Factor Analysis of Upper Extremity Prosthetic Patient Acceptance

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INTRODUCTION

Although there have been a number of studies that have attempted to investigate prosthetic upper limb prosthetic acceptance, very few have provided conclusive evidence to assess the overall clinical probability of wear. In a recent survey of upper limb prosthetic practitioners collective estimations were made with respect to the priority of the various factors that contributed to Upper Limb rejection as well as the rejection rates by level. From these factors a Bayesian forecasting model was constructed to provide an initial estimation of prosthetic acceptance.

METHOD

From initial phone interviews and previous upper limb survey 12 factors were identified as possible contributors to overall acceptance including: Amputation Level, Functional Advantage, Patient Gadget Tolerance, Time to Initial Fit, Confidence of Prosthetist, Quality of Patient/Prosthetist Relationship, Socket and Harness Comfort, Weight, Cosmetic Quality, Therapy and Training, Peer and Family Support, and Age of Patient.

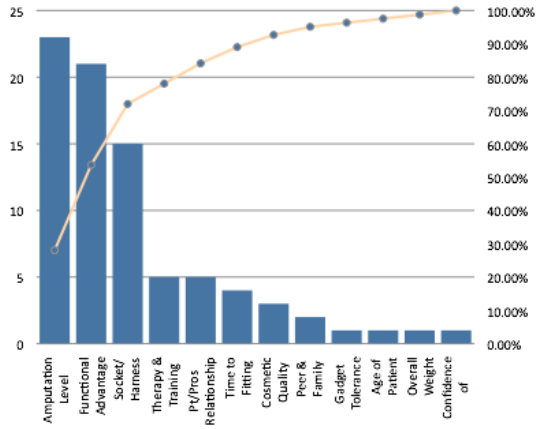
A survey was constructed and posted on a third-party survey hosting website from October 20 to November 8, 2013. There were 58 respondents who self-assessed their skill level which was normally distributed among novices, intermediates, experts, and specialists.

RESULTS

Their aggregate responses with respect to level were recorded to be 79.6% for transrandial, 57.8% for transhumeral, and 32.8% for shoulder disarticulation which is fairly similar to the original study done in 1958 which indicated 75% for transhumeral, 61% for transhumeral, and 35% for shoulder disarticulation (Berger, 1958). When asked about the degree of strength each factor affects acceptance the aggregate opinion was that “Amputation Level” was the highest at 79.6, followed by “Functional Advantage” at 78.3, “Socket and Harness Comfort” at 77.7, “Peer and family Support” at 76.3, “Amount of Therapy and Training” at 73.5 and “Quality of Patient-Prosthetist Relationship” at 72.6.

DISCUSSION

From this survey of the 12 factors those with the most consistent significance are listed in order: 1) Amputation Level, 2) Functional Advantage, 3) Socket & Harness Comfort, and 4) Peer/Family Support and 5) Prosthetic Competency. Many examinations fail to also include the important role of the peer and family support as well as the prosthetist-patient relationship. This could represent the consistency of smaller, but more innovative populations to accept technology.



CONCLUSION

There are methods of functional prediction in lower extremity prosthetics such as the AMPPRO Ambulation Test and Amputee Mobility Detector (AMP) (Gailey, 2001, Stevens, 2009) that utilize greater degrees of probability and forecasting. One factor is that clinicians and researchers have both attempted to find a single factor that can influence success or failure. The characteristic of the high rating for all of the factors may indicate that clinicians were unable to delineate between the factors and rank those with greater probability. This could be that different combinations of factors greatly vary from patient to patient, that prosthetists differ widely in their opinions about rejection, or that prosthetists in general do not have a grasp of why rejection occurs. There appears to be some discrepancies as to whether rejection and acceptance are converses of each other. The question remains why acceptance rates have been largely unchanged and vary so greatly.

CLINICAL APPLICATIONS

The amputation acceptance levels were used with the other factors using a 4-point value scale of .10, .25, .50, or .75 and calculated using Bayes’ Theorem for a number of case studies. Although not validated they may serve as analytic tool to assess subjective values of acceptance.

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STRATEGIES TO OPTIMIZE THE QUALITY OF LIFE FOR PERSONS WITH HIGH LEVEL UPPER LIMB AMPUTATION

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INTRODUCTION

This presentation focuses on the broad spectrum of factors influencing optimum patient rehabilitation in complex upper limb amputation cases. The foundation of this approach is based on the experience that our clinical team has developed while providing over 600 unique upper limb prostheses per year. The use of multiple outcome measures identifies challenges and maximizes rehabilitation potential in a complex and highly structured approach. These measures focus on: 1) identifying specific challenges and progress, 2) flexibility to modify the rehabilitation plan 3) use of the collective information received across the organization to identify trends so that the care model is always being optimized. Because most current validated outcome measures lack comprehensive information specific to this patient population, we have developed outcome measures to recognize factors influencing successful prosthetic rehabilitation.

METHOD

Subjects: Persons with upper limb absence, treated in our centers. Our baseline expectation is that the prosthesis will be well fitted, comfortable, well suspended and have optimized control strategies for the patient to control the device.

Apparatus: The team incorporates patient goals into a prosthetic care plan that leverages technology to design an innovative prosthesis to meet individual patient needs.

Procedures: Industry standard validated measures are administered at intervals to gauge progress and augmented by internally-developed innovative outcome measures, surveys and questionnaires. While not yet validated, the internally developed measures provide a more detailed insight into the factors that affect long-term prosthetic functionality.

Data Analysis: Feedback from all forms of outcome tools, inventories and surveys are integrated into a constantly updated treatment plan. These updates include prosthetic modifications, software and control input improvements and therapy modalities and exercises that shift from basic prosthetic management to complex tasks and home/community/work reintegration.

RESULTS

Our treatment plan builds on the foundation sited under Methods, with a comprehensive team approach throughout the lifetime of the patient care experience. Constant improvements to the evolving treatment plan are based on outcome results, survey feedback and wellness inventories. These tools keep the Center staff focused and cohesive as challenges and progression is managed for the individual patient. Family, household, work-place and community re-integration are factored into all treatment plans. The goal of personal independence is fostered and encouraged with each and every individual throughout each step of the rehabilitation process.

DISCUSSION

This presentation focuses on the bigger picture of factors beyond a well fitted prosthetic solution to achieve optimum patient rehabilitation in complex high level upper limb amputation cases. Utilizing a collaborative comprehensive team approach throughout the entire patient care cycle is critical in achieving the goal of independence for each individual. Key factors including a highly structured approach, the use of outcome measures, wellness inventories and patient satisfaction surveys are important indicators to assist the rehabilitation team in achieving the constantly evolving goals of the patient.

CONCLUSION

Clinical expertise in selection of appropriate technology for improved outcomes is essential. Innovative socket interfaces with a combination of components and sophisticated terminal devices maximize function. Concomitant training with therapists knowledgeable in the operation of this technology for optimal prosthesis utilization provides the foundation for patient success.

CLINICAL APPLICATIONS

Administering outcome tools, wellness inventories and patient satisfaction surveys allows the staff to optimize the rehabilitation experience. Those with advanced skill in treatment of this population can best facilitate patients in overcoming some of the unique obstacles they and their healthcare providers face. Return to independence is the key to success.

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MENTAL HEALTH SCREENING IN UPPER LIMB OUTPATIENT PROSTHETICS CLINICS: IDENTIFYING CHALLENGES TO PROSTHETIC REHABILITATION SUCCESS

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INTRODUCTION

Advanced Arm Dynamics includes wellness screening questions in our initial assessment of patients in order to comprehensively address any and all obstacles that may interfere with an excellent rehabilitation treatment outcome without the unnecessary burden and potential for patient perception of the stigma of a formal mental health evaluation. The wellness screening was carefully designed to inform prospective prosthetics recipients of how they compare to other people in areas such as coping style, perceived quality of life, and other areas that have been shown in the rehabilitation research literature to have an impact on how people perform after acquiring a physical disability.

METHOD

The Wellness Inventory (WI) is a short battery of seven validated screening instruments that measure resilience (J. Block & Kremen, 1996), health-related quality of life (OPUS), pain (SF-36/12), depression (Kirkcaldy & Tynes, 2006), alcohol use (AUDIT-C), drug use/misuse, and posttraumatic anxiety (PC-PTSD).

RESULTS

During the initial prosthetic assessment of 57 adult prospective prosthetics recipients, the WI was administered by the examining OT. During the informed consent process, the participants were advised that the wellness screening did not constitute a formal psychological evaluation, no patient-doctor relationship was formed with the consulting psychologist, and no diagnosis would be rendered. The WI was administered orally to the participants who read the large-print items and response choices along with the examiner. In order to minimize participant burden inherent in completing paper-and-pencil measures, the examiner recorded participant verbal responses on a standardized response sheet. The results were then scored and summarized in a brief summary report by a licensed psychologist with separate sections in the report for the insurer, the referring physician, and the clinical staff and suggestion of recommended topics to review with the participant.

The sample of participants was 78.9% Caucasian with mean age of 43.4. Of the sample, 75.4% had experienced traumatic amputation with an average of 9.2 years since injury. Over 50% reported that pain interfered moderately to extremely with their ability to perform their normal work. Of the sample, 49% screened positive for depression and 17.6% screened positive for PTSD. As indicated by their WI responses, participants were provided with referrals to appropriate mental health care providers.

DISCUSSION

The potential for mental health obstacles are quite prevalent at the time of initial contact in the out-patient prosthetic rehabilitation setting.

These results indicate the value of clinician awareness of potential challenges in upper limb prosthetic fitting in the out-patient rehabilitation setting. Clinicians' educated in the existence of these potential challenges may better serve their patients with this awareness and incorporation of clinical interventions to identify and address them.

The implementation of this screening tool and subsequent corresponding intervention adaptations allow for patient focused intervention and prosthetic rehabilitation techniques geared to mitigate potential obstacles to

CONCLUSION

High prevalence of mental health concerns in this sample of participants confirms the need to include screening at time of initial contact. The results of the WI are designed to promote patient self-understanding during treatment and beyond and, if indicated, to mobilize provision of mental health services by appropriate providers in their locale.

CLINICAL APPLICATIONS

The Wellness Inventory is designed to educate upper limb amputee patient as to potential obstacles to successful rehabilitation and to mobilize provision of mental health services by appropriate providers in the patient's locale.

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INNOVATIVE APPROACHES TO CHANGING FEATURES ON AN EXTERNALLY-POWERED PROSTHESIS

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INTRODUCTION

With the increasing functionality of many externally-powered multi-articulating hands, comes the question of how to best access all the features with available control strategies. Previous research has been done to determine various EMG-based and alternative control methods to improve more natural functioning [1,2]. There are scenarios that often raise questions related to maximizing functionality such as when an individual is limited to a single myosite to control the system and how they may take advantage of the available grip patterns.

METHOD

Several supplements to standard externally-powered control have been created. A recent development in control technology, grip chips™ are small, Bluetooth-enabled devices which utilize low-power frequency to communicate and access a variety of grip patterns. The i-limb™ ultra revolution hand detects and decodes the broadcasted data when within range of the grip chip. Each grip chip can be programmed to broadcast unique data that will place the hand in a grasp pattern/gesture, or it can make a new group of grasp patterns (known as a "favorite"). The form-factor and flexible nature of the grip chips allow for immediate grip access to perform a variety tasks.

A second supplemental control method, is a mobile app allowing for quick access to grip patterns by touching the desired grip (known as a "quick grip™") on a compatible mobile devices such as a smartphone or tablet. Licensed clinicians and users testing grip chips were asked how to best utilize these features.

RESULTS

Various ideas for the implementation of these tools were discussed and tested.

Quick grips were seen as an excellent means for testing various grip patterns/postures with novel tasks and in therapy settings in order to determine which grip patterns work best for the individual and with specific tasks.

Bilateral users of the i-limb ultra revolution, can activate features in both hands off of one grip chip. An example would be using a grip chip to put both i-limb hands in precision pinch mode during buttoning when dressing. This precision pinch would aid in this fine motor task and reduce the time typically required to have both hands enter functional features.

For grasp patterns that are frequently used for just one specific task, the benefit of the grip chip to enter that feature without the need of a trigger was seen as a benefit. For example, the mouse feature for a computer mouse would not be used for other tasks. Therefore, the grip chip could be attached to the mouse or nearby for easier access to that mode. A second complementary grip chip with index point could also be used when typing. Another example of the effectiveness of grip chips is the use of 2 finger trigger for cleaning supply spray bottles. The user could place a grip chip in the cabinet where the user keeps their cleaning supplies. A final example for a user is putting a grip chip programmed for don/doff near the closet to make dressing easier.

"Favorites" were seen to be beneficial for the features needed in the work environment and may differ from home, hobbies, or the car. For example, the user can create a group of grips that they find beneficial for driving to keep in the car. This favorite could then be activated either through the use of the app or with the grip chip left in that location.

DISCUSSION

With various options available for control, the clinicians involved must evaluate the users' ability to utilize these options and determine when to incorporate them into the fitting process. Basic control of the device is still needed prior to implementation of these additional features, modes, favorites, and switching options. Additionally, some users may not be comfortable with the technology of using the app-based system. They may benefit from the clinician setting up the various grip chips as their main means of changing features.

CONCLUSION

The addition of control with grip chips and a mobile app allow users to change grip patterns and hand features in new and innovative ways.

CLINICAL APPLICATIONS

Expanding options in grip patterns and positions for multi-articulating hands continue to be developed. The ability to control these features must also continue to advance to allow users to take advantage of the technology.

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Traumatic Upper-Extremity Amputations: An Epidemiologic Study using the National Trauma Data Bank

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INTRODUCTION

Major extremity trauma and amputations have been a recent focus of study given the high prevalence of extremity injuries in recent military conflicts. While many studies in the orthopaedic literature have focused on developing predictors of outcomes following severe lower extremity trauma in order to guide clinical treatment, there is little data examining the epidemiology and outcomes of severe upper extremity trauma. While the vast majority of major amputations are in the lower extremity, upper extremity amputation results in the highest levels of impairment of all extremity war injuries (Ficke and Bosse, 2011). Despite the impact of these amputations, the distributions of various upper extremity amputations and their relative frequency of complications and reoperations have not been described. We used the 2012 National Trauma Data Bank (NTBD) to evaluate these questions.

METHOD

Subjects: 421 subjects who underwent an upper-extremity amputation secondary to trauma were gathered from the NTDB. The NTDB draws from 900 trauma centers from around the U.S. and contains over three million incident trauma cases. *Procedures*: We conducted a secondary data analysis of the 2012 NTDB Research Data Set, using means and frequencies to characterize our patient population and describe the distribution of upper limb amputations. *Data Analysis*: Multivariable regression models were fit in order to identify which variables significantly influence length of hospitalization, rate of reoperation, and adverse surgical complications.

RESULTS

A total of 421 patients underwent an upper-extremity amputation secondary to a traumatic upper limb injury, representing 0.05% of all NTDB trauma admissions. 80.1% were male and 19.9% were female. 66.8% were White. The 421 patients had 595 amputation-related procedures performed. Table 1 shows the incidence of amputations, re-amputations, and proximal extension procedures at the four most frequent levels. The most frequent diagnostic codes for all upper limb amputations were traumatic amputations of the forearm or hand (6.6%), traumatic amputations of the upper arm (4.8%), and open fractures of the humerus (2.0%). 15.4% of amputees experienced major post-surgical complications. The most frequent major complications included pneumonia (4.9%), organ/ space surgical site infections (3.1%), and acute kidney injury (2.7%). Table 2 provides the incidence of major complications, average length of hospitalization, and percentage of patients needing assistive care in a specialized nursing or rehabilitation facility following discharge. Predictors of major post-surgical complications included Injury Severity Score (ISS) ($p<0.001$) and the presence of compartment syndrome ($p=0.003$). Risk factors for amputation among those with an open forearm fracture included age ($p=0.005$), location of the fracture (proximal greater than distal) ($p=0.002$), and presence of compartment syndrome ($p=0.043$).

Amputation Level	Frequency (%)	Re-amputations (%)	Proximal Extension (%)
Through Humerus	32.3	29.3	2.0
Through Elbow	7.5	34.3	8.6
Through Forearm	25.4	29.7	7.6
Through Hand	13.3	8.1	4.8

Level	Hospitalization (days)	Complications (%)	Discharge (%)
Through Humerus	18.8	18.4	44.1
Through Elbow	15.6	20.0	40.0
Through Forearm	15.1	13.9	60.2
Through Hand	12.0	10.9	65.5

DISCUSSION & CONCLUSION

We report a high rate of complications and reoperations among trauma-related upper limb amputees. We identified predictors for post-surgical complications and amputation that have not been described in the literature. Future therapeutic studies should focus on modifiable risk factors for re-amputation and surgical outcomes.

CLINICAL APPLICATIONS

Traumatic Upper-Extremity Amputations: An Epidemiologic Study using the National Trauma Data Bank

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This work will contribute to the sparse epidemiologic literature on traumatic upper-extremity amputations and provide prognostic information for patients with limb threatening injuries.

