL Inc (USA), Osseo-PL GmbH (Germany), AQ Implants GmbH (Germany) and Permedica S.P.A (Italy).

Outcomes Associated with the Intrepid Dynamic Exoskeletal Orthosis (Ideo): A Systematic Review of Literature

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BACKGROUND

A recent development in the area of "limb salvage" is the ultra-high performance AFO. One such AFO is the Intrepid Dynamic Exoskeletal Orthosis (IDEO). Results of a systematic review of outcomes of the IDEO and associated return-to-run program will be presented.

Perception on Functional Changes and Mobility in Unilateral Transfemoral Amputees Using MPKs

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BACKGROUND

Microprocessor knees (MPK) have shown to increase quality of life (QoL)[1], of which mobility is a major determinant[2]. Amputees' QoL also depend on satisfaction with their prosthesis[3]. Increased physical activity has shown to improve psychological, social and physical well being[4], additional factors of QoL.

The purpose of this study was to measure the influence of a new MPK on mobility, functioning and satisfaction with unilateral transfemoral amputees.

AIM

The primary hypothesis aimed to show improvements in functioning and satisfaction (PEQ MS 12/5) and mobility (6MWT) when using the new MPK; and secondary if these correlate to each other.

METHOD

19 unilateral transfemoral subjects within the functional MFCL K3, K4 level were recruited in an IRB approved multi-center study. Participants were measured at baseline with their current MPK, at the initial fitting with the new design and after 3 weeks adaptation at which point in time 6MWT and PEQ MS 12/5 were performed. The cohort was stratified into two groups MPK1 and MPK2 according to the type of previous MPK to determine if either group would differ.

RESULTS

17 (14 male) finished the study protocol and were included in the analysis 2 users dropped out. The average age of the sample was 41.7 (29-68) years (MPK1: 36.6 (32-44); MPK2: 44.5 (29-68)) and average weight was 79.47kg (56.7-104.3) (MPK: 76.1kg (56.7-87.5); MPK2: 81.3kg (59-104.3)). Although the MPK2 group was both heavier and older (including 2 users over 65) there was no statistical difference between the groups. Mobility improved statistically significant ($p>0.05$) for the entire group. The primary outcome, PEQ MS12/5, improved significantly ($p>0.05$) from 3, 10 at baseline to 3, 63 at 3 weeks follow up and users walked significantly ($p>0.05$) more 69.41m (447.94-517.35m) on average during the 6MWT.

No significantly different outcomes were observed in between the groups MPK1 and MPK2, neither at baseline, nor at 3 weeks follow up.

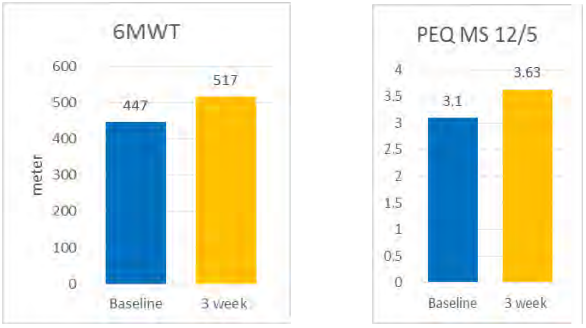

Figure 1. Statistical significant improvements (< 0.05) with the new MPK in 6MWT and PEQ MS 12/5 indicating a correlation of mobility to user satisfaction in functioning

DISCUSSION & CONCLUSION

The typical 6MWT performance of transfemoral K4 Level amputees is 419.76 m and the minimal detectable change is 45m. The results indicate that the users step up to another performance level which is close to those of active duty service members of the US army. The PEQ MS 12/5 ratings show a significant improvement reaching close to the maximum of the score.

Significant correlation with PEQ average in 3 weeks was found indicating increased mobility improves perceived functioning and satisfaction in the studied cohort.

The new MPK significantly improved the mobility and satisfaction in prosthetic function for active unilateral transfemoral users.

REFERENCES

1. Hafner, B. J., Arch. Phys. Med. Rehabil. 2007.
2. Asano, M., Prosthet. Orthot. Int. 2008.
3. Zidarov, D., Arch. Phys. Med. Rehabil. 2009.
4. Deans, S. A., Prosthet. Orthot. Int. 2008.