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A Focus on the Patient Experience:

Advanced Upper Limb Prosthetic Rehabilitation vs. Hand Transplantation

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INTRODUCTION

Dramatic advances have been made in electric multi-articulating hands and hand transplantation surgery during the last several years. There has been little "cross-transfer" of information however, between the worlds of upper limb prosthetics and hand surgery. The need to bridge these gaps becomes more evident when individuals, who have sustained unilateral and bilateral limb loss, seek to find the most appropriate direction to pursue in trying to achieve functional independence. It is critically important to enable these individuals to understand the important aspects of; time from procedure to "function," costs, amount of therapy required, medications, potential complications, sensation , pinch and grasp , functional outcomes, as well as the appearance the hand. To date there has never been a national or international effort to compare these domains as they relate to the patient experience following prosthetic rehabilitation and hand transplantation, and how these individuals would define "success."

METHOD

Five unilateral and bilateral transradial amputees, and five unilateral and bilateral hand transplant subjects, from the United States and Austria will be presented as it relates to their unique rehabilitation experience specific to receiving a state-of-the-art multi-articulating hand prosthesis, or receiving a composite tissue allotransplantation, also knows as a hand transplant. The specifics of the evaluation and preparation for prosthesis or transplant, duration of therapy required, time frames of function, potential complications, costs, and both subjective and objective outcomes of these ten individuals, are presented in a manner that captures the salient features of amputee rehabilitation and the hand transplantation experience.

RESULTS

To date there is not a uniform assessment or metric that captures the outcomes of these distinctly different patient populations. The learning objective of this presentation is to present the overall patient experience following transradial prosthetic rehabilitation, and hand transplantation, and relate that "success" as these individuals define it.

DISCUSSION

As significant advances are being made in the field of electric multi-articulating hand technology, hand transplantation surgery has produced dramatic functional results as well. .

CONCLUSION

It is incumbent upon all of us to be as educated as possible about each aspect of these patient experiences, and the outcomes possible, so we can assist the individual with upper limb loss, to make the most informed decision, as it relates to each of these unique opportunities and options.

CLINICAL APPLICATIONS

The information gathered can be used to improve the patient experience by helping them understand the important aspects of time from procedure to "function," costs, amount of therapy required, medications, potential complications, sensation , pinch and grasp , functional outcomes, as well as the appearance the hand.

PARTIAL HAND SOLUTIONS INVOLVING A COLLABORATIVE MULTIDISCIPLINARY APPROACH

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INTRODUCTION

According to studies (Dillingham, MacKenzie 2002), there are approximately 16,000 amputations performed at a level distal to the wrist every year and proximal to the wrist number around 1,600 per year. Until recently, the vast majority of available prosthetic components and technology advancements have focused on the smaller subgroup. The functional benefit of prosthetic usage for patients with multiple finger amputations proximal to the DIP joint has been demonstrated both in terms of measurable "improvements in 3-finger-pinch and grip strengths" and the "global subjective improvement in the ability to perform activities" as reported by patients themselves (Lifchez et al. 2005). We also know that studies indicate several factors for abandonment. Those include comfort, training, experience of the clinic team, being part of the decision process, function and others (Biddiss, Chau 2007).

A thorough clinical evaluation with a team including the patient, prosthetist, therapist and surgeon will give a rounded approach to the options both surgically and prosthetically (Carlsen, Prigge 2014).

Socket design is paramount for the partial hand amputation level. It must be designed to maintain suspension, maximize functional wrist utilization and enable all functions remaining in the hand. Selecting the components that fulfil the patient's functional needs and utilizing an expedited fitting procedure is necessary to see quick achievement of optimized fittings.

METHODS

Two cased studies will be presented focusing on the care given by a multidisciplinary team to address surgical, therapy and prosthetic considerations to enhance function.

LEARNING OBJECTIVES

1. Understand the potential a multidisciplinary team has to maximize patient outcome. This includes surgical options, therapy considerations and prosthesis design.
2. Identify critical design features of partial hand sockets
3. Understand the passive functional options for partial hand amputations

CASE STUDY 1

Patient is a five-year-old male with bilateral partial hand loss secondary to a fall into a day old camp fire pit at 13 months of age. The original presentation was bilateral transmetacarpal partial hands with no fingers or thumbs present. At age four the parents opted to have a toe transfer done on his right hand.

A passive functional device was devised and patient was trained for proper use and positioning. He uses the device daily while at school and for other daily activities.

CASE STUDY 2

57 year old male with bilateral partial hand amputations, MCP level at fingers and thumbs, secondary to severe frostbite in 2012. In 2013 he underwent a great toe transfer. The surgery was successful but he had no ability to grasp anything with the thumb because there was nothing to oppose it. The physician considered doing other toes but his health and physical conditions of the vessels supplying his toes were not ideal to consider transferring a smaller toe. This left a dilemma as the toe transfer alone did not produce the functional outcome desired.

A device was fabricated and intensive therapy was performed to educate the patient on his prosthesis.

With the prosthesis the patient was more independent with his ADL's. The physician after seeing the functional advantages of this device has scheduled a toe transfer for his other hand.

CONCLUSION AND CLINICAL APPLICATIONS

Case studies demonstrate how this collaborative approach has led to unique information and idea exchanges between surgeons and prosthetics teams to explore detailed surgical approaches such as toe to hand transfers that subsequently require the most current socket design and advanced prosthetic technology to successfully fit partial hand amputations. The synergy between the teams produces results that individuals acting alone cannot achieve.

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FORCE LIMITING AUTO GRASP (FLAG) – ENHANCING FUNCTION OF ELECTRIC TERMINAL DEVICES

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INTRODUCTION

A high pinch force electric terminal device (TD) may reach pinch forces of 20-25 lb (88-110 N) in an instant, potentially crushing a fragile object.

New myoelectric TD wearers typically do not have well-developed proportional control. They must be cautious to control their grip force, especially using their TD around children. The goal of this project was to develop a simple, easily enabled force limit feature so the wearer of a high-force myoelectric hand can easily limit their pinch force whenever desired.

Specific Criteria:

-The wearer must be able to turn the feature on/off at will, and control pinch force predictably and easily.
-When enabled, the limited pinch force must safely handle a light plastic cup, an eggshell, or a child's hand, and also allow incrementally increasing the force to reach a desired level of grip force.
-Auto-grasp is also desired, i.e., automatic response to electrode slip or loss of contact with skin.

METHOD

The FLAG feature was designed to be integrated into electric hands and hook-type TDs, manufactured by Motion Control. A small, efficient force sensor is utilized to determine the lightest possible pinch force, after the FLAG feature is enabled, and controls are integrated into the on-board microprocessor, with new control software & firmware, and a 'beeper', for audible feedback.

The wearer enables FLAG by a simple "hold-open" command, for 3 sec.- a 'beep' confirms success. The next grip by the TD is limited to ~2 lb. Each additional 'pulse' of the input signal increases the force ~2 lb. To disable the feature, the wearer repeats the 'hold-open' sequence, confirmed by a double 'beep'.

A randomly selected subset (n=6) of those currently utilizing the feature volunteered to respond to a short questionnaire, usually by phone. All subjects are adults, wearers of myoelectric TDs, all with unilateral UE limb loss, either transradial, or transhumeral. Two subjects were novice wearers of a myoelectric TD, one of whom also used single channel control.

Subjects have used the FLAG feature one month at least, and length of prior experience varies from one month to over 11 years.

RESULTS

FLAG SURVEY OF WEARERS (n= 6)

	SUBSET OF QUESTIONNAIRE QUESTIONS	Yes	No
1	FLAG increases the tasks performed	5	1
2	FLAG provides an additional benefit	5	1
3	FLAG is easy to turn ON and OFF	6	0
4	FLAG 'Beep' is easy to hear	6	0

Figure 1- The six subjects questioned so far felt their number of tasks have increased, adding benefit to their prosthesis. The interviews reveal that the more experienced wearer needs the FLAG feature less than new wearers, whose control of pinch force is less secure.

	TASKS PERFORMED w/ FLAG:	Used	Not Used
1	Holding Plastic Cups & Water Bottles	6	0
2	Handling/Playing With Children	6	0
3	Holding Foods, e.g., cone, Fresh Fruit, Toast	5	1
4	hobby and work activities	6	0

Figure 2- From the interviews, some tasks are common to nearly all users. The everyday handling of disposable cups and drink bottles, fresh fruit, ice cream cones, are accomplished more easily with FLAG, and playing with children is safer.

DISCUSSION

Clearly, the FLAG users generally found the feature beneficial, and cited increased utilization of their prosthesis because of it. Due to limited space, the tables do not cite the length of usage, but the most experienced wearers all wished they had the feature *while learning* to master proportional myoelectric control. Even so, all but one of the six surveyed felt the feature added to the tasks they could perform with their prosthesis, and also provided new benefits. No User Interface (U.I.) is required for FLAG as yet, but it is planned for future implementation, to allow adjustment to the wearer's preferences.

CONCLUSION

The new FLAG feature makes a positive contribution to wearers of electric TDs, and has been shown to be easy to learn and to enable/disable at will in daily use.

CLINICAL APPLICATIONS

Safety and security of using a high pinch force electric terminal device are enhanced by utilizing the FLAG feature. New wearers are especially aided, while

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developing their control skills, since FLAG helps avoid damaging fragile objects, or alarming children.

NOVEL UPPER LIMB PEDIATRIC PROSTHETIC DESIGN: A CASE STUDY

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INTRODUCTION

The decision to fit a child with a prosthesis at an early age is a complicated matter. Varied rates of acceptance and rejection have been reported. Studies have indicated lack of function and lack of comfort as reasons for rejection (Wagner et al., 2007 & Postema et al., 1999). When presented with the challenge of fitting a child with bilateral absence at the elbow the authors strove to design a prosthesis system that would address these two concerns.

METHOD

Presented is a case study of a boy with bilateral congenital absence at the elbow. At the time of initial evaluation he was four and half months old. In a review of relevant literature the authors found little guidance on what to fit for this patient's presentation. Prosthetic componentry appropriate for the patient's age and level of amputation were limited. A variety of novel solutions were created.

Passive Prostheses

At seven and a half months the patient was seen for initial fitting of passive prostheses. The prostheses utilized roll-on silicone liners and lanyards secured on the lateral frame for suspension. This method allowed the parents to quickly don the liners and secure the prostheses and eliminated the necessity of a harness.

Available pediatric elbow components available did not provide internal and external rotation while maintaining an appropriate prosthetic elbow hinge center. A pair of passive positional joints with detent resisted motion, previously designed for use as adult finger joints, were used for the elbow hinges. The diminutive size of the joints allowed them to be mounted to the forearm section in which the humeral section could rotate.

Figure 1. Myoelectric Prosthesis

Figure 2. Patient at 22 months of age

Myoelectric prostheses

At 18 months of age the patient returned for initial fitting of myoelectric devices. The adjustability of the sockets was a larger concern as it was important for these devices to be usable for a longer period of time. Donning accuracy was also an inherent concern as skin and electrode contact was necessary. Lanyard suspension was again used. Holes were cut into the roll on liners to allow for skin contact with the electrodes. In order to maximize volume adjustability free floating panels of rigid frame and socket were created from the anterior, posterior, and medial walls. A BOA™ mechanical lacing system was utilized to create the closure. The resultant socket and frame system was very flexible and adjustable while also being firm and stable during use. Ease of donning and doffing was improved due to the increased visibility to the channels for the lanyard. The parents were able to visually confirm the location of the holes in the liner and manually position the electrodes during the donning process. This drastically improved the repeatability of electrode contact.

A new larger joint was designed and fabricated to provide a detent resisted motion similar to the previous joints but able to resist the greater weight of the terminal devices. The joint was affixed to the forearm section with a single pivot point distally that allowed approximately 45 degrees of rotation in both internal and external rotation.

RESULTS

Passive Prostheses

The passive prostheses were accepted well by the patient and no signs of distress or discomfort were noted. The patient was able to "hold" objects and in most cases chew on them. Patient and parents preferred unilateral wear times as the contralateral limb was available for sensory input. Normal range of motion maintained.

Myoelectric prostheses

As with the passive devices the patient showed no signs of distress and tolerated donning and wear well. Normal shoulder range of motion was observed. At 22 months of age the patient demonstrated active operation of terminal devices in order to grasp objects. Bilateral wear times were more common and tolerated.

DISCUSSION AND CONCLUSION

The designs presented were successfully integrated into daily life by the patient and the parents. The custom nature of the components used provided the pathway to success. Finding creative ways to maximize function and comfort does not guarantee continued use but does provide the best opportunity for successful prosthetic usage.

CLINICAL APPLICATIONS

This case has clinical relevance to pediatric upper limb prosthetic fittings.

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FIRST CLINICAL FITTING OF AN INDIVIDUAL AFTER BILATERAL TMR WITH PATTERN RECOGNITION CONTROL

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INTRODUCTION

Targeted Muscle Reinnervation (TMR) surgery (Kuiken et al., 2009) and pattern recognition (PR) are two synergistic technologies that greatly enhance prosthesis control. Through nerve transfers to spare 'target' muscles, TMR provides increased access to motor control data for high-level upper limb amputees. Pattern recognition algorithms decode this information to enable intuitive control of many degrees of freedom (DOFs). Even in bilateral amputees, TMR has previously been performed on only one limb. In 2011, TMR surgery was performed bilaterally for the first time. The patient was subsequently fit bilaterally with Complete Control PR control systems (Coapt LLC). This case study outlines the successful clinical fitting and functional outcomes of a bilateral upper limb amputee using PR-controlled myoelectric prostheses after TMR. Surgeries were performed at Northwestern Memorial Hospital (NMH) in Chicago; prosthetic fittings and occupational therapy took place at the Rehabilitation Institute of Chicago (RIC).

METHOD

In 2010, a 43-year-old male lineman sustained a severe electrical burn injury and required a left-side amputation at the shoulder-disarticulation level and a right-side amputation at the transhumeral level. TMR surgery was first performed on the patient's left side in January 2012. Four months later, TMR surgery was performed on his right side; a gracilis muscle free flap was surgically transferred from his right leg due to loss of the biceps muscle. In August 2012, the patient was first fit with a conventionally controlled myoelectric prosthesis on his left side. Occupational therapy (three, one-week visits, with daily sessions each lasting about 90 minutes) began at this time and focused on myosite strengthening, developing a home exercise program, prepositioning, and grasping and releasing in various planes of movement. At discharge from therapy, he was able to pick up and release light objects on a table. However, he could not perform his identified goals of feeding himself or drinking from a cup or bottle.

In September 2012, the patient was introduced to PR control on his right side through custom software (CAPS) (Kuiken et al., 2009) and a virtual reality system. Training, which totaled five hours, included establishing repeatable and unique movements. The patient used an IRB-approved research prototype PR controller for three months at home on his right side. In November 2013, both of the patient's prostheses were fitted with Coapt Complete Control PR system. At this time, the patient received occupational therapy for four days and used PR control on his left side for the first time.

RESULTS

During the November 2013 fitting, using the commercial PR systems, the patient quickly became proficient at using both his prostheses. He was able to perform the same movements on both sides (e.g., hand open with the right and left electric terminal devices (Motion Control) at the same time, as well as opposing movements (e.g., wrist pronation on the right and wrist supination on the left), also at the same time. Additionally, in outcome measures (the Box and Blocks and Clothespin Relocation tests), the patient demonstrated comparable functional control on both sides using PR, despite the different amputation levels. In the Box and Blocks test, he was able to move an average of 10 blocks using his left-side device, even though it was his first experience of using PR on his left side.

Using the PR system, the patient easily controlled elbow function. He also demonstrated proficiency at retrieving and placing crushable cups in a cupboard, folding towels, pouring water from a bottle to a cup, drinking from a water bottle, feeding himself finger foods, and carrying a laundry basket. At his six-month follow-up visit in May 2013, the patient was able to perform several functional tasks, including eating with a fork, preparing simple meals and cleaning up, and completing yard work.

DISCUSSION

Although the patient received much more occupational therapy training for conventional myoelectric control than for PR, he was unable to perform functional tasks using conventional control. With PR, the patient could perform the same movements and opposite movements bilaterally and at the same time for all DOFs. The cognitive load imposed by conventional control would make such movements very challenging to perform, indicating that PR control is more intuitive.

CONCLUSION

Pattern recognition is now commercially available, and TMR continues to be performed in hospitals worldwide. Together with effective occupational therapy, these technologies provide improved prosthesis control for upper limb amputees.

CLINICAL APPLICATIONS

TMR is a clinically accepted procedure. PR is now a viable option that clinicians can consider in the treatment of individuals with upper limb amputations.

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A Unilateral Three-Loop Energy Flow Model at the Peak of Ankle Power Generation in Human Gait

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INTRODUCTION

An energy flow method for human movement was published in late 70's. Its beauty lies in the capability to integrate kinematics and kinetics and it offers a natural and systematic tool to explore the biomechanical behaviour of human movement, the mystery of which would not be easily discovered otherwise. However, the method involves linear algebra and abstract concepts, which becomes such a barrier that the application of the method has not been recognized.

The objective of this research was to introduce and analyze a graphical model of a unilateral three-loop mechanical energy flow in a unique way to explore the biomechanics of the ankle push-off.

METHOD

Subjects: 10 able-bodied young subjects.

Apparatus: A gait laboratory equipped with Optotrak motion system and two AMTI force plates.

Procedures: Subjects were asked to walk with shoes along a 10-meter walkway at self-selected speed. Kinematic and kinetic data were collected.

An Energy Flow Model: By taking the mean value, a mechanical energy flow diagram of the right leg at the peak instant of ankle push-off is shown in Figure 1. The Joints are marked with circled plus (power generation) or minus (power absorption) signs. Squared upwards (or downwards) arrows from bar are for the segments, where upwards direction means increase in energy change. Joint powers (ground, ankle, knee and hip) and segmental energy change rate (foot, shank, thigh and pelvis) of the right leg during a gait cycle were computed and shown with numbers in Watt/Kg. The arrows and numbers showing the amount of energy flow in Watt/Kg were used to depict energy flows either going into a joint to a segment (inflow) or the other way around (outflow). In Figure 1a, there are two rows of energy flows, upper one (rotational energy flows) and lower one (translational energy flow). A simplified model is shown in Figure 1b where the thick arrows are the net energy flows.

RESULTS

There exist three biomechanical loops in a unilateral energy flow model, i.e., an ankle loop, a knee loop and a hip loop, each of which presents how the rotational and the translational energy flows are configured between two respective segments. At the peak of the ankle push-off (Figure 1a), the ankle loop or the hip loop was characterized by a caudally directed power source and a cranially directed translational energy flow. The caudally directed power source such as the ankle or the hip relayed the proximal segment outflow and reinforced it before transmitting it to the distal segment. The knee loop was differentiated from the loops of the ankle and the hip by a confluent power sink.

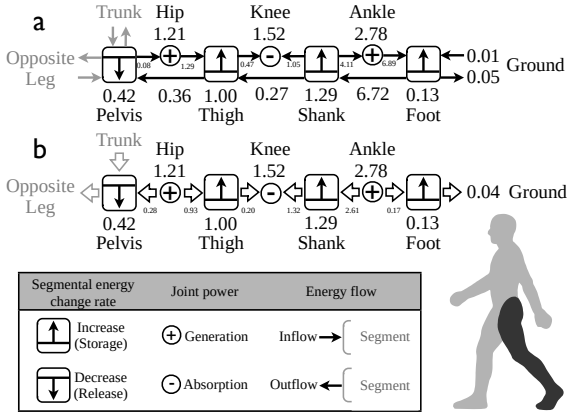

Figure 1. A unilateral energy flow model for human gait at the peak of ankle push-off power generation. a, A detailed model involving both rotational and translational flows and showing three biomechanical loops. b, A simplified model showing net flows only.

Within the ankle loop, the ankle accepted a shank outflow (4.11), boosted it with the generated ankle power (2.78), and produced a boosted foot inflow (6.89), which was about 2.5 times as much as the ankle power alone. At the same time, the foot that kept only 0.13 Watt/Kg for itself, an almost perfect convertor, converted the boosted energy flow into a cranially directed translational flow of 6.72 Watt/Kg that mostly was used to push the shank to move cranially. The shank tilted anteriorly, through which it used 4.11 Watt/Kg to resist against the ankle plantarflexor and also 1.05 Watt/Kg to resist against the knee extensor.

The knee in its loop absorbed the power of the merging shank and thigh outflows. The shank reserved a fair amount of mechanical power (1.29) but could only contribute very little amount of translational power (0.27) to the flexed thigh.

The hip, a caudally directed power source, relayed a weak pelvis outflow of 0.08 Watt/Kg, boosted it with

A Unilateral Three-Loop Energy Flow Model at the Peak of Ankle Power Generation in Human Gait

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its own power of 1.21 Watt/Kg to flex the thigh. While keeping 1.00 Watt/Kg for itself, the flexed thigh used 0.47 Watt/Kg to resist against the knee extensor and 0.36 Watt/Kg to push the pelvis cranially. The pelvis received the inflow of 0.36 Watt/Kg but required extra power to store 0.42 Watt/Kg for itself, let alone outflow to the trunk.

CONCLUSION

The three essential loops in the energy flow diagram have told us an in-depth story about the push-off in human gait. The foot might be more important than the ankle because it converts a rotational energy flow of the boosted ankle power into a cranially directed translational energy flow of a great amount. The joints modify the movement of the shank and the thigh, and thus prevent detrimental effects in order to maintain human gait.

CLINICAL APPLICATIONS

The energy flow model of human gait can be used to analyze the pathomechanics of human movement for the design of prosthetic and orthotic devices.

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The Edinburgh Visual Gait Score and the Prosthetic Observational Gait Score as Outcome Measures in Orthotics and Prosthetics

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INTRODUCTION

Visual diagnosis of a patient's gait in real time is subjective, lacks accuracy and relies on the clinician's training and experience (Toro, 2003). Observation of a moving activity is difficult, because of the limited ability of the eye to discern rapid motion (the flicker fusion rate of the eye is about 16Hz for most people, making it physically impossible to see events lasting less than 60 ms or so) and the complexity of many body segments moving simultaneously. (Kirtley) Gait assessment assists in determining the degree and cause of abnormality and it can be used as an outcome measure to evaluate the effectiveness of interventions (Kawamura, 2007).

A recent article in Gait and Posture systematically reviewed observational gait assessment tools in pediatrics. The review found the Edinburgh Visual Gait Score (EVGS) to have better reliability and validity than the other tools. The Prosthetic Observational Gait Score (POGS) was adjusted from the POGS for unilateral lower limb prosthetic users.

This review will summarize the research that has been done on the EVGS and POGS.

METHOD

A comprehensive computerized bibliographic databases search was performed in the following databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 to current), Clinical Pharmacology, Cochrane Library, Excerpta Medica Database (EMBACE; 1980 to current), Journal Citation Reports, NUcat, Ovid MEDLINE, PubMed (1966 to current), PsycINFO (1806- current), Scopus, Web of Science, and The Journal of Prosthetics and Orthotics Online Library (1989- current). The following search terms were used: (Observational gait assessment) AND (Observation Or Video) AND (Gait OR Walk) AND (Analyze OR Assess).

Only observational and video gait analysis tools that assess gait were included. Studies on Instrumented Gait Analysis (IGA) data alone were excluded. Dissertations, conference abstracts and other sources of unpublished that were studied by a reputable institution were included.
In addition, the citations and bibliography were scanned and examined for inclusion.

RESULTS

Several observable gait assessment tools have been developed over the past two decades for use in Prosthetics and Orthotics. Each tool was reviewed for consistency and reliability. The most reliable tool in the literature was found to be the Edinburgh Visual Gait Score. Ong et al investigated the reliability and validity of EVGS for inexperienced observers and found that inexperienced observers were reasonably reliable and ranked scores similarly but less accurately than their experienced counterparts (Ong, 2008).

The Prosthetic Observational Gait Score was developed based on the Edinburgh Visual Gait Score for unilateral lower limb amputation. The score established good intra-observer repeatability; however, at best moderate inter-observer repeatability was reported initially.

The University of Strathclyde and the National Health System in Wales have been studying the effects of using observational gait scores with video analysis tools to increase the reliability. The studies involving video analysis suggest that video increases the inter-rater and intra-rater reliability of the EVGS and POGS Gait Scores.

DISCUSSION

While Instrumented Gait Analysis (IGA) is the accepted gold standard, each session can take approximately three to six hours for assessment and interpretation (Narayanan, 2007). IGA is needed to prove the validity of observational gait assessment tools, but it is not a practical outcome measure for clinicians. Clinicians require simple and cost-effective outcome measures to analyze the kinematic parameters of gait in their day-to-day practice (Rathinam, 2014).

CONCLUSION

Observational gait tools are often and widely used as an essential tool for an assessment of gait problems. (Rathinam, 2014). The research done on the EVGS and POGS suggest that these are the best observational gait assessment tools available to clinicians in Prosthetics and Orthotics. The EVGS and POGS provide a systematic, repeatable, and methodical approach to observational gait analysis.

CLINICAL APPLICATIONS

The EVGS [and the POGS] are extensive tools to identify gait deviations and are sensitive enough to pick up changes following intervention (Gupta, 2012). Observational and video observational gait assessments provide a simple and easy to use tool for clinicians to integrate into practice.

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Analysis of Bamboo Reinforced Composites for use in Orthotic and Prosthetic Application

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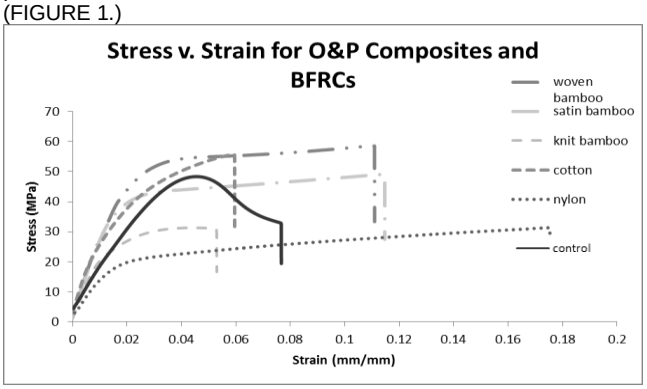
INTRODUCTION

Bamboo fiber reinforced composites (BFRCs) were found to have many improved mechanical characteristics when compared to the plain resin, cotton, nylon and carbon fiber for the reinforcement for orthotics and prosthetics (O&P). Laminations in O&P are typically made with high strength material such as carbon fiber on the inner and outer surfaces with a cotton or nylon core to enhance resin retention. Due to the fact that BFRCs are able to be produced sustainably and manufactured with mechanical properties either equal or superior to current O&P materials, it is anticipated that they will be able to replace many of the synthetic fiber reinforced composites in orthotic and prosthetic laminations (Taj et. al, 2007).

METHOD

4 layers of bamboo fiber (plain woven, satin woven and knit (Bamboo fabric store, Hackensack, NJ) were formed into composites using Acsys acrylic epoxy resin (Acsys Orthopedic, Cedar City, UT) over a polypropylene mold. Multiple batches of BFRCs were produced and analyzed through tensile (ASTM D638) and 3-point flexure (ASTM D790) using an Instron (Instron, Norwood, MA. Scanning electron microscopy (SEM) was done to image the fracture surfaces. The BFRCs were compared against typical fibers used in O&P (cotton, nylon and carbon fiber) using the same process.

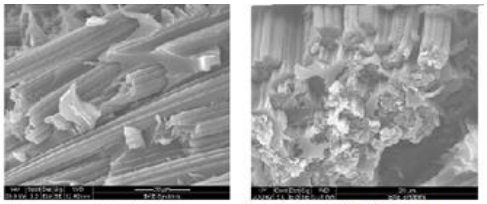
(FIGURE 1.)



RESULTS

The composites demonstrated minimal batch variation at the 95% confidence interval when comparing ultimate tensile strength (UTS) and strain upon failure. The BFRCs show comparable strength to, greater stiffness than and higher strain to fail than cotton fiber reinforced composites (CFRCs). The BFRCs demonstrated significant gains in strength: (σ_{uts} +13%), ductility (ε_f +75%), and elastic modulus (E +79%). Plain woven BFRCs demonstrated optimal mechanical properties when compared to the satin and knit fabrics. Woven BFRCs and CFRCs were found to have the greatest UTS while the nylon composites had the greatest strain-to-failure. While the carbon fiber composites showed significantly higher flexural and tensile strength, there was a limited range of strain to failure and deflection from neutral axis (Fig1). This results in a high risk of catastrophic failure with strain or deflection.

The SEM images (Fig 2) show that there has been resin saturation through the fiber matrix, but no chemical adhesion or wetting between the fibers and the resin. A decrease in the degree of fiber wetting was found to have a detrimental effect on the mechanical properties of the given composite(Okubo et. al, 2004). The topics of fiber hydration and surface modification will be investigated further as this research continues.



(Figure 2 SEM imaging of the samples)

DISCUSSION

The BFRCs have displayed a much higher strain to failure and deflection from neutral axis than the carbon fiber reinforced composites. This suggests that the material will plastically deform rather than catastrophically fail due to excess stress. This feature is very important regarding orthotic and prosthetic device security and patient safety.

CONCLUSION

Woven BFRCs were found to have the potential to replace cotton and nylon composites. Additional research will be conducted to further improve and understand the mechanical properties of these materials and evaluate their performance in full scale orthotic and prosthetic devices. This research begins to provide a standard for material selection to ensure specific device qualities.

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QUANTIFYING COMPENSATORY MOTION OF AMPUTEES FOR IMPROVED PROSTHETIC PRESCRIPTION AND TRAINING

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INTRODUCTION

At the University of South Florida, the Robotic Human Body Model (RHBM) was created with the goal of improving upper extremity prosthetic prescription, training, efficacy and design (Lura, 2012). Currently the 25 degree of freedom (DoF) model predicts the movement of able bodied subjects using a weighted least norm (WLN) solution algorithm (Dubey, 1995). The algorithm assigns appropriate penalization weights (PW) which restrain each joint based on how high the value is. However it was simpler to incorporate the WLN in the RHBM by using the inverse of the PWs, so higher values of these coefficients translate into greater mobility. The RHBM will use the joints that have the least penalization more to achieve a position and orientation in space. This helps to select the optimum joint angles for the desired position and orientation. In the context of human motion simulation, the algorithm will achieve a human-like pose by using the same joints a human would. This will help selecting a prosthesis that will allow the amputee to perform tasks with minimal compensatory motion. The purpose of this paper is to compare the PWs between able- bodied subjects and amputees in an effort to quantify compensatory movement

METHOD

Ten able bodied persons and five males with an amputation on the left side below the elbow (transradial amputees) participated in the study. They performed activities of daily living (ADL) including drinking from a cup, brushing hair, eating using a fork and a knife, lifting a laundry basket and opening a door. Movement was recorded using a Vicon (Denver, CO) motion capture system. The movement data were imported to Matlab (Version 2011, Mathworks, Natick, MA). Joint centers (JC) and joint angles of the upper limbs and torso were calculated. Using those data a 25 degree of freedom (DOF) model was created for simulation. A PW value was generated and assigned to each JC. Each PW value changes the probability of the JCs utilization. This allows the model to simulate the appropriate joint to use to perform a task in a human like way

RESULTS

In Figure 1 the inverse of the PWs with the most interest are compared, the higher the inverse of a weight, the more mobility of the JC. The JCs presented here are torso extension (T.E.), Lateral torso flexion (L.T.F.), Torso rotation (T.R.), Right carrying angle (R.C.A.), Left carrying angle (L.C.A.).

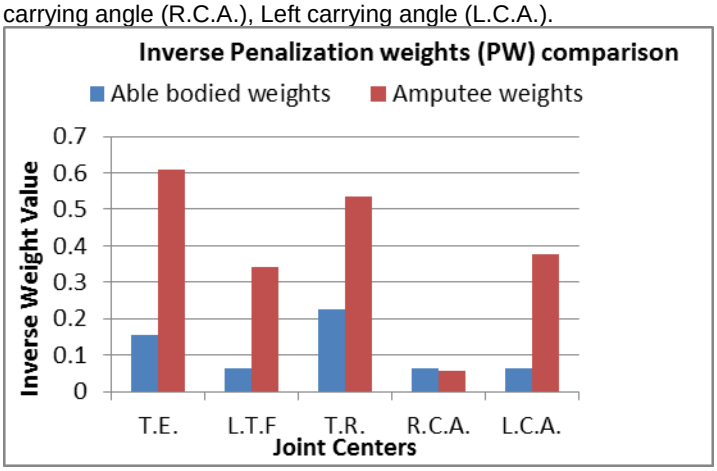

Figure 1 Inverse Penalization Weights

DISCUSSION

The higher values of the torso inverse PWs are translated into higher mobility of the torso. This was expected since amputees are known to use their torso more but here a more quantifiable approach is presented. The right carrying angle is the same in both able-bodied and amputees but the left carrying angle is higher in amputees since they are missing the wrist. It should be noted that part of the left carrying angle mobility is caused by the slip between the residual limb and the prosthesis which adds some instability to the upper extremity.

CONCLUSION

Assigning PW to penalize each JC effectively quantifies its movement and as a result it is possible to model the motion of the human body. Future research will incorporate the socket slip in the model in a more integrated way.

CLINICAL APPLICATIONS

By evaluating the compensatory motion of amputees in an objective quantifiable way, improvements for fitting and training prosthesis users can be made.