PROOF ACTIVITIES OF DAILY LIVING IN THE LOWER EXTREMITY PATIENT FROM DAILY CLINIC PRACTICE

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INTRODUCTION

Recent Medicare auditing practice has underscored the growing movement towards evidence-based practice and objective outcomes assessment in prosthetics and orthotics. Demonstrating variable cadence and proof of capability of ADL is difficult, if not impossible, without a spacious, high tech laboratory facility – complete with expensive equipment and trained staff. We report on the testing of a turn-key system that allows the required assessment without placing any markers on the subject and that can be operated by a single prosthetist in a 15'x15' room. This allows a professional engaged in daily practice to integrate collecting objective measures into their clinical workflow, automatically generating reports for patient history and outcomes.

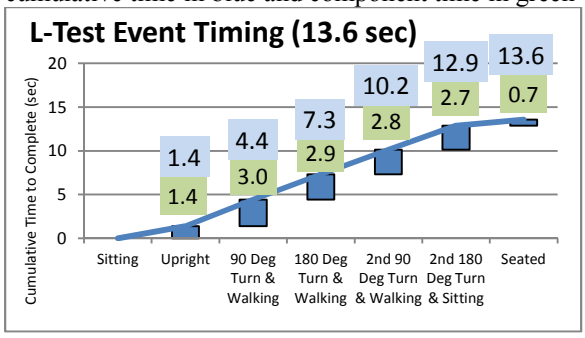
METHODS

Preliminary data will be presented from 2 different tests used to quantify Activities of Daily Living (ADLs): the timed-Up-And-Go Test1, and a 2x2 L-Test[3]. Subjects are de-identified yet segregated population of 21-76 yr. old male and female subjects, non-impaired, and with lower limb amputation. Trials for the 2x2 L-Test are 49 subjects completing 77 trials, while initial data for the TUG is 11 subjects & 23 trials. An eight camera system collected 60Hz movement data, while in-shoe load sensors collected both feet at 92 Hz. Subjects performed the 2x2 L-Test at their fastest safe and stable pace, and a recording of the TUG Test was taken at a self-selected and fast pace, after practice.

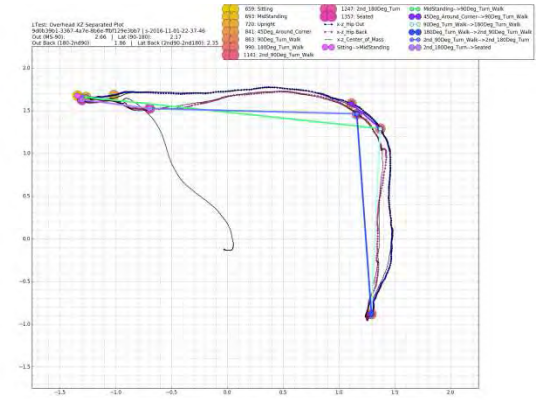
The 2x2 L-Test (8 m walk) consists of Sit-To-Stand, a 2m walk, a 90 deg. turn & 2m walk, a 180 deg. turn & a 2m walk, a 90 deg. turn & 2m walk to the seat, finishing with a 180 deg. turn & Stand-To-Sit. Data were post-processed automatically by the GaitKeeper System to generate reports.

RESULTS

Figure 1. Timing of activities for the L-Test from a representative subject, from GaitKeeper® Reporting, cumulative time in blue and component time in green



L-Test: Automated algorithm identifying component parts and timing of the 2x2 L-Test.



DISCUSSION

With the known ceiling effects of the TUG test for active, healthy young adults and older active adults[2], the 2x2 L-Test shows greater capability to indicate change across a broad population, and indicate components of the test where intervention could be given to improve specific task capability. Knowing specific times for just the sit-to-stand portion could allow a professional to enhance PT and training for that task, which would normally go unreported with classical stopwatch measurement.

The use of a complete gait lab to capture data allows significantly more insight into the segment activities during a test, as well as reduced operator influence on test results. The system allowed a single operator to collect objective data quantifying ADL performance in a relatively small space – that is readily available in many prosthetic clinics. Total setup time would be 3-5 minutes, with data collection time for the described tests 5-7 minutes per patient. The GaitKeeper system is currently in use in prosthetic clinics, using it daily to document patient outcomes for record keeping, billing justification, and audit protection.