Acknowledgements: This research and development project was conducted by University of South Florida and is made possible by a research grant that was awarded and administered by the U.S. Army Medical Research & Materiel Command (USAMRMC) and the Telemedicine & Advanced Technology Research Center (TATRC), at Fort Detrick, MD, under Contract Number: W81XWH-10-1-0601.

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An Interim Analysis of Body Powered Prosthetic Terminal Devices

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INTRODUCTION

Body powered prostheses allow upper extremity amputees to control prehensors without the assistance of an external power system. Various prehensors can be attached to the prostheses and are controlled manually with a harness system through scapular abduction. Although 85,000-90,000 people have lost an upper limb in the United States, only a small percentage are using a prosthesis mostly due to the limited function and flexibility the current devices provide.[1] Voluntary closing (VC) terminal devices are thought to provide enhanced proprioception, kinaesthetic awareness and grip forces compared to voluntary opening (VO) alternatives. This study directly compared the function of VC and VO devices during a series of tasks and activities of daily living (ADL).

METHOD

Subjects: Nine able-bodied males, and one able-bodied female used VO and VC with a prosthetic simulator. Two males with a transradial amputation (TRA) used both the VO and VC prehensors with a body-powered prosthesis.

Apparatus: An 8 Vicon (Englewood, CO) camera motion capture system with 29 reflective markers placed at specific points on the subject's body were used to track the subject's motion. The completion time of each task was recorded.

Procedures: The University of South Florida's Institutional Review Board approved the protocol and each subject was asked to complete a consent form. Subject's then completed a unilateral lift, bilateral lift, Box and Blocks test, a towel fold, and a cutting task.

Data Analysis: Marker locations were used to define a forearm and an upper limb segment and the elbow joint angles were calculated as the relative orientation between these two segments using Euler angles. The elbow range of motion (ROM) was calculated by subtracting the minimum angle from the maximum angle. This determined the flexion (positive) angle and extension (negative) angle. The sternal linear displacement was also measured in the medial lateral direction from right (positive) to left (negative) in relation to a fixed point.

RESULTS

Figure 1 shows the elbow angle ROM for both the VO and VC prehensors from two of the amputees during the bilateral and unilateral lift tasks. Figure 2 shows sternal linear displacement for 10 of the controls and 2 TRAs for both VO and VC prehensors during all tasks.

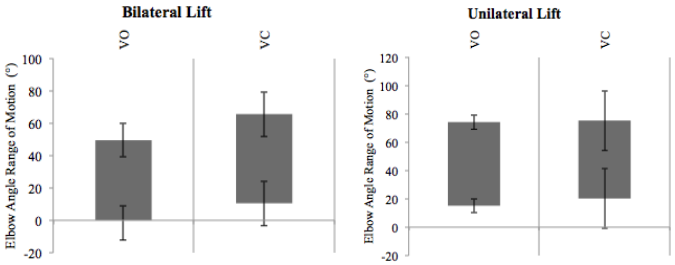

Figure 1: Elbow angle range of motion for amputees during the Bilateral and Unilateral Lift tasks

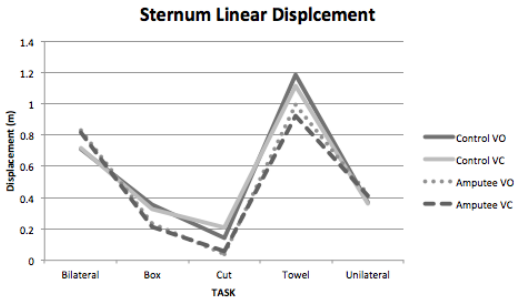

Figure 2: Sternum Linear Displacement during all tasks

DISCUSSION

As shown in Figure 1, the VC prehensor allows for a larger elbow ROM. This suggests the VO prehensor may limit elbow motion. Figure 2 shows there to be less linear sternal displacement in the majority of tasks when using the VC prehensor. This suggests when using the VO prehensor, the subjects had to depend on trunk movement to compensate for the limited function in order to complete the tasks. Future work will involve further data analysis.

CONCLUSION

These interim results show that the VC prehensor allowed for a greater elbow angle ROM and is less limiting compared to the VO design. When using the VC prehensor, subjects used less medial-lateral trunk movement to complete the tasks.

CLINICAL APPLICATIONS

This interim data shows how the VC terminal device can allow greater elbow angle ROM and limits less function in several applications over the voluntary VO design.

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A PROPOSED CLINICAL ALGORITHM FOR DORSIFLEXION FREE AFOFCS

BASED ON CALF MUSCLE LENGTH, STRENGTH, STIFFNESS AND SKELETAL ALIGNMENT

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Child Development Centre, Bangor, UK

INTRODUCTION

An Ankle-Foot Orthosis Footwear Combination (AFOFC) with a dorsiflexion free function, often combined with a 90 degree plantarflexion stop function, is a commonly investigated orthosis. However, the research to date has a number of problems, particularly when related to gait: Research often seeks to determine whether a fixed ankle or hinged/dorsiflexion free AFO design is optimum for diagnostic groups or categories; Dorsiflexion free AFOs have been investigated with study subjects who have contraindications to their use; AFOFCs with dorsiflexion free design have been coupled with fixed metatarsal phalangeal joints (MTPJs) which may adversely affect ankle joint kinematics; Some literature states that movement at the ankle joint is essential for gait which is incorrect.

METHOD

An algorithm, to determine whether an AFOFC with a dorsiflexion free function is likely to be the optimal prescription for gait, can be created if a few key requirements for normal barefoot gait are considered.

RESULTS

An algorithm is presented.

DISCUSSION

The algorithm takes into account the following:(1)At 40% gait cycle maximum stance knee extension occurs, at this time the ankle is dorsiflexed 10-12°, there must be sufficient gastrocnemius length to allow these kinematics.(2)The ankle dorsiflexes to 10-12° during mid-stance, there must be sufficient length and sufficiently low tone in soleus and gastrocnemius to allow this movement.(3)The ankle is prevented from excessively dorsiflexing in mid-stance and is maintained in a quasi-stiff position of dorsiflexion in terminal stance by the actions of the calf muscle, there must be sufficient strength to achieve this.(4) Ankle dorsiflexion in gait is coupled with stable bony alignment of the foot.

CONCLUSION

This paper presents a clinical algorithm to determine suitability for a dorsiflexion free AFO design, defined here as free movement into dorsiflexion range.

CLINICAL APPLICATIONS

This algorithm is useful in clinical practice and for future study designs. It produces a standardised approach to determining suitability for a dorsiflexion free design of AFO as defined here.

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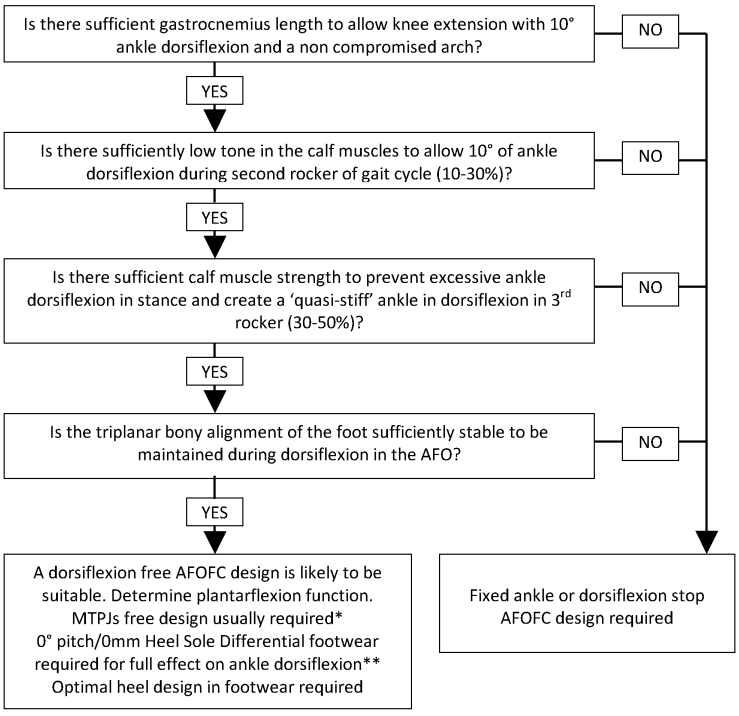

* An AFOFC with MTPJ free design is usually required, to allow MTPJ extension during third rocker, and patients who meet the criteria for a dorsiflexion free AFO usually meet the criteria for an MTPJ free design. If they do not a rocker sole profile is required on the footwear as restriction in MTPJ extension may produce excessive ankle dorsiflexion, a compensatory response required to enable normal shank kinematics if MTPJs are fixed and not compensated for by a rocker sole profile.

** To obtain 10-12° of ankle joint dorsiflexion in gait the dorsiflexion free AFO needs to be combined with footwear that has a 0mm Heel Sole Differential (HSD) or 0 degree pitch. For each degree of pitch in the footwear there will be a reduction of one degree of ankle dorsiflexion. This is because gait requires normal shank kinematics and ankle joint kinematics adjust to the pitch of the footwear to achieve this. In normal gait the shank is 10-12° inclined at the end of mid-stance, 30% GC. A 10-12° pitch in the footwear negates the need for any ankle dorsiflexion to achieve this.

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Changes in gastrocnemius length with AFO-FC tuning

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INTRODUCTION

Ankle foot orthosis footwear combinations (AFO-FCs) may be prescribed to individuals after stroke to address gait problems such as ankle plantar flexor contracture, excessive stance phase knee flexion, or inadequate knee flexion in swing (Jagadamma et al. 2010; Carse et al. 2014). Solid AFO-FCs have recently been demonstrated to improve walking speed and kinematics using a tuning method, which uses heel wedges to set a shank-to-vertical-angle (SVA) and adjust the position of the ground reaction force with respect to the hip and knee joints (Owen, 2010). One mechanism by which this tuning method is thought to improve walking kinematics is by reducing the operating length during walking of tight muscles such as the gastrocnemius. Contracture and spasticity are common after stroke and altering the operating length of the gastrocnemius may improve knee kinematics. The purpose of this study was to evaluate how gastrocnemius operating length changed after tuning AFO-FCs in an individual with hemiplegia following stroke.

METHOD

Subjects: Motion analysis was performed over three visits for a male subject with hemiplegia following stroke (46 years old, 190cm height, 88.5kg mass).

Apparatus: An eight-camera motion capture system and 6 force plates were uses to acquire motion analysis data.

Procedures: At the first visit, the subject walked with his prescribed posterior leaf spring (PLS) AFO and was fit with a custom solid AFO-FC with an initial tuned SVA of 15˚ incline. After five months he returned for a second gait analysis with the AFO-FC and the AFO-FC was retuned to an SVA of 12˚ incline. He returned one month later for the final motion analysis.

Data Analysis: Using the motion analysis data, a musculoskeletal model of the lower-extremities (Delp et al., 1990) was scaled to the subject using OpenSim. For each test condition, the subject's joint angles and moments were determined using inverse kinematics and inverse dynamics, respectively. The gastrocnemius operating length was evaluated as the distance of a muscle's path from origin to insertion from the inverse kinematics during the gait cycle. The test data were compared to a group of speed-matched unimpaired subjects.

RESULTS

The AFO-FCs (see the dashed and solid black curves, Figure 1) had shorter gastrocnemius operating length than the maximum gastrocnemius length measured during passive ankle dorsiflexion in the clinical exam (horizontal dotted lines, Figure 1c). The AFO-FCs improved knee flexion in swing and support time in stance (circles and vertical lines, Figure 1) compared to walking without an AFO and PLS AFO. However, the AFO-FCs had a greater knee flexion angle in stance. The original PLS AFO had minimal effects on kinematics and gastrocnemius length compared to walking with shoes alone.

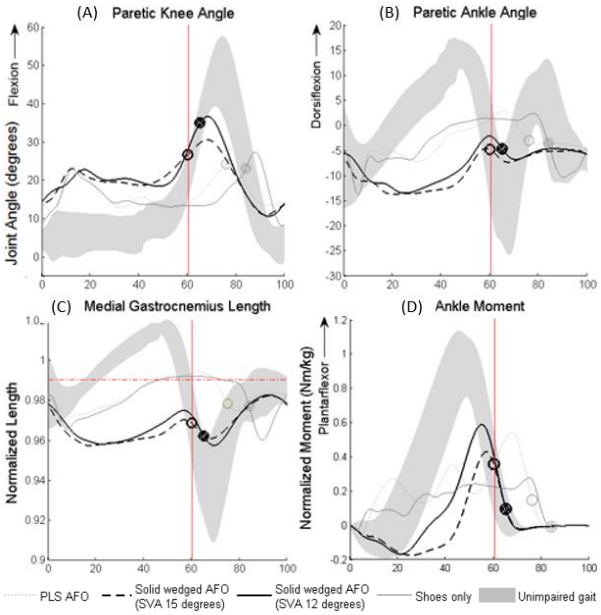

Figure 1. Sagittal plane kinematics of the knee (A) and (B) ankle during the gait cycle. The medial gastrocnemius operating length was normalized to the length of the muscle in anatomic position (C). Sagittal plane ankle moment was normalized to mass (D). The shaded area represents the mean ± 1 standard deviation from speed-matched unimpaired subjects.

DISCUSSION

Overall, the AFO-FC improved walking function for this individual. Although the AFO-FC reduced gastrocnemius operating length, knee extension in stance did not improve due to the inclination of the shank with the SVA and a reduced ankle plantar flexion moment.

CONCLUSION

Tuning AFO-FC improves joint kinematics and kinetics as well as controls gastrocnemius length.

CLINICAL APPLICATIONS

Musculoskeletal modeling can be used to evaluate muscle specific responses to AFO design and assist in prescribing and tuning AFOs in the future.

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Effect of ankle-foot orthosis plantarflexion resistance on lower-limb kinematics and kinetics in patients with stroke

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INTRODUCTION

Patients with stroke are generally provided with an ankle-foot orthosis (AFO). AFOs can assist their mobility through improvement in tempo-spatial, kinematic and kinetic parameters of gait. AFO's plantarflexion resistance resists movement of the ankle joint toward a plantarflexion direction and plays an important role at initial contact in stance and during swing in hemiplegic gait. Therefore, an AFO whose plantarflexion resistance is appropriately tuned could benefit the patients (Yamamoto et al., 2011). Previous studies suggested that plantarflexion resistance would affect ankle and knee joint kinematics (Kobayashi et al., 2011; Kobayashi et al., 2013). However, its effect on the kinetics has not been systematically studied. The aim of this study was to investigate the effect of AFO plantarflexion resistance on ankle and knee joint kinematics and kinetics by systematically changing the plantarflexion resistance of an articulated AFO.

METHOD

Subjects: Ten subjects with chronic stroke (2 females/8 males) participated in this study. Their mean age was 56 (11) years old and mean time since stroke was 6 (3) years.

Apparatus: A custom articulated AFO with plantarflexion resistance adjustable joints was developed and its resistance was quantified by an AFO mechanical testing device (Gao et al., 2011). A Vicon 10-camera motion analysis system (Vicon Motion Systems, Oxford, UK) and a Bertec split-belt fully instrumented treadmill (Bertec corporation, Columbus, OH, USA) were used to collect kinematic and kinetic data.

Procedures: Gait analysis was performed under 5 different plantarflexion resistance conditions [R1 (lowest resistance) to R5 (highest resistance)] wearing the custom articulated AFO in each subject.

Data Analysis: The data were post-processed with Visual3D (CMotion, Germantown, MD, USA). The sagittal ankle and knee joint data of 5 steps were normalized to stance and plotted under each plantarflexion resistance condition.

RESULTS

Change in plantarflexion resistance of the articulated AFO generally affected the ankle and knee joint angles and moments across subjects. Figure 1 shows the effect of systematic changes of plantarflexion resistance of the AFO on ankle and knee joint moments in a representative subject.

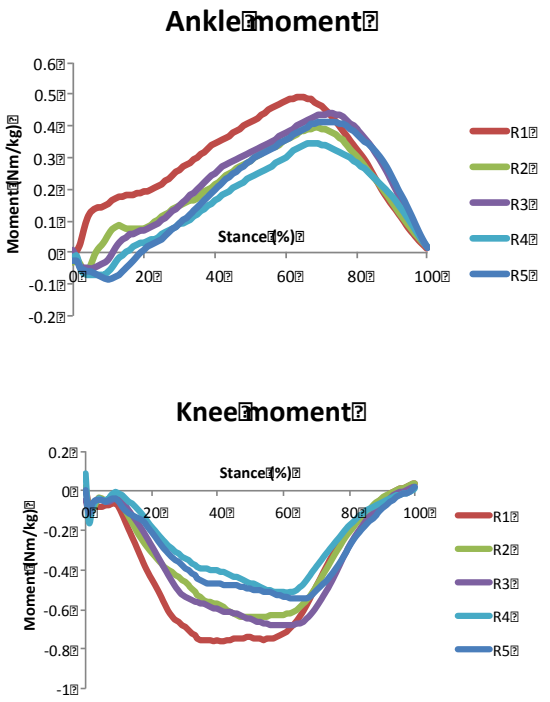

Figure 1. Effects of plantarflexion resistance [R1 (lowest) to R5 (highest)] on sagittal ankle and knee joint moments in a representative subject.