REFERENCES

1. Podsiadlo D, Richardson S. The timed" Up & Go": a test of basic functional mobility for frail elderly persons. Journal of the American Geriatrics Society. 1991;39(2):142-148.
2. Schoene D, Wu SMS, Mikolaizak AS, et al. Discriminative Ability and Predictive Validity of the Timed Up and Go Test in Identifying Older People Who Fall: Systematic Review and Meta-Analysis. Jnl American Geriatrics Society. 2013;61(2):202-208.
3. Deathe & Miller, The L Test of Functional Mobility: Measurement Properties of a Modified Version of the Timed "Up & Go" Test Designed for People With Lower-Limb Amputations, *Physical Therapy*, 2005; 85:626-635.

DISCLOSURE

Wilson Steele is a Biomechanist and Co-founder at Anatomical Engineering, Inc.

SINGLE-STAGE OSSEOINTEGRATED RECONSTRUCTION AND REHABILITATION OF LOWER LIMB AMPUTEES

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INTRODUCTION

Osseointegration has emerged recently as a novel approach for the reconstruction of amputated limbs 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 at least 4 months and up to 18 months for the completion of reconstruction and rehabilitation from the time of the initial surgery. The study evaluates the safety and efficacy of a single-stage osseointegration procedure performed in our centers, which dramatically reduces the time of recovery to approximately 3-6 weeks.

METHODS

The inclusion criteria are age over 18 years, unilateral trans-femoral amputation and experiencing socket-related problems or difficulties in using socket prostheses. Functional (Six Minute Walk Test, Timed Up and Go, and K-Levels) and quality of life (Questionnaire for persons with a Trans-Femoral Amputation, and Short Form Health Survey 36) outcome measures are recorded pre-operatively and at defined post-operative follow-up intervals up to 2 years. Post-operative adverse events (infection, revision surgery, fractures, and implant failures) are also recorded. The pre- and post-operative values are compared for each outcome measure, and the benefits and harms of the single-stage procedure will be compared to results obtained using a previously employed two-stage procedure.

RESULTS

Significant improvements for all outcome measures were observed compared to pre-operative values which were very similar to the results obtained using the two-stage procedure. The occurrence levels of adverse events including the infection rate and revision rate were also similar to the single-stage procedure.

DISCUSSION

These preliminary results suggest that single-stage osseointegration surgery for trans-tibial amputees can be considered safe and effective treatment for amputees experiencing socket-related discomfort. This protocol has the potential to shorten the rehabilitation time to 3-6 weeks which dramatically reduces the time of recovery.

DISCLOSURES

Dr. Al Muderis consults for and receives royalties from companies including: Osseointegration International Pty Ltd (Australia), Osseo-PL Inc (USA), Osseo-PL GmbH (Germany), AQ Implants GmbH (Germany) and Permedica S.P.A (Italy).

STANDING ON UNEVEN GROUND – HOW LOWER LEG AMPUTEES BENEFIT FROM MICROPROCESSOR CONTROLLED PROSTHETIC FEET IN AN EVERYDAY TASK.

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INTRODUCION

Conventional prosthetic feet sufficiently support lower leg amputees in walking and standing on level ground. When ambulating on uneven ground, an everyday task like standing can become challenging. The limited adaptivity of the conventional prosthetic foot requires compensational strategies of the user such as an unnatural posture that is often associated with high stresses in the leg joints and demanding muscle effort.
The aim of the study was to show which concepts implemented in current microprocessor controlled prosthetic feet (MPF) are beneficial for amputees and lead to a natural posture while standing on inclines and declines.

METHODS

In this study 4 transtibial (TT) and 4 transfemoral (TF) amputees took part. Five different MPF (Meridium, Elan, Proprio, TSA, Raize) and the everyday prosthesis were used to investigate standing on level ground, on an incline of 10° and on a decline of -10°. Lower leg joint angles, external joint torques and ground reaction force (GRF) distributions between prosthetic and sound side were calculated with the recorded kinematic (Vicon system) and kinetic data (2 Kistler force plates).

RESULTS

The GRF distribution, the joint angles and joint torques (both sides) change in dependence of situation and used feet. Largest differences in the parameters caused by the MPF are found while amputees faced a decline. Most striking results are: an almost uniform GRF distribution for all feet on level ground and for MPF which fully adapt to the inclinations; flexing knee torques for MPF which do not fully adapt to the inclinations (prosthetic side for TT, both sides TF), knee torques about zero for feet which fully adapt, and extending knee torques for MPF which combine a full joint adaptation to the inclination and an auto-adaptable dorsiflexing stop (Figure 1). Large inter-individual variations in the leg joint angles were also observed, except for the Meridium.