DISCUSSION

Plantarflexion resistance of the AFO appeared to have a very systematic effect on ankle and knee joint angles and moments. Knee flexion moments were reduced by increasing plantarflexion resistance of an AFO, suggesting an improvement in knee hyper-extension.

CONCLUSION

Plantarflexion resistance of an articulated AFO needs to be tuned for each patient to optimize gait.

CLINICAL APPLICATIONS

Articulated AFOs can benefit patients with stroke the most when their plantarflexion resistance is appropriately tuned.

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MOTION CONTROL OF A NOVEL ANKLE FOOT ORTHOSIS MAXIMIZING LEVERAGE AND STIFFNESS – GAIT STUDY

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INTRODUCTION

Despite their prevalence of use, motion control of ankle foot orthoses (AFOs) has been subjectively characterized (McCollough, 1970) and lacks rigorous evidence based on uniform testing and analysis (Kobayashi, 2011). Third party payers have demanded more rigorous evidence by healthcare professionals to justify use of orthoses as a treatment. Therefore, the purpose of this investigation was to clarify a general principle of orthoses that maximizing leverage and stiffness will produce maximum motion control. To test this principle, we quantified motion control of a novel AFO maximizing stiffness and leverage and predicted that the AFO in ankle STOP condition will decrease ankle motion compared to AFO in ankle FREE and CONTROL (no AFO) conditions during walking.

METHOD

Subjects: Fourteen healthy subjects (8 females, 6 males, age 21.04 ± 0.89 yrs, height 171.19 ± 4.11 m, mass 65.74± 4.72 kg) gave written informed consent to participate in a protocol approved by the Georgia Tech Institutional Review Board.

Apparatus: 3-D gait lab using six high speed cameras (Vicon, 120 Hz), 16 reflective markers taped to the lower limbs of subjects and a custom dual belt treadmill with imbedded force plates (AMTI, 1080 Hz) were used to collect joint motion, ground reaction forces and joint moments respectively during walking.

Procedures: Subjects walked at preferred speed (1.34±0.09 $m \cdot s^{-1}$) using an ankle foot orthosis-footwear combination (AFO-FC) in three walking conditions: CONTROL condition (bilateral footwear combination, no AFO), FREE condition (use of contralateral footwear with ipsilateral AFO-FC in a no constraint condition) and STOP condition (use of contralateral footwear with ipsilateral AFO-FC in a maximal constraint) (Figure 1).

Data Analysis: All motion and force data in the sagittal plane were synchronized, filtered and time normalized to 100% of the gait cycle. Mean ankle joint angle and moments in each condition were analyzed using 95% confidence interval and repeated measures ANOVA with Bonferonni post-hoc comparison.

RESULTS

Subjects exhibited decreased ipsilateral ankle range of motion to within 3.7±2.1° in STOP condition compared to 27.7±4.2° in CONTROL condition without the AFO (p=0.000) and 24.2±3.6° in FREE condition (p=0.091) and no difference in ankle moments (p>0.05). Ankle motion and moments were no different between the three conditions on the contralateral leg (p>0.05). Cadence was similar in CONTROL, STOP and FREE conditions (p>0.05).

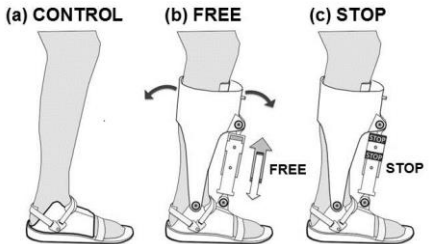

Figure 1. Ipsilateral ankle motion conditions. **(a)** No AFO (CONTROL) with footwear, **(b)** AFO FREE with footwear, **(c)** AFO STOP with footwear

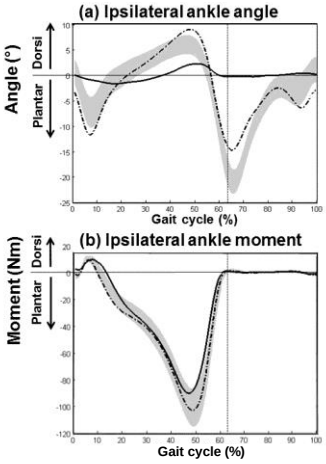

Figure 2. **(a)** Ipsilateral ankle angle (°) and **(b)** ipsilateral ankle moment (Nm). Data normalized to gait cycle (%) in CONTROL, FREE and STOP conditions during minute 4. 95% confidence interval of CONTROL (shaded), mean of FREE (dotted line) and mean of STOP (solid line) for all 14 subjects. Toe off in CONTROL (vertical dotted line).

DISCUSSION

AFO-FC in STOP limited motion during stance phase when the ankle experiences the greatest joint moments and is typically where one might see lack of motion control. An explanation for the consistency in limited ankle motion despite considerable ankle torque is related to the mechanism of AFO motion control that engages a three force system.

CONCLUSION

These findings support a general principle for maximizing leverage and stiffness in the design of AFOs to produce effective control of ankle motion.

CLINICAL APPLICATIONS

Maximizing leverage and stiffness and including a three force system in the design of AFOs relate to its effectiveness in the control of ankle motion.

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MOTION CONTROL OF A NOVEL ANKLE FOOT ORTHOSIS MAXIMIZING LEVERAGE AND STIFFNESS – STATIC LOADING STUDY

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INTRODUCTION

While many ankle foot orthosis (AFO) systems have demonstrated effectiveness in improving gait for a variety of pathologies, details of their motion control capabilities are not fully known [Kobayashi, 2011]. A potential source of error in quantifying motion control of AFOs is due to motion artefact of markers attached to the orthosis and footwear instead of subjects' skin. Therefore, basic biomechanical investigations are needed to evaluate the potential error in quantifying motion control of AFOs at the foot and ankle complex. Our goal was to validate motion control of a novel AFO in an anatomical rather than orthosis-based marker model using bone anchored markers on cadaveric limbs and compared these to skin anchored markers on the limbs of healthy subjects under the same conditions. We predicted there would be similar limb segment motion of cadaveric and healthy limbs in AFO STOP condition and in AFO FREE condition.

METHOD

Participants: The right lower limb of two cadavers (shank length 45.2±1.9 cm) and two healthy subjects (shank length 47.6±1.2 cm, age 41.5±10.6) used the novel AFO in experimental conditions. Prior to participation, healthy subjects gave written informed consent approved by Georgia Tech Institutional Review Board.

Apparatus: A custom carbon composite AFO was bolted to an adjustable loading apparatus. Reflective markers (taped to skin of healthy subjects and anchored into bone of cadaveric limbs) were located at the tibia, fibula and calcaneus. Six motion capture cameras (120 Hz, Vicon,) recorded the location of reflective markers during the protocol.

Procedures: Cadaveric and healthy subjects' limbs using AFO in STOP and FREE conditions were unloaded to 0 Nm in neutral position and loaded to 149 Nm to produce ankle plantarflexion (PF) and loaded to 29 Nm to produce dorsiflexion (DF) moments matched to peak moments achieved in prior trials of healthy subject treadmill walking.

Data Analysis: 3-D coordinates of tibia, fibula and calcaneus markers were synchronized, filtered and analyzed to render a sagittal plane limb segment angle during each trial. The mean change in limb segment angle for each condition was analyzed using independent samples t-test.

RESULTS

Limb segment dorsiflexion angle from unloaded to loaded trials in STOP compared to FREE condition of healthy and cadaveric limbs was significantly (p<0.05) reduced (0.3±0.1° compared to 11.7±0.4° in healthy and 1.6 ±0.7° compared to 7.6±1.4° in cadaveric); and limb segment plantarflexion was significantly (p<0.05) restricted to 3.0±1.0° compared to 14.4±2.4° (healthy) and 1.7±0.9° compared to 15.0°±0.7° (cadaveric) (Figure1).

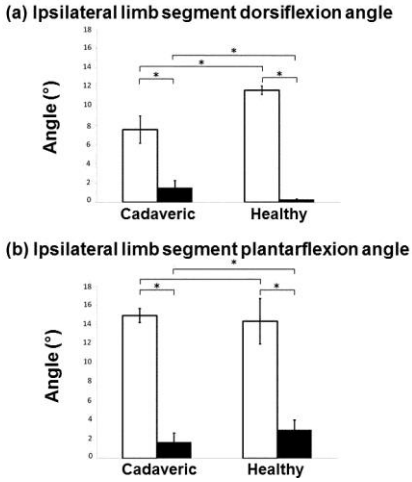

Figure 1. Mean ipsilateral limb segment angle (mean±standard deviation) in AFO FREE (open) and STOP (solid) conditions of cadaveric limbs (n=2) and healthy limbs (n=2) in **(a)** dorsiflexion, and **(b)** plantarflexion. *significant (p<0.05).

DISCUSSION

We were able to simulate conditions during stance phase of gait by statically imposing PF and DF moments equivalent to stance phase of gait. Findings from this static loading study revealed similar trends of motion control by the AFO as in the gait study. Based on these findings, the novel AFO consistently limited motion in the STOP condition and provided less restricted motion in the FREE condition.

CONCLUSION

Due to similarity of findings in ankle and limb segment motion in gait study and this static loading study, use of markers attached to the periphery of an AFO and footwear appear suitable for quantifying motion.

CLINICAL APPLICATIONS

Overall, the small differences in ankle plantarflexion and dorsiflexion motion controlled in the STOP condition highlights an important clinically relevant finding that an AFO ultimately must engage skeletal structures to provide motion control. In addition to the general principle of leverage and stiffness in the control of motion, the girth and compliance of a person's overlying soft tissues superficial to the underlying skeletal structures in the areas of the three force system to control plantarflexion and dorsiflexion in an AFO will likely also influence the magnitude of motion control performance.

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Consequences of Observable Gait Deviations

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INTRODUCTION

The vast majority of people with lower limb amputation who use a prosthesis walk with at least one gait deviation. Over time, the altered forces on the skeletal and soft tissues of the intact limb can lead to degenerative conditions. (Nolan, 2003). While there have been reviews published on the secondary physical conditions associated with lower-limb amputation and long-term prosthesis use, this review was conducted to search for observable gait deviations of persons with lower limb amputations. Addressing a potentially harmful gait deviation requires that we observe it and correct underlying causes. How can deviations be observed? Instrumented gait analysis is not available to most clinicians. We rely on observation either with or without technological enhancement. Knowing which deviations are observable will allow us to focus on those deviations and use readily-available technologies to assist our observation and do a better job addressing the underlying causes. Furthermore, how can a patient learn from this data that will help them reduce secondary conditions?

METHOD

In July 2014, a comprehensive computerized bibliographic databases search was performed in the following databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 to current), Clinical Pharmacology, Cochrane Library, Excerpta Medica Database (EMBACE; 1980 to current), Journal Citation Reports, NUcat, Ovid MEDLINE, PubMed (1966 to current), PsycINFO (1806- current), Scopus, Web of Science, and The Journal of Prosthetics and Orthotics Online Library (1989-current). The following search terms were used: (Secondary Effects gait deviations amputee) AND (Long Term effects gait deviations) AND (Osteoarthritis amputee) AND Osteopenia amputee) AND (Osteoporosis amputee) AND (Back Pain amputee). In addition to the electronic database search, a further search tracking citation of all of the primary studies were scanned and examined for inclusion. Inclusion criteria were studies, commentary, literature reviews or case studies relating to the long term biomechanical effects of gait deviations for persons with lower limb amputation. The articles were to have been published in last 20 years (except for Burke article, which was included as a "classic reference") Exclusion criteria were dissertations, conference abstracts, and design or validation studies were excluded or articles printed in a language other than English.

RESULTS

Several articles in this review referenced the following observable gait deviations as the cause for secondary physical conditions

1. Abnormal posture
2. Lateral trunk bending
3. Pelvic tilt or increased lumbar lordosis
4. Decreased hip extension of the residual limb of TF amputees.
5. Reduced prosthetic side knee flexion in early stance phase, and sound side excessive stance-phase knee flexion angles during early stance-phase for transtibial amputees.
6. Hip-hiking and vaulting.
7. Reduced late-stance ankle dorsiflexion occurring at opposite heel contact.
8. Incorrect timing of initial plantarflexion to dorsiflexion transition occurring during early to late stance phase.
9. Step length asymmetry
10. Slower walking speeds and increased double support time.

DISCUSSION

Back pain, osteoarthritis of the sound limb, osteoporosis on the amputated side and sound side foot breakdown are the common secondary conditions that are caused by the observable gait deviations in persons with lower-limb amputation. If the practitioner is looking to reduce the chances of the conditions, it is helpful to know which deviations are more detrimental. From the review of the articles, it seems that leg length discrepancy is a key factor in causing many of these deviations which in turn lead to the secondary conditions.

CONCLUSION

Leg-length discrepancy is a major cause of concern for persons with lower limb amputations because it can lead to many secondary physical conditions. It can be observed during gait initiation as well as lateral tilting of the pelvis in the frontal plane, pelvic torsion in the sagittal plane, lumbar scoliosis, and step asymmetry.

CLINICAL APPLICATIONS

People who have a prosthesis that is the same length as the intact limb have fewer incidences of back pain. (Gailey, 2008), and they are able to create a more symmetrical step length. Patients often ask that the prosthesis be made shorter. Careful consideration and patient education should be taken in order to reduce the long-term damage of this change.

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Improved Gait Symmetry Following Amputee-Specific Physical Therapy

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INTRODUCTION

Following amputation, an amputee must re-learn how to walk in the presence of an altered neuromuscular system. A goal of prosthetic rehabilitation is to reduce asymmetries between the prosthetic and sound leg to potentially decrease the negative effects of long term exposure to increased force and work demand on the sound leg (Burke et al., 1978; Ephraim et al., 2005). An amputee-specific physical therapy program provides structured motor learning to aid in developing proper gait mechanics, yet such practice is not standard potentially due to limited evidence showing improved gait. The purpose of this study was to determine whether amputees undergoing an amputee-specific physical therapy rehabilitation have improved gait symmetry, assessed through common kinetic measures of gait (Winter 2009).

METHOD

Subjects: Two groups of individuals with unilateral transtibial amputation, divided according to whether they had previously undergone the amputee-specific therapy program (AmpPT group: n=12; age: 56.67 ± 11.14 yrs; ht: 177.04 ± 7.96 cm; mass: 107.57 ± 14.65 kg; yrs since amputation: 5.9 ± 5.1 yrs) or not (No-AmpPT group: n=11; age: 48.64 ± 11.01 yrs; ht: 179.10 ± 9.03 cm; mass: 94.94 ± 21.08 kg; yrs since amputation: 8.7 ± 6.7 yrs) consented to participate in this University IRB approved study. All subjects were previously classified as either K3 or K4 level by their prescribing physician and/or prosthetist.

Procedures: A retrospective analysis was performed on a group of individuals previously recruited to a different study. Due to the retrospective nature of the analysis, subjects were not randomly assigned to each group but were divided based on history. The therapy group received 2-3 sessions per week for 3 months. Subjects walked overground at a self-selected pace while kinetic and kinematic data were collected.

Data Analysis: Asymmetries were determined through dependent t-tests (α=0.05) comparing sound and prosthetic leg kinetic variables.

RESULTS

Of the 23 kinetic variables tested, 17 measures showed significant difference between the sound leg and the prosthetic leg for the group that did not receive the amputee-specific physical therapy (Table 1). For the group that had previously received therapy, only 4 variables showed significant differences between the sound and prosthetic leg.

Moments	Ankle Dorsiflexion	
	Ankle Plantarflexion	
	Knee Extension	*
	Knee Flexion	*
	Hip Extension	*
	Ankle Absorption	*
	Ankle Generation LS	*
Powers	**Knee Absorption ES**	*
	Knee Generation ES	*
	Knee Absorption LS	*
	Hip Generation ES	
	Hip Absorption MS	
	Hip Generation LS	*†
Ground Reaction Force	**Peak Break Force**	*†
	Peak Propulsion Force	*
	Peak Lateral Force	*†
	Peak Medial Force	
	Peak Vertical Force ES	*
	Peak Vertical Force MS	*
	Peak Vertical Force LS	*
	Braking Impulse	*†
	Propulsion Impulse	*

Table 1: Kinetic Variables Tested.
ES- Early Stance, MS- Midstance, LS- Late Stance
*****Sig. at p<0.05, prosthetic vs. sound leg, No-AmpPT group
† Sig. at p<0.05, prosthetic vs. sound leg, AmpPT group

DISCUSSION

Individuals that previously underwent an amputee-specific physical therapy program have a more symmetrical gait. Increased symmetry in kinetic measures indicates less force and energy demands on the sound leg in order to effectively walk. An amputee-specific physical therapy program designed to improve lower limb strength, core strength, range of motion, center of mass shifts, sound limb deviations, and static and dynamic balance leads to improvements in gait compared to traditional amputee therapy models that focus more on walking. If a symmetrical gait is considered better, then it is possible to deem that amputees undergoing an amputee-specific physical therapy program walk better with likely decreased long term complications to the sound leg.

CONCLUSION

A physical therapy program designed specifically for individuals with amputation can improve gait symmetry. Large emphasis is placed on tasks beyond standard repetitive walking.

CLINICAL APPLICATIONS

Prosthetists should encourage patients to receive physical therapy. Therapists should be trained in aspects of therapy focused on pre-prosthetic exercise, proprioceptive neuromuscular re-education, and normal gait.

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Energetic cost of gait and functional mobility: a comparison of vacuum, suction, and sleeve suspensions

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INTRODUCTION

Daily fluctuation in residual limb volume can affect prosthetic fit and comfort. Vacuum assisted suspension systems (VASS) anchor the prosthetic socket on the residual limb, minimizing fluctuations, reducing pistoning and peak socket pressures (Beil 2002), thereby improving comfort. Still, the extent to which VASS improves function and mobility is unclear. The purpose of this study is to quantify VASS-induced improvements in performance-based and self-reported outcome measures. Here we present preliminary data from an ongoing study to test the hypotheses that VASS will 1) reduce the energetic costs of gait and 2) improve outcomes measures related to function, mobility and quality of life.

METHOD

To date, 10 subjects (8 males; 7 transtibial, 1 transfemoral, 2 knee disarticulation; 5 traumatic, 5 non-vascular; 45.1±12.0 years; 179.9±7.5 cm; 88.3±10.8 kg) completed the study. Inclusion criteria include: current use of VASS for ≥6 months, ≥1 year since amputation and ability to walk without assistance for six minutes. Subjects performed three tasks using each of three, randomly assigned, suspension setups: 1) VASS, 2) suction with inactive vacuum, and 3) suspension sleeve without one-way valve. For Task 1 subjects traversed an 8m walkway while motion capture tracked 22 passive reflective markers. From these motions, as per Board (2000) we calculated a symmetry index (SI) for stance time and step length (SL) as 100*[(prosthetic-sound)/½(prosthetic+sound)]. Task 2 was the 10 meter walk (10 mW) test to assess maximum speed. For Task 3, subjects walked a carpeted, indoor track for six minutes at a self-selected pace while the rate of 0_2 consumption (ml/min) was measured using a portable device. Energetic cost was calculated as the mean rate of consumption over the final two minutes normalized by mass (kg) and mean speed during that time (m/min). Total distance and socket comfort score (0-10) after six minutes were noted. For Tasks 2 and 3 data is presented for 9 and 8 subjects, respectively. Variables were compared across suspension using an ANOVA and LSD correction with significance at p≤0.05.

RESULTS

Stance time was significantly more asymmetric for sleeve compared to VASS and suction, but similar between VASS and suction (Table 1). There was no effect of suspension on SI for SL. Times for the 10 mW test were significantly less for VASS compared to sleeve. There were no differences in energetic costs or total distance walked over six minutes, but comfort systematically decreased across all conditions.

	VASS	suction	sleeve
10 mW (s)	3.6±0.7*	3.7±0.7	3.9±0.7*
6 min walk (m)	486±95	474±86	473±81
cost (ml /kg ·m)	0.17±0.03	0.17±0.04	0.17±0.04
socket comfort	8.8±1.2*^	7.3±1.1^&	5.7±1.7*&
SI - SL (%)	1.8±7.3	2.5±7.9	1.6±7.6
SI - stance (%)	-3.5±5.5*	-3.8±6.4&	-21.3±3.9*&

Table 1. Outcome variables; larger absolute SI indicate more asymmetry. SI<0 indicate larger sound-side values; *p≤0.05 VASS vs. sleeve, ^p≤0.05 VASS vs. suction, &p≤0.05 suction vs. sleeve

DISCUSSION AND CONCLUSION

Despite greater stance time symmetry with VASS (which is consistent with Board et al (2001)), energetic costs across conditions were similar. Thus temporal asymmetry alone may not necessarily be associated with the economy of amputee gait. While a study by Mattes et al (2000) demonstrated an association between the two, in that study asymmetry was induced by adding mass on the prosthetic, making it difficult to isolate the effects of asymmetry. Still, an association is logical, and given similar SL symmetry between conditions, similar energetic costs may not be unexpected. Although VASS has been shown to improve SL symmetry (Board 2000), this was measured over 30 minutes to allow residual limb volume loss similar to that seen over a day. If volume loss increases asymmetry (and inefficiency), then benefits of VASS may go unnoticed unless sufficient time (i.e., >6 minutes) is provided to allow significant volume loss after vacuum removal. Similarly, any benefits of improved comfort on gait should also become more apparent with walking duration and seemingly with increasing speed as well. The more "intimate" fit offered by VASS may provide increased control of the prosthetic limb, which may be necessary to achieve greater speed. Indeed, 10mW time was 10% faster with VASS. While energetic costs of amputee gait do increase with speed (Genin 2008), if VASS facilitates faster speeds this may also allow less energy to be utilized to increase speed beyond preferred. In conclusion, VASS provides improved comfort, maximum speed, and stance symmetry. Future work will consider if VASS improves energetic costs when walking longer than six minutes and/or above preferred walking speeds.

CLINICAL APPLICATIONS

VASS may prevent speed- and comfort-related limitations in activity for high functioning amputees.

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Effect of Ankle Immobilization on Able-Bodied Gait as a Model for Understanding Bilateral Transtibial Amputee Gait

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INTRODUCTION

A critical function of the foot-ankle complex during walking is to facilitate advancement of the stance limb through heel, ankle, and forefoot rockers and generation of power during pre-swing (Perry, 1992). These features are altered or diminished for bilateral transtibial amputees (BTAs) when using passive foot-ankle mechanisms and they must rely on compensatory mechanisms to advance the lower limbs and maintain forward ambulation (Su, 2007, Major, 2013). The purpose of this study was to determine the effects of ankle immobilization on able-bodied (AB) gait to serve as a model for understanding BTA gait and associated compensatory mechanisms when active ankle motion and power generation is unavailable.

METHOD

Subjects: Nine AB individuals (27±3 yrs, 1.75±0.10 m, 76±17 kg) were included in this study. Additionally, data from ten BTA prosthesis users (50±18 yrs, 1.73±0.08 m, 82±16 kg) in a previous study (Major, 2013), were included for comparison.

Apparatus: The subjects were fitted with a modified Helen Hayes marker set (Kadaba, 1990). Kinematics were measured with an eight-camera digital motion analysis system (Motion Analysis Corporation (MAC), Santa Rosa, CA). Kinetic data were collected with six force plates (AMTI, Watertown, MA) embedded in a 10 m walkway.

Procedure: Subjects were recorded walking at normal and fast self-selected speeds, without and with casts, respectively. The bilateral casts (Delta-Lite Fiberglass (BSN Medical Ltd., Brierfield, UK)), were fitted from below the knee joint to the toes with the ankle joints in a neutral position to prevent ankle joint motion.

Data Analysis: OrthoTrak software (MAC) was used to estimate joint kinematics and kinetics.

RESULTS

Normal walking speeds were markedly different between the no cast (1.02±0.18 m/s) and cast (1.34±0.1 m/s) conditions. Since no appreciable difference in walking speed between the fast-walking cast (1.4±0.3 m/s) and normal-walking no cast (1.34±0.1 m/s) conditions was observed, these data are compared along with fast self-selected walking speed BTA data. Ankle range of motion (ROM) was greatly reduced in the cast condition, from 31.1±3.3 degrees to 8.4±3.0 degrees. A four-fold decrease in ankle power generation occurred at pre-swing in the cast condition compared to control (Figure 1a). Trunk lateral flexion ROM (Figure 1b), trunk transverse rotation ROM (Figure 1c), and peak hip power generation during pre-swing (Figure 1d) increased compared to control.

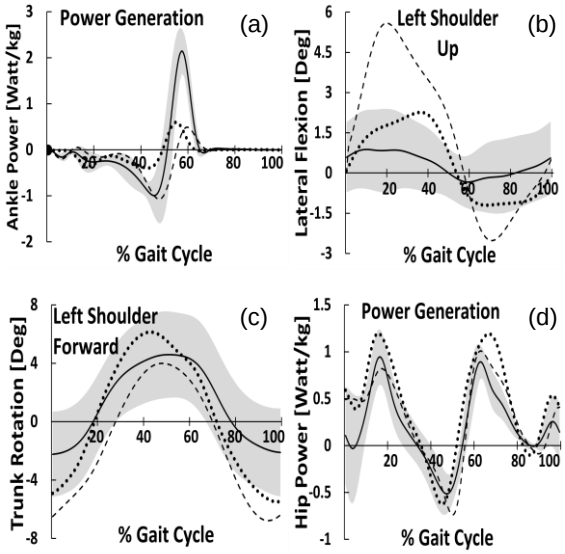

Figure 1. Ankle power (a), lateral trunk flexion (b), trunk rotation (c), and hip power (d) for non-casted (solid line; gray band=standard deviation), casted (dotted line), and BTA data (dashed line).

DISCUSSION

Ankle joint immobilization resulted in a substantial decrease in ankle power generation during pre-swing, which may have been compensated for by increased hip power to achieve limb advancement. The modifications in trunk movement may also act as compensatory mechanisms to maintain forward ambulation. The hip and trunk compensations observed in the cast condition appear to resemble gait patterns of BTAs.

CONCLUSION

These results suggest that the absence of active ankle motion and power generation contribute to the development of compensatory mechanisms observed in BTAs' characteristic gait patterns.

CLINICAL APPLICATIONS

Understanding of the compensatory motions resulting from reduced active ankle joint contribution help inform lower limb prosthetic design for improving bilateral amputee gait quality.

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Differences in Movement Speed when Bilateral Transfemoral Amputees use Stubby or Full Length Prostheses

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INTRODUCTION The prevalence of bilateral transfemoral amputation (BTFA) is unknown. BTFAs comprise a small sub-group of lower-limb amputees, but their impairment is considerable. In inpatient settings, BTFAs likely have severe comorbidities (i.e. cardiac & mental health issues) as well as advanced age. Younger BTFAs may remain quite active though considerable impairments are still documented. A recent systematic review reported the energy demand associated with BTF prosthetic ambulation was so high (i.e. ≥400% of non-amputee demand) that BTFA patients with comorbidities will likely utilize a wheelchair as a primary means of mobility. BTFA gait speed may be impaired by ≥24% of non-amputees'. The purpose of this study was to determine if BTFAs, using stubby or full length prostheses, moved faster in multi-directional stepping and comfortable walking and to determine both groups' movement speeds compared to published non-amputee data.

METHOD A retrospective cohort design was used. Records were reviewed following a BTFA clinic where spatiotemporal gait and four-square step test (4SST) times were collected. Subjects had to be healthy enough to attend the clinic and utilize a prosthesis. Subjects walked a 4.9m GaitRite walkway, comfortable walking speed, 5 times. Cadence, velocity, and hand-recorded 4SST times (4 trials/subject) were of interest in this analysis. Patients were asked which limb they perceived to be the dominant limb by answering the question: "With which leg would you kick a ball?" This was corroborated by measuring and comparing which residuum was longer. 2 subject groups were assessed: 1) full length, articulated prosthesis users and 2) stubby prosthesis users. Some subjects may have had both prosthesis types. However, they were only assessed as part of one group or the other depending on which prosthesis they used most.

Data were assessed for normality and outliers. Normally distributed data were analyzed using independent samples *t*-tests. Otherwise Wilcoxon rank-sum test for median differences was used. NCSS PASS statistical software was used for analyses (Kaysville, UT). Statistical significance was set at $p \leq 0.05$. The intention to treat plan for missing data was group mean imputation.

RESULTS 22 BTFA prosthetic users participated. 17/22 used full length and 5/22 used stubby prostheses. Prosthetic socket, suspension, feet and knee(full-length) combinations varied. Group amputation etiology was 81% traumatic. Mean(MN) age for full length (FLU) users was 28.4±8.8y and comparable to stubby users' (SU) age: 29.5±13.4y($p>0.05$). BMI(MN) for FL users was 23.8±2.5kg/m^2 and lower than SU's: 27.5±6.9kg/m^2($p<0.001$). For movement speed, 4SST times and cadence were similar (both 3% difference; $p>0.05$) between groups. Comfortable gait velocity was 40% greater in the FLU group (* $p=0.01$; Effect Size= 2.2 [Large])

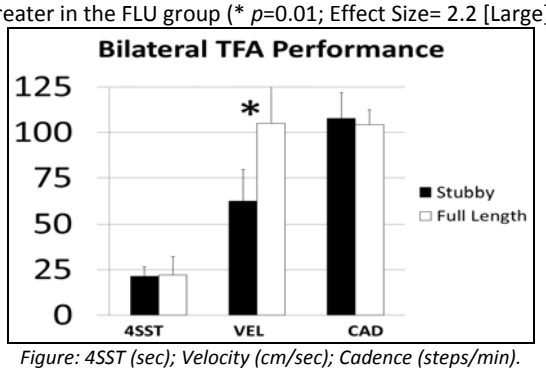

Figure: 4SST (sec); Velocity (cm/sec); Cadence (steps/min).

DISCUSSION & CONCLUSIONS BTFAs using stubbies can complete 4SST at times comparable to full length prosthesis users. SUs positioned themselves closer to the cane intersection during testing, creating a shorter travel distance. FLUs had surprising difficulty side-stepping, thus increasing their 4SST time. Both BTFA groups took longer to complete 4SST than non-amputees (≤10sec in some cases). For cadence, there was no significant difference between groups. Here, patients sought to step at a comfortable rate, demonstrating consistent motor control regardless of condition. BTFAs were walking a gait mat, alone, as opposed to socially walking beside someone, which may alter stepping rate and velocity. For velocity, there was a 40% difference, where SUs walked slower than their FLU peers. The consistent cadence is not surprising as step length in stubbies will be decreased, which is easily confirmed with future work. This finding has similarities to what might be expected when comparing the gait pattern of people with shorter limbs (i.e. shorter than average people, children, dwarfism) with those having longer limbs. That is, in order to walk at comparable speeds, those with shorter limbs must use higher cadence or, use a similar cadence but walk slower as seen here. In summary, both BTFA groups completed overground walking and multi-directional step tests and moved slower than non-amputees. Stubby users had a greater disadvantage in linear walking.

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‡PRESENTERS

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EFFECT OF TWO ORTHOTIC APPROACHES ON ACTIVITY LEVEL, BALANCE & SATISFACTION IN CHILDREN WITH CEREBRAL PALSY

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INTRODUCTION

Children with Cerebral Palsy (CP) are at risk of experiencing activity limitations and participation restrictions as a result of their impairment(s), which may affect their overall health, well-being and quality of life (Calley et al., 2012). Hence, an overall goal of intervention, including orthoses, is to enable activities and participation (Morris & Condie, 2009). It has been suggested that orthoses that restrict motion may impose greater activity limitations than those that facilitate normal patterns of joint motion (Morris, 2002). However, very few studies have explored the effect of different orthotic designs on activity levels of children with CP (Harvey et al. 2008). Hence, the purpose of this project was to evaluate whether the degree of ankle motion restriction affects activity level, balance and satisfaction in children with CP. We compared complete ankle motion restriction using a solid ankle-foot orthosis-footwear combination (AFO-FC) to resisted, articulated motion using an adjustable dynamic response AFO with supramalleolar orthosis (ADR-AFO).

METHOD

Subjects: 5 children with CP aged 6-10; GMFCS I–III; 1 hemiplegia, 3 diplegia, and 1 asymmetric diplegia.

Design: Randomized cross-over before and after trial, AABCBC design.

Procedures: Evaluations of steps/day (assessed using the StepWatch (Modus Health LLC, Washington DC) attached to the orthoses), balance (assessed using the Pediatric Balance Scale, PBS), distance walked over 6 minutes (6MWT), patient-reported lower extremity functional status (LEFS), health-related quality of life (HR-QOL) and satisfaction with device (SwD) (assessed using the Orthotic and Prosthetic Users' Survey, OPUS), and participation (assessed using Life-H) occurred twice: with the existing, prescribed orthoses (assessed 4 weeks apart) and then with each study orthosis. Subjects were randomized to AFO-FC or ADR-AFO for 4 weeks each, alternating once for each orthosis (total 16 weeks).

Data Analysis: Descriptive analysis of data in chronological order to allow for assessment of order effects and then by orthosis.

RESULTS

Subjects spent most of their time inactive with low to moderate step activity when active. Only the hemiplegic and asymmetric diplegic subjects had some high step activity rate. Average daily steps were consistently higher in the AFO-FC for Subject 2 and ADR-AFO for Subject 4. Results were mixed for other subjects.