DISCUSSION

The different MPF concepts influence the stance behavior of the amputees. It can be deduced that the ability of the foot to lock in a dorsal direction once adapted fully to the inclination is the key for a nearly natural posture. For lower leg amputees such a posture includes an almost uniform distribution of GRF between prosthetic and sound side as well as joint angles and joint torques comparable to non-amputees. Only one of the investigated feet, the Meridium, was able to fully fulfill these criteria.

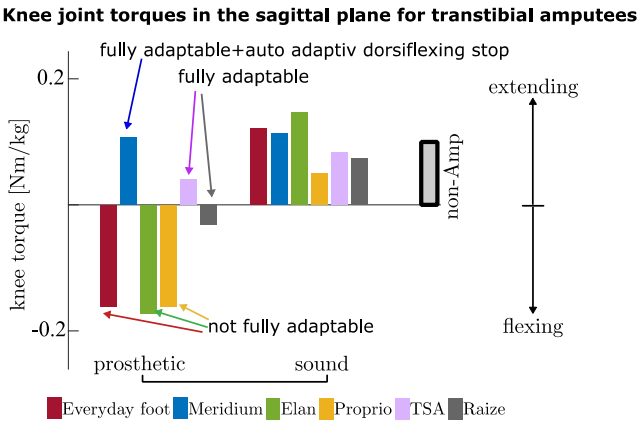

Figure 1. Knee joint torques for prosthetic and sound side for TT while standing on a decline of -10°. The different concepts of the feet determine the acting torques and influence the posture.

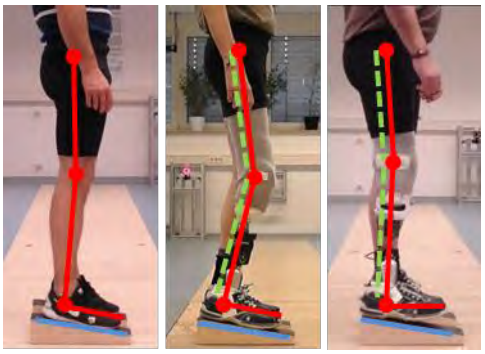

Figure 2. Examples of observed postural strategies in standing on an decline. The amputees use compensatory strategies to cope with the lack of adaptability.

The observed large inter-individual variations in the posture are attributed to user-specific compensation strategies to cope with the lack of adaptability (Figure 2). These variations vanish if equipped with an appropriate MPF.

DISCLOSURE

All authors are fulltime employees of Otto Bock. The feet investigated in this study are from different prosthetic manufactures (Otto Bock, Fillauer, Össur, Blatchford).

TECHNICAL AND CLINICAL CONSIDERATIONS FOR THE DEVELOPMENT OF 3D PRINTED UPPER-LIMB PROSTHESES FOR CHILDREN

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INTRODUCTION

Advancements in computer-aided design (CAD) programs and additive manufacturing (3D printing) offer the possibility of designing and printing customized upper-limb prostheses at a low cost[1,2]. However, there is a lack of specific technical descriptions and clinical evidence supporting the use of 3D printed prostheses. The purpose of this investigation was to provide technical considerations and clinical evidence of the possible benefits and obstacles in the use of upper-limb 3D printed prostheses in pediatric populations. This information is crucial for clinicians interested in exploring the use of 3D printed prostheses for their patients.

METHOD

Technical Considerations: A description of the technical considerations associated with the design, 3D printing processes, and current Food and Drug Administration (FDA)[3] recommendations for testing and characterization for upper-limb 3D printed prostheses are examined.

Clinical Evidence:

Study 1: Five Children (three boys and 2 girls; 12 to 17 years of age, all with congenital digit reductions) form the Instituto Teletón Santiago, Chile, which is one of the main institutions in South America providing rehabilitation to children. Each child was fitted with a 3D printed upper-limb prosthesis. Assessment of the limb function was completed with the modified Bilan Score 400. Testing was completed before delivery of the prosthesis, then at 1 month and 4 months of use. In addition, the Upper Extremity Functional Index (UEFI) was used to evaluate the perceived functionality of upper-limbs before the use of the prosthesis and after 4 months of use. A descriptive analysis of the data was performed by each participant.