With the exception of Subject 4, all subjects walked less total steps/day in both test orthoses than they did in their originally prescribed orthoses. Total steps/day were consistently higher in the AFO-FC for Subject 3 and ADR-AFO for Subjects 4 and 5. Subjects 1 and 2 had mixed results.

With the exception of Subject 2, baseline PBS scores were consistent and did not exceed the minimal clinically important difference (MCID) (Chen et al. 2013). Balance seemed to be more affected by time in the study than orthosis design with Subjects 2, 3 and 5 demonstrating clinically important change over the course of the study. Clinically important differences between orthoses were observed for various pairs of conditions but without any consistent pattern.

Baseline scores on the 6MWT were consistent for 3 subjects. There was no consistent trend over the course of the rest of the study. Distance was consistently greater for the ADR-AFO in Subject 3 and for the AFO-FC in Subjects 1 and 4. Performance of other subjects was inconsistent across orthotic conditions.

Overall scores for OPUS-LEFS were inconsistent. There was no trend over time and only Subject 2 had a higher score consistently for the AFO-FC. Results for other subjects were inconsistent across orthotic conditions. For HRQOL baseline scores were consistent for 4 subjects. There was no trend over time and only Subject 1 had a consistently higher HRQOL for the ADR-AFO. Results for other subjects were inconsistent across orthotic conditions. For SwD, baseline scores were consistent for 3 subjects. Subject 1 was consistently more satisfied with the ADR-AFO, while the remaining subjects had inconsistent results across orthotic conditions.

Baseline Life H Total Score was reasonably consistent between all testing occasions except for Subject 5. For Subject 4 the ADR-AFO scored slightly, but consistently higher than the AFO-FC. There were no consistent differences between orthoses for the other subjects.

DISCUSSION

Overall results were mixed with regards to whether subjects performed better with the ADR-AFOs or AFO-FCs. Based on patient-reported measures, ADR-AFOs were preferred.

CLINICAL APPLICATIONS

Mixed effect of orthoses not only across subjects but within the same subject based on different measures provides some support for the idea that orthotic benefit might be situation/task specific, supporting the use of time and resources to customize orthotic intervention; the need for patient specific tuning; and the potential utility of bimodal or multi-modal AFOs.

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BENEFITS OF BRACING KNEE OSTEOARTHRITIS

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INTRODUCTION

Knee osteoarthritis (OA) is a common joint disease, affecting ~6% of the population older than 30 years (Felson, 1998). Knee OA is characterized by complaints of knee pain, gait disturbance, stiffness, and functional limitations leading to reduced activity and impaired quality of life (QoL) (Murphy, 2008, Baert, 2012, Brouwer, 2006). Bracing the OA knee to unload the diseased compartment is an underutilized treatment. This study investigated if use of a decompressive knee brace can improve clinical, functional and biomechanical factors.

METHOD

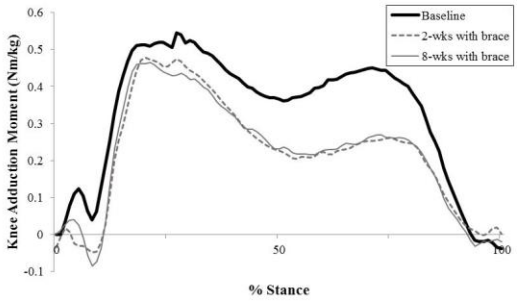
Nineteen with knee OA (15 medial) participated: mean age 55 years; KL grade (II =5, III =10, IV =4).

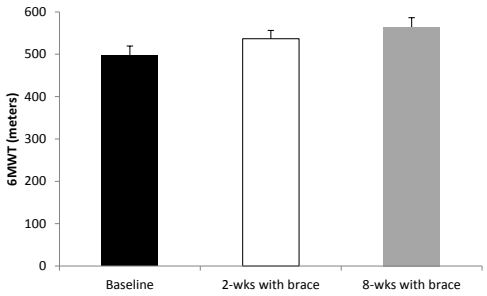
Procedures: At baseline subjects were measured for the Rebel Reliever (Townsend Design) knee brace. Subjects underwent gait analysis to identify knee adduction moment (KAM) and knee adduction impulse (KAI) of the involved leg. Subjects also completed a 6-minute walk test (6MWT), strength testing (knee extensors/flexors) on a Biodex, and completed the Knee injury and Osteoarthritis Outcome Score (KOOS) and the Activities Balance Confidence Scale (ABC). One week following base, subjects were fit with the brace, instructed in its use, and repeated the KOOS and ABC. Two and 8-wks after receiving the brace, subjects underwent testing similar to base with the knee brace on except during strength testing. Subjects also returned surveys 3-months and 6-months after fitting.

Data Analysis: Repeated measures ANOVA's with were used to detect differences in KAI, KAM, strength, and 6MWT at base, after 2-wks and 8-wks of brace use. KAI and KAM reported only for those with medial OA. Repeated measures ANOVA's were also used to detect differences in KOOS and ABC at base, fitting, 2-wks, 8-wks, 3-months, and 6-months.

RESULTS

The KAI (Fig 1. area under curve) and peak KAM in the 2nd half of stance was significantly reduced from base compared to both 2- and 8-wks of brace use ($p<0.05$). Subjects walked significantly further at 2- and 8-wks on the 6MWT (Fig 2) than at base and at 8-wks compared to 2-wks ($p<0.05$). Knee extension and flexion strength, measured by average peak torque and power significantly improved from base to 8-wks ($p<0.001$). Of the 14 subjects that returned the KOOS and ABC through the 6-month session, no significant changes were found when comparing base to fitting, indicating pain and function remained problematic prior to brace use. However, significant improvements in pain, symptoms, ADL's and QoL were found when comparing 2-wks, 8-wks, 3-month and 6-month report to base (all $p<0.01$).





DISCUSSION

Use of the Rebel Reliever for 8-weeks resulted in a reduction of potentially detrimental adduction forces at the knee for those affected with medial disease. Further, use of the brace improved functional walking capacity, improved knee muscle function and provided significant changes in reported pain and symptoms, ADL's and QoL measures. All changes in KOOS exceeded suggested values for clinically important changes, indicating the changes had a meaningful impact in the life of the participants.

CONCLUSION

Using the Rebel Reliever for knee OA is effective in reducing potentially biomechanical forces and improving function and QoL.

CLINICAL APPLICATIONS

We believe bracing individuals with knee OA is safe and effective and should be used as a mode of treatment, leading to meaningful functional changes.

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NOVEL BRACE FOR THE TREATMENT OF PCL INJURY

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INTRODUCTION

The Jack´s PCL brace is used to treat injuries to the PCL ligament. This brace imparts a constant anteriorly directed load to the tibia. However as noted in by Janssen 2012, the tension in the PCL increases as the knee flexes (figure 1). A brace has recently been designed to apply a variable anteriorly directed load, via a dynamic tensioning system (DTS),to the tibia to mimic the tension in the PCL (figure 2). The purpose of this biomechanical study is to demonstrate that this new design of brace imparts a dynamic anteriorly directed force to the tibia that is similar to the varying tension in the PCL during knee flexion.

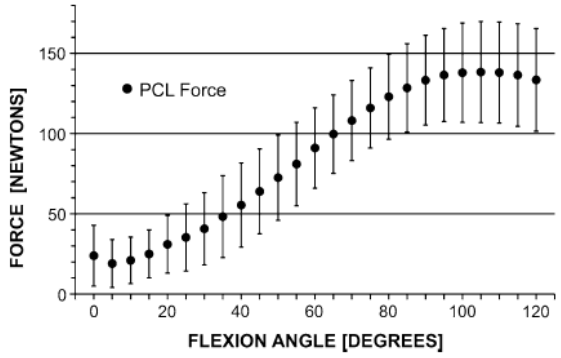

Figure 1 - Tension in the PCL throughout flexion

METHOD

Five healthy subjects were fit with an custom sized brace. A force transducer was placed beneath the DTS to measure force exerted against the posterior calf (figure 2). Subjects were instructed to stand shoulder width apart with straight legs. The force data were then logged as the subjects performed six squats, one squat being 0° to 90° to 0° knee flexion (judged visually). The force cuves were normalised over 100% and averaged across individuals and users.

RESULTS

The average force curve over all subjects can be seen in Figure 3.

DISCUSSION

The force exerted against the posterior calf was seen to increase and decrease during knee flexion in a linear fashion. This is closer to the tension seen in the PCL during knee flexion as described by Janssen 2012. Due to the variable nature of tension in the PCL during flexion a brace that exerts a constant force is either applying too much or too little force for most knee angles. The DTS allows the amount of force applied to vary in a similar fashion to PCL tension promoting a better position of the femur on the tibia throughout knee flexion. The reduced force in extension may also reduce discomfort.

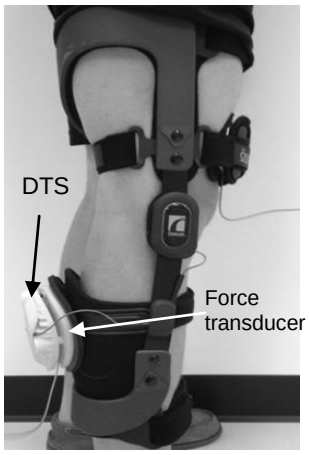

Figure 2 – Brace, DTS and force transducer

CONCLUSION

The new brace applies an anteriorly directed force that increases linearly with knee flexion in the same manor that PCL tension increases with knee flexion.

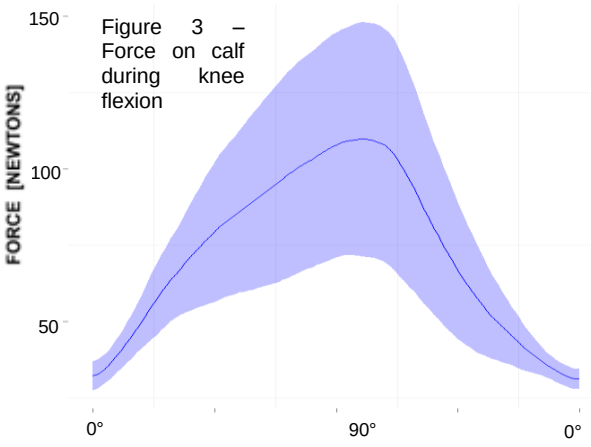

Figure 3 – Force on calf during knee flexion

CLINICAL APPLICATIONS

This new device may be beneficial for rehabilitation following both surgical or non-surgical treatment of the injured PCL.

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A 3D Printed Wrist-Driven Orthosis with Expanded Thumb Range of Motion

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INTRODUCTION

Wrist-driven orthoses (WDOs) facilitate a pinch grip for people who are capable of wrist flexion/extension but have limited finger control. Current designs for WDOs are difficult and time-consuming to fabricate. Further, many users do not like wearing them due to poor comfort, function, and aesthetics (House, Gwathmey and Lundsgaard, 1976). These challenges were the inspiration for using 3D printing to improve fabrication and function of custom WDOs. 3D printing creates models from digital files by printing numerous layers of very thin horizontal slices of the model, one on top of the other. The advantages of 3D printing include rapid prototyping, cost-effective manufacturing, and high levels of customizability. These advantages can be especially useful when dealing with custom medical devices and complex geometry, such as orthoses.

METHOD

SolidWorks, a 3D modeling software, was used to recreate the form of traditional WDOs. The WDO was made up of a forearm piece, a hand piece, pieces that go above and below the hand, the thumb, a four-bar linkage, and a fingertip piece. These pieces were printed on a MakerBot Replicator using an affordable and widely available bioplastic commonly used in 3D printing, polylactic acid (PLA). After printing, the pieces were connected using post screws. Padding was added at the wrist, thumb, and top and bottom of the hand to improve subject comfort. Velcro straps were used at the thumb and two places on the forearm to secure the WDO to the individual.

This design recreated the motion and function of the traditional WDO. An advantage of 3D modeling and printing is that the design can be quickly modified and tested. To improve upon the traditional WDO, design modifications were made to increase the range of motion (ROM) by allowing the thumb to move with the fingers and create a more natural grasping action. To enable this function, a four-bar linkage was added between the thumb and the finger that allows the thumb to move in conjunction with the fingers with wrist flexion and extension.

The ROM of both the original WDO and the modified design were tested using a goniometer to measure the angle between the tips of the thumb and the index finger at fully closed and open positions.

RESULTS

The 3D printed WDO took 6-6.5 hours to print (Figure 1). The total material costs were approximately $9.50 for the PLA, screws, padding, Velcro, Instamorph, and Loctite. The modified WDO design increased the ROM by 20° by engaging both the fingers and thumb in motion during wrist flexion and extension (Table 1). This improvement will allow users to pick up a wider range of objects.

Table 1. ROM of Original and Modified WDOs

	Original WDO	Modified WDO
Fully Closed	5°	0°
Fully Open	55°	70°
ROM	50° ROM	70° ROM

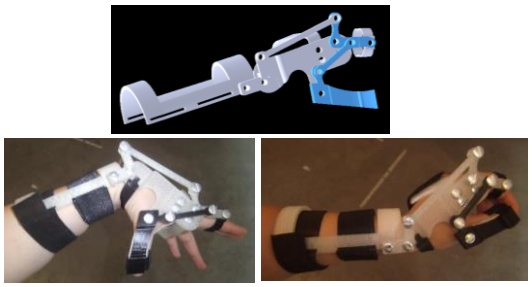

Figure 1. Modified WDO Design

DISCUSSION

The modified WDO design enabled greater hand aperture with minimal increases in device complexity or weight. Future work will evaluate the device with individuals with spinal cord injury to determine if it provides a more natural grip.

CONCLUSION

3D printed orthoses have the potential to ease fabrication, enhance aesthetics, reduce cost, and improve function. New designs, such as the modified WDO created in this study, can be customized to meet the unique needs and functional ability of each individual.

CLINICAL APPLICATIONS

The low cost of materials, enhanced aesthetics, and easier customizability of 3D printed orthoses have the potential to improve WDOs and other orthoses for individuals with spinal cord injury and other neurological disorders.

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ACKNOWLEDGMENTS

The authors wish to thank Ann Yamane, MEd, CO, LO for her advice on this project, as well as the mechanical engineering students Nicole Hastings, Kenn Peterson, John Harrison, and Derek Miller for assisting in creating the traditional WDO design.

A Functional Orthotic Design for the Ambulatory Clubfoot Child

Lin, Robert

INTRODUCTION

Talipes equinovarus (clubfoot) is a three-dimensional, idiopathic, congenital deformity not associated with any other abnormalities in the majority of cases. Clinical presentation includes a complex combination of metatarsus adductus, supination, varus through the hindfoot, equinous throughout the foot, and an overall medial displacement of the foot compared to the knee. It has been approximated that 150,000-200,000 children each year are afflicted internationally and 80% of those cases are occurring in developing countries according to the Ponseti International Association (2001). A "standard of care", The Ponseti Method, has been established to treat the deformity effectively. This care includes serial casting techniques with specific manual manupulation, surgical means as needed and subsequent foot abduction orthoses. Long-term night and daytime bracing techniques are not as succinctly established. Preferred care of the Orthopedic Department at Connecticut Children's Medical Center is to continue bracing the affected foot/ankle with custom thermoplastic day and night articulated ankle-foot orthoses (AFOs) once the patient begins ambulating and into early adolescent development. The purpose of the articulated night and day AFOs are to prevent the deforming forces of clubfoot from relapsing during early adolescence. An articulated AFO that provides a moment on the foot/ankle complex opposite to the deforming forces of clubfoot is theorized to be optimal. The purpose of this single subject case study is to define and compare the ankle kinematic and kinetic profiles of the standard articulated AFO, and the new offset hinged AFO, during ambulation. A comparison between barefoot walking of the same subject will also be made.

Your abstract must not exceed one page.

METHOD

Overall purpose: To understand the gait characteristics of a patient using the daytime offset hinged AFO compared to the standard hinged AFO during ambulation.

Hypothesis #1: The sagittal plane ankle range of motion will increase with the offset hinged AFO in comparison to the standard hinged AFO.

Hypothesis #2: The ankle power generation will be highest during barefoot walking and lowest during standard hinged AFO walking and in-between for the offset hinged AFO.
gle throughout the gait cycle, maximum plantar flexion angle, maximum dorsiflexion angle, peak knee flexion/extension angle, peak knee varus/valgus angle, and mean knee rotation angle during stance. Ankle kinetic parameters will also be evaluated including: peak ankle plantar flexion moment and power generation in stance.

Methods

Clinical Examination

The planned study is a prospective case study to evaluate gait changes caused by the offset hinged brace as compared to a traditional articulated AFO in a single patient with unilateral clubfoot. The patient's involved lower extremity would be molded for the fabrication of custom thermoplastic AFOs appropriate for the

patient following the standard of care for fabrication and fitting of AFO's at Connecticut Children's. Once fabricated, they would be fitted and the appropriate footwear would be donned.

The patient will then be sent to the Center for Motion Analysis for a comprehensive gait analysis to evaluate brace function using the current clinical protocol for evaluation of patients with braces. This protocol (standard of care for all patients coming to the Center for Motion Analysis) includes a full clinical exam and comprehensive motion analysis.