Study 2: Five children (two girls and three boys, 3 to 10 years of age) with absent digits (one traumatic and four congenital) participated in this study and were fitted with a 3D printed prosthetic hand. Gross dexterity, anthropometric measurements, active range of motion, and strength measurements were assessed before and after 6 month of using a low-cost 3D printed prosthetic hand. Seven separate two-way repeated measures ANOVAs [2 x 2; hand (affected versus non-affected) x Time (before and after)] were performed to analyze the data. A p-value of ≤ 0.05 was considered statistically significant for all comparisons.

Study 3: Nine children (two girls and seven boys, 3 to 16 years of age) with upper-limb reductions (one with traumatic finger amputations, one with transradial congenital reductions and seven with congenital digit reductions) were fitted with a 3D printed transitional prostheses. Their parents completed a survey at 1 and 3 months asking to quantify the time their child used the prosthesis on a daily basis in addition to the type of activities they performed with the prosthesis.

RESULTS

Technical Considerations: A practical guide to effectively and safely 3D print upper-limb prosthesis is presented. The manufacture of a prosthetic component or orthotic device is only a small part of the creation of a prostheses or orthoses. The components that are included in the completed prosthesis or orthosis must be adjusted and aligned by a properly educated, trained, and certified healthcare professional such as an orthotist or prosthetist.

Clinical Evidence:

Study 1: At 1 month and 4 months of use, the median change for hand function for the unaffected and affected limbs were -11% and -4% and -9% and -2%, respectively. The overall median change percentage for the perception of upper-limb functionality was -62%.

Study 2: There were significant hand × time interactions for the forearm circumference [$F(1,4) = 16.90$; $p = 0.02$], active ROM flexion [$F(1,4) = 12.70$; $p = 0.02$,], and active ROM extension values [$F(1,4) = 8.80$; $p = 0.04$]. There was no significant hand x time interaction, however, for wrist flexion strength [$F(1,4) = 1.48$; $p = 0.29$], and wrist extension strength [$F(1,4) = 0.05$; $p = 0.84$].

Study 3: Nine parents reported that their children used the device 1 to 2 hours a day, 3 reported using it longer than 2 hours and 1 reported using it only when needed. Furthermore, the parent also responded that their children used the device for activities at home (9), just for fun (10), to play (6), for school activities (4), and to perform sports (2). Four children reported malfunctioning and/or breaking of the 3D printed prosthetic device after 3 months of use.

CONCLUSION

The main finding of our studies is that the initial prosthesis design of the Cyborg Beast was not a functional solution for congenital pediatric patients with remnant opposition and pinch function (Study 1), but significantly increased forearm circumference (Before=16.70±1.86 cm and After=17.80±1.48 cm), wrist active ROM flexion (Before=54.60±14.48° and After=68.40±14.29°), and active ROM extension (Before=40.40±37.75° and After=47.00±36.42° cm) after 6 months of use (Study 2) and can be incorporated in several activities at home and in school. However, 44% of our research participants reported durability issues and/or malfunctioning of these devices after 3 months of use.

SIGNIFICANCE

Technical considerations and clinical evidence are crucial for healthcare professional interested in exploring the use of 3D printed prostheses for their patients. Although durability of 3D printed prostheses is a major concern, the practicality and cost effectiveness represents a promising new option for clinicians and their patients. The supervision of a certified prosthetist is crucial for the proper development and use of 3D printed prostheses.

REFERENCES

1. Zuniga JM, Carson AM, Peck JM, Kalina T, Srivastava RM, Peck K. The development of a low-cost three-dimensional printed shoulder, arm, and hand prostheses healthcare professional for children. Prosthetics and orthotics international. Apr 26 2016.
2. Zuniga JM, Katsavelis D, Peck J, et al. Cyborg beast: a low-cost 3d-printed prosthetic hand for children with upper-limb differences. BMC research notes. Jan 20 2015;8(1):10.
3. FDA. Technical Considerations for Additive Manufactured Devices. Available from: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm499809.pdf. 2016.

DISCLOSURE

Jorge M. Zuniga, Ph.D. and his research team are the designers of the 3D printed hand prosthesis Cyborg Beast.

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The Future of Craniofacial Prosthetics

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BACKGROUND

Craniofacial prosthetics for certified prosthetists.

The Impact of Medial Foot Wedge on Tibia Angle in Coronal Plane

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INTRODUCTION

The coronal plane motion is less studied compare to sagittal plane motion. However its effect is more diverse and acute. Medial and lateral wedges are used to reduce the biomechanical changes of the knee joint in varus or valgus deformities. There was no evidence found in the literature about effectiveness of the wedges on the tibia alignment. The purpose of this study was to assess the impact of medial foot wedges on the tibia angle in coronal plane.

This research work is focused to find the relationship between the medial foot wedge and the changes that it causes in the tibia angle in the coronal plane.

METHODS

23 healthy subjects, underwent the gait analysis without medial wedges and with 6 & 12 mm medial wedges. Different UK size medial foot wedges were manufactured considering thickness of the medial edge covering 2/3rd of the foot length. A modified Helen Hayes Marker placement system was used for the placement of the reflective markers. The tibia motion in coronal plane was recorded using Vicon® motion system. The data were analysed using IBM® SPSS® 21.0.

RESULTS

The minimum and maximum tibia angles (1.6° to 6.0°) in coronal plane, with and without the intervention of medial foot wedges, in stance phase were considered for analysis. There were no significant differences (p=0.05) recorded in tibia angles both with and without the wedges (Table-I). The mean tibia ROM (Range of Motion) shows 4.2° of tibia motion in coronal plan.

Side	Wedges Comparison (mm)		Angle	Mean Diff	Standard Error	Significance Diff (p)
Left	0	6	Min	0.042	0.083	0.615
	6	12		-0.064	0.086	0.456
	0	12		0.022	0.084	0.790
	0	6	Max	0.108	0.069	0.121
	6	12		-0.212	0.076	0.006*
	0	12		0.104	0.070	0.140
Right	0	6	Min	0.004	0.094	0.969
	6	12		-0.096	0.093	0.304
	0	12		0.092	0.101	0.360
	0	6	Max	0.129	0.084	0.127
	6	12		-0.072	0.083	0.385
	0	12		-0.057	0.082	0.491

Table-I. Significance Difference Between the Variables.
* Significant $p<0.05$

DISCUSSION

This study was the first to specifically assess the impact of the medial foot wedges on the tibia angle. Although statistically the results demonstrate no significant change in the tibia angle with the use of the medial foot wedges, however the data of tibia ROM in coronal plan would allow the researchers and clinician to better assess the patients needs.

REFERENCES

1. Butler RJ, et al. *J. Orthopaedic Research;* 25, 1121-27, 2007
2. Crenshaw S, et al. *J Clinical Orthopaedics And Related Research;* 375, 185-92, 2000
3. Haim A, et al. *J Biomechanics;* 41, 3010-16, 2008
4. Hinman RS, et al. *J Clinical Biomechanics;* 27, 27-33, 2012

THE USE OF OSSEOINTEGRATED TITANIUM IMPLANTS TO TREAT TRANS-TIBIAL AMPUTEES

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INTRODUCTION

Osseointegration has emerged as a novel approach to resolve persistent socket prosthetic issues by attaching the prosthetic limb directly onto the skeletal residuum. Until recently, this procedure has been performed mostly in trans-femoral amputee (TFA) patients. However, since August 2012, osseointegration has been performed on eligible trans-tibial amputee (TTA) patients in our centers. This paper represents the first pilot study to examine the results of performing osseointegration in the tibia. The objective of this study is to describe the reconstruction strategy and clinical management protocol used in the treatment of TTA patients with osseointegrated implants, as well as to report preliminary assessment of the safety and efficacy of the protocol in this particular group of patients.

METHODS

This is a prospective pilot study of 15 patients, consisting of 8 males and 7 females, aged 37-77 (mean 55.1) years at surgery, with minimum two-year follow-up. Selection criteria included age over 18 years, unilateral TTA patients who had socket-related problems. All patients received osseointegrated implants which were press-fit into the amputated limb. 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). Adverse events recorded included 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 for all outcome measures were observed. The occurrence levels of adverse events including the infection rate and revision rate were similar to trans-femoral osseointegration cases.

DISCUSSION

These preliminary results suggest that osseointegration surgery for trans-tibial amputees is a safe and effective alternative treatment for amputees experiencing socket-related discomfort. This protocol has the potential to expand the application of osseointegration to help patients who have below the knee amputations.

DISCLOSURES

Dr. Al Muderis consults for and receives royalties from companies including: Osseointegration International Pty Ltd (Australia), Osseo-PL Inc (USA), Osseo-PL GmbH (Germany), AQ Implants GmbH (Germany) and Permedica S.P.A (Italy).

Video Gait Analysis used in Online Learning for students of Orthotics and Prosthetics

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BACKGROUND

Observational Gait Analysis is a skill that is learned over time with practice. But Orthotics and Prosthetics schools have trouble getting patient models and the budget to support real-world observational gait analysis. Visual diagnosis of a patient's gait in real time is subjective, lacks accuracy and relies on the clinician's training and experience[1]. Online learning is becoming more popular and widely used in higher education, but there are concerns about how problem solving or critical thinking skills can be encouraged in online courses. Allen and Seaman (2011) found that thirty-one percent of all higher education students take at least one course online. With the increase of online learning, instructors must create authentic practices that will allow students to use the information in a more purposeful way. Content that has been provided with "hands on" instruction can be challenging to move online and if not implemented properly, will not prepare the learner for the work force. Clinical training sites have seen a decrease in productivity and some have limited these opportunities to students[2]. There is potential for using a video gait analysis tool to increase the student learning of the skill of observational gait analysis.

AIM

The overall aim was to investigate the effects of a video gait analysis learning management system on Master's students learning in Orthotics and Prosthetics.

METHOD

Firstly, students were introduced to an asynchronous online learning platform with the ability to conduct video gait analysis. Asynchronous online learning was used for every other week of content. Synchronous online learning was used for the other week content. Secondly, the students were surveyed about their experience with the new learning technique and asked questions about the different methods (asynchronous or synchronous online learning).

RESULTS

The methods of data analysis were based on the results of a survey of a 5 point Likert Scale. When asked if the asynchronous online video analysis content was useful, 54.55% of the students answered strongly agree, and 45.45% answered agreed. When asked about the synchronous online content was useful, 9% strongly agreed, 45.5% agreed, 9% neither disagreed or agreed, and 36% disagreed.

DISCUSSION & CONCLUSION

The literature suggests that other healthcare educators are also concerned with how to properly prepare students for the real world, since the apprenticeship model is fading away[3]. As healthcare educators, we can learn from the best practices of professions to ensure a successful implementation of online learning to encourage problem-solving skills and prepare our students for the work place. While the methods of Community of Inquiry (COI) and Problem-Based Learning (PBL) are well-known structures for online learning, there are a few other themes that were noted while conducting this investigation.

Orientation and Structure: It is not as simple as taking your content and putting it online. If deeper learning is the goal, faculty will need to be trained, and curriculum restructured[4]. To test the student's readiness for online learning, the Self-Direct Learning Readiness survey can be used. Students who score low on the SDLR prefer teacher directed activities[3]. But student performance in the course was not effected by whether the students were or were not ready for self-directed learning[3].

Facilitation: It is clear from the literature that moving from a teacher centered to a learner centered approach is vital in fostering the development of critical thinking. It is still important for the instructor to be present in the course, and light guidance is more effective than directives[3]. "Minimal but timely and critical encouragement by the Instructor" promotes a guided inquiry approach[5]. Students appreciate the the instructor asking tough questions that encouraged deeper thought[6].

Authentic Application: Developing skills to create lifelong learners is the best approach to prepare students for a "world that continually redefines itself"[7]. Traditional educational framework doesn't fit within the changing healthcare environment. Authentic learning environments and real work applications can increase student interest by giving the learner more responsibility for their learning[7]. Student satisfaction increases when the assignment are relevant[6].

Student's brains are changing, and we must change the way we teach in order to attract fun and engagement. Lectures are not effective in fostering higher level thinking [8]. If the skill we want to teach is to observe motion, then a multiple choice test is not going to measure a student's comprehension. Liddell et al. (2002) found that medical school students that utilized a tutorial session for learning a skill were more confident in applying their skills in practice and utilized their skills more frequently. Video Analysis provides an authentic assessment that can be measured in a real- life context but without patient models[9].

REFERENCES

1. Toro, B.; 2003 *Physiother Theor Pract*
2. Costello, E.; 2014 *Online Learning*
3. Gould, K.; 2015 *Jour of Online Learning & Teaching*
4. Czerkawski, B.; 2014 *Int Jour On E-Learning*
5. Kam, R.; 2012 *Higher Learning Research Comm*
6. Hosler, K.; 2012 *Educational Media International*
7. Barber, W. 2015 *Electronic Journal of E-Learning*
8. Issacs, G.; 1994 *Studies in Higher Education*
9. Gagné; 2005; *Principals of Instructional Design*

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