The clinical examination will include an assessment of the patient's passive range of motion and manual muscle testing of:

1. Ankle Plantar flexion and Dorsiflexion (range of motion and strength)

2. Ankle Inversion and Eversion (range of motion and strength)

3. Knee Flexion and Extension (range of motion and strength)

4. Hip Flexion and Extension (range of motion and strength)

5. Hip Abduction and Adduction (range of motion and strength)

6. Hip Internal and External Rotation (range of motion only)

7. Foot-Thigh Angle

8. Bi- malleolar axis (angle)

9. Femoral Anteversion (angle)

10. Silfverskiold Test

11. Varus/ valgus laxity at ankle & knee

Motion Analysis

The motion analysis will follow the standard clinical test commonly employed in the Center for Motion Analysis. Sixteen retro-reflective 14 mm motion capture markers (small plastic balls covered in silver tape) will be placed on the patient. These markers would be aligned to specific bony landmarks using hypo-allergenic double sided tape. The markers would be placed on the C7 spinous process, and right and left clavicles midway between the sternal notch and distal end of the clavicle. Markers will also be placed on the right and left ASIS, sacrum, right and left thigh, right and left lateral femoral condyle, right and left shank, right and left lateral malleoli, and on the right and left foot, as dictated by the current motion capture model used at the Center for Motion Analysis.

The patient will then be asked to walk along the blue walkway as they would normally walk if they were in school. The data collection will take place until we have three right and left foot strikes on the force plate. All data will be collected using a VICON 512 motion capture system at 120Hz.

Once the initial walking trials are completed the patient will change their brace and the patient will repeat the walking trials in the same manner. In total the patient will walk under three conditions barefoot (to obtain a baseline of the patients gait pattern and understanding of the impact of both AFO designs) using the standard articulated AFO, and using the offset hinge AFO. Each condition will include about three walking trials in order to assess continuity amongst each condition. The patient will be at the Center for Motion Analysis for about 2

hours. A database of healthy ambulators of the same age will be used for comparison purposes.

Once all the testing is completed all of the reflective markers will be removed and will be allowed to leave. The motion data will then be post-processed using VICON workstation software and plotted in VICON polygon for the visual assessment of the kinematic profiles. The values required for the descriptive statistics will be calculated using a custom Matlab program designed at the Center for Motion Analysis for the specific purpose of looking at specified gait parameters.

The kinematic and kinetic parameters that will be analyzed in the three conditions include the following:

1. Peak ankle dorsiflexion in stance (deg)
2. Time to peak ankle dorsiflexion in stance (% gait cycle)
3. Ankle sagittal plane range of motion (deg)
4. Mean foot progression in stance (deg)
5. Mean knee angle in stance (deg)
6. Peak knee flexion/extension angle (deg)
7. Peak knee varus/valgus angle (deg)
8. Knee rotation range of motion in stance (deg)
9. Peak ankle plantar flexor moment in stance (Nm/kg)
10. Peak ankle power generation in stance (W/kg)

A single subject assessment of the offset hinged AFO is intended to provide preliminary investigation data and serve as a resident orthotist project with the National Commission on Orthotic and Prosthetic Education (NCOPE). A single subject study initially is anticipated to generate further studies and research to draw broader conclusions.

RESULTS

.

DISCUSSION*Subject Demographics/ History*

The single subject for the case study met the inclusion criteria for the study as listed in the protocol. Specifically, the pt was a 6.5yo male with a height and weight of 114 cm (45in) and 18.1 kg (40#), respectively. At birth, the pt was treated by Dr. Jeffrey Thomson of the CCMC Orthopedics department, and by Hanger Clinic, CCMC for his orthotic needs. The pt was treated per the standard Ponsetti method, including a tibialis anterior lengthening (TAL) during serial casting as an infant.

The subject never required daytime AFO use after ambulation began. However, the subject still continues use of an articulated off-set hinged static progressive night time AFO to prevent plantar flexion contracture long term.

Procedures

The subject was molded to fabricate AFOs for the study. Both the traditional and off-set hinged AFOs were fabricated from the single plaster of paris positive model to reduce variability. The AFOs were fabricated with 5/32” thickness natural polypropylene and small Becker Tamarack joints per standard AFO vacuum forming methods. For visual assistance, the off-set hinged AFO was fabricated with red straps and the tradition with blue, see Figure 6.

Figure 6: posterior view of traditional hinged AFO (left) and off-set hinged AFO (right)

Each AFO was to fit to the patient appropriately. Per the subject's mother, he was compliant for the planned weaning schedule of one hour per brace each day for seven days. There were no changes in skin condition during the weaning period. The subject stated that during the weaning period, the off-set AFO was "more comfortable".

The subject returned for the next appointment at the Center for Motion Analysis. The subject was vaguely familiar with the laboratory from a gait lab evaluation at about the age of four. Clinical examination was executed per the protocol and results are listed in **Tables 1 and 2**.

Gait analysis results are listed in **Tables 3, 4, and 5**. The raw data results were expanded to include more information than initially indicated in the protocol. The data for peak knee flexion was reported specifically during each phase of the gait cycle (swing and stance). Similarly, the data for peak knee extension was reported for the stance phase and the gait cycle overall to capture heel strike to heel strike completely. The timing of each parameter was also included in the data for ease of interpretation. Timing of each parameter is reported as the percentage of the gait cycle (% GC). The tables are broken up into an assessment of the hip, knee, and ankle of the left side. Each condition (barefoot, traditional hinged AFO, and off-set hinged AFO) is reported within the tables for each joint. Values are based upon a best representative trial. Means reported for some parameters reflect an average of three runs. In the data, external rotation is indicated with a negative value whereas internal rotation is a positive value. Power generation is reported as a positive value and absorption as a negative. Lastly, dorsiflexion is a positive value and plantarflexion is a negative value.

Table 1: Clinical examination findings of passive range of motion (ROM) and manual muscle testing (MMT)

Assessment	ROM Right (degrees)	ROM Left (degrees)	MMT Right	MMT Left
Ankle Plantar	WNL	WNL	WNL	WNL

flexion				
Ankle Dorsiflexion Knee at 0° Knee at 90°	5 20	0 0	WNL WNL	WNL WNL
Ankle inversion	Full	Full	WNL	WNL
Ankle eversion	Full	Limited	WNL	WNL
Knee flexion	Full	Full	WNL	WNL
Knee extension Hip at 0° Hip at 90°	+10 -40	+15 -40	WNL	WNL
Hip flexion	WNL	WNL	WNL	WNL
Proximal Hamstring (Straight Leg Raise)	80	WNL	n/a	n/a
Hip Abduction	55	60	WNL	WNL
Hip Adduction	WNL	WNL	WNL	WNL
Hip internal rotation	55	55	WNL	WNL
Hip External Rotation	50	40	WNL	WNL

Foot-Thigh	-5	-15
Bi-malleolar axis	10	15
Femoral anteversion	30	30

Table 3: Kinematic parameters of the left pelvis/ hip

Left Side Pelvis/Hip Kinematics
Mean Pelvis Rotation in GC (°)
Mean Hip rotation in GC (°)

Discuss your results. Relate your results to those of other authors. Draw out the main conclusions and clinical implications, if any, of your work. Indicate future directions that you are pursuing.

CONCLUSION

State your conclusion and give a concise explanation.

CLINICAL APPLICATIONS

In an effort to maintain clinical relevance, every abstract will need to include a brief indication of its clinical applications.

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Author, B. J. Biomech 11, 34-67, 1999.
Author, C. Clin. Biomech. 33, 1013-1014, 1990.

Include only key references, usually no more than five. Do not include titles of articles or chapters, only the journal or book title, journal volume, and page numbers. Use the "References" style. The font is smaller and hanging indents are produced.

Table 2: Clinical examination findings continued

Assessment	**Angle Right**	**Angle Left**

CURRENT CONCEPTS IN TRANSFEMORAL SOCKET DESIGN

Mark Muller, CPO, FAAOP, MS
California State University Dominguez Hills

INTRODUCTION

Until 2009, the Transfemoral (TF) level amputation was the prevalent major amputation surgery in the United States (Beliati, 2013). Transfemoral prosthetic socket design and construction have a long history in our profession (Gholizadeh, 2014). Yet the profession still lacks clinical standards of practice. A presentation has been created that will review the evolution of TF socket design; discuss current designs being utilized; and summarize the curriculum with applicable outcome measures of TF prosthetics that are being taught at the accredited Masters level orthotic and prosthetic practitioner programs in the United States.

Learning objectives for this presentation include:

- Recall previous TF socket designs;
- Outline the history of TF education;
- Describe the National Commission on Orthotic and Prosthetic Education (NCOPE) current curriculum standards and institutional instruction for TF socket design; and
- Compare and contrast current practical TF socket designs; their biomechanical function, material science, suspension, impression techniques clinical applications and applicable outcome measures.

Background: The first patents awarded for TF prosthetic designs were given in England in 1790 and 1800 with the first U.S. patent for a TF artificial limb given in 1846 (G.E. Marks, 1896., US Patent # 4834, 1846). In 1949, the first formal TF instructional course began at the University of California Berkeley and consisted of short-term lessons focused on the fabrication and alignment of a transfemoral suction socket design. Then, in the 1950's, the University of California Los Angeles, New York University and Northwestern University began formal education programs in prosthetics (Anderson 1961). Currently, there are eleven NCOPE accredited education institutions for prosthetics and orthotic practitioner programs. While most schools follow the *lecture, demo, then do*, clinical model (Plack, 2011), all have differing theories and alter in practical techniques for quadrilateral, Ischial containment and sub-Ischial socket designs. It is understandable why there are differing socket designs due to the nature of each TF residual limb's anatomy, limb size and length, so it would be clinically beneficial to understand what socket designs are being implemented in clinical practice and why each institution chooses to teach the style they do.

METHOD

The information gathered for this presentation is cited from US patent searches as well as a literature search using various data bases with terms that included 'artificial limbs', 'above knee', 'interface', 'sockets', 'artificial legs', 'transfemoral', and 'education'. Current orthotic and prosthetic (O&P) textbooks listed on the American Board for Certification's (ABC) 2010 *Examination Question References and Recommended Reading List* where utilized. The 2010 NCOPE *Core Curriculum for Orthotists and Prosthetists Guidelines* as well as the *Practice Analysis of Certified Practitioners in the Disciplines of Orthotics and Prosthetics* published by ABC in 2007 are also referenced. Interviews were conducted with current faculty at NCOPE accredited O&P practitioner programs such as: the California State University Dominguez Hills; University of Hartford; Northwestern University Prosthetic-Orthotic Center; St. Petersburg College and the University of Washington. Additional interviews were conducted with the Vice President of Prosthetics and the Director of Clinical Education for Hanger Clinic as well as multiple facility owners and certified practitioners of O&P accredited facilities.

RESULTS AND DISCUSSION

With the information gathered from interviews and literature cited, it is clear that there is no 'one' TF socket design that would be appropriate and applicable for every user of TF prosthetics. The prosthetic practitioner requires the ability to differentiate between designs to determine which would be best for their unique patient. Therefore, this presentation has been created to: review the history, contrast the current status of institutional instruction, compare clinical practical use and present the potential future direction of TF socket designs as it relates to the biomechanics of fit, types of suspension, impression technique, and fabrication science. The presentation also covers potential psychosocial and functional outcome measures appropriate for use within TF socket design acceptance.

CONCLUSION

A potential conclusion would be for the newly formed Orthotic Prosthetic Educators Council to discuss the current need for a standardized education platform in TF socket designs that would address the current needs of the profession. It would also be beneficial to create curriculum assessments that better justify the techniques taught at the institutional level so the profession

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has a solid foundation of knowledge to base their clinical decisions on.

CLINICAL APPLICATIONS

An overview of differing TF socket designs as they relate to biomechanical fit and function, material science, suspension and impression techniques will increase the audience's knowledge base in TF practical theory. This will allow the practitioner to be better prepared to make the most appropriate clinical choices for their patients.

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DEVELOPMENT OF AN EMPIRICAL METHOD TO ASSESS RESIDUAL LIMB MOTION BENEATH PROSTHETIC SOCKET

INTRODUCTION

The United States has approximately 1.7 million people living with limb loss [1]. To maintain ambulation, patient specific prosthetic devices are designed. Research related to prosthetic socket fit include pressure distribution at socket to limb interface [2], residual limb bone kinematics within socket [3], and prosthetic socket fit and pistoning [4]. The current research study presents the development of a novel method to measure residual limb motion beneath the surface of a prosthetic socket using motion capture technology. Engineering principles combined with clinical need may have implications for identifying tissue breakdown which may lead to ulcer formation on regions of the residual limb at the socket interface.

METHOD

Twenty-two retro-reflective thin-disc markers were placed beneath a clear transparent test socket manufactured out of Thermolyn. A 12 camera Vicon system tracked the locations of all 22 markers and these data were compared to markers placed on the outside of the socket and pylon. The prosthetic replica incorporated a plaster mold, interfaced with a standard gel liner and pin suspension system. Future work will replace plaster with a deformable replica of a below knee amputee. Distances measured between markers were compared to the inter marker distances captured with the motion capture system when the residual limb replica was placed into the test socket. Dynamic trials were then collected of emulated clinically observed pistoning by vertically displacing the limb upward and capturing marker movement patterns relative to the prosthesis (Figure 1).

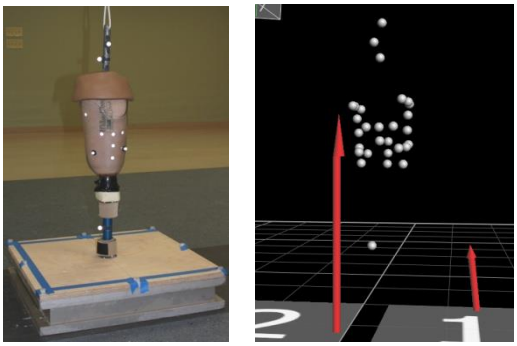

Figure 1: Testing setup and image with cameras

RESULTS

Results (Table1) demonstrate an approximate 2mm displacement between tibial tubercle(TT)/Medial Tibial Plateau (MTP) and the distal fibula (DF). Only 0.23mm displacement was seen at the proximal fibula(PF). Static caliper values compared to measured distances are within the camera system error band, accurately measuring locations beneath the surface of a socket.

Table 1: Displacement results (in mm)

	Caliper dist.	Static meas. w/ MC	Dynamic ROM
TT/MTP	35.37	35.28 +/- 0.02	35.09 – 37.45
PF	35.72	35.88 +\- 0.04	35.65 – 35.88
DF	45.35	45.47 +/- 0.5	46.09 – 48.70

DISCUSSION AND CONCLUSION

Future work will implement this testing method in individuals presenting with trans-tibial amputation. Uneven regional deformation is an important finding because clinicians may be underestimating the deformation that is happening at the bony prominences, where tissue breakdown is common, compared to soft tissue regions. The results of this study encourage a novel methodology to be applied to individuals presenting with amputation during walking to empirically assess clinical pistoning and the distribution of deformation within the socket.

CLINICAL APPLICATIONS

Several clinical factors play a role in ulcer formation including: time since amputation, degree of tissue remodeling, presence of bony prominences close to the surface of the skin, quality of socket fit, distribution of forces on limb. Information obtained from this experiment may be used to inform clinicians on different methods of socket modifications to decrease risk of ulcer formation.

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Development of Metrics for Quantitative Evaluation of Socket Fit

INTRODUCTION

A quality socket fit is essential to optimize the performance of the prosthesis and lead to patient acceptance of the device. Currently, patient feedback and qualitative prosthetist assessment are often the sole methods used to compare socket fit and performance. New socket designs are regularly being developed, but comparing these new approaches to more standard designs is difficult. Therefore, as part of a larger study that focused on the development of a volume adjustable socket, LTI endeavored to develop quantitative metrics to differentiate between good-fitting and poor-fitting sockets.

METHODS

Subjects: 9 subjects with transfemoral amputation participated in the study.

Research Tools: Three tests were developed to compare three different socket fit conditions. These are referred to as the 1) resisted pursuit tracking (RPT) test, 2) balance pursuit tracking (BPT) test and 3) wobble test. The RPT (Figure 1) requires the user to control a cursor by moving their residual limb to track a moving target. Resistance to this movement is created by restricting air flow through pneumatic cylinders. The BPT requires the user to shift their center of pressure to move a cursor to track a moving target. The wobble test is a modified postural sway test in which the users are required to bear a majority of their weight on the prosthesis while standing with the prosthetic leg on a hemispherical balance board. The concept behind each test was that a better coupling between the residual limb and the socket would lead to better performance on the test.

Procedures: Three socket conditions were tested for each subject: 1) their everyday socket, 2) a volume adjustable socket that was purposely oversized (since limb volume couldn't be reliably controlled the socket was oversized to simulate limb volume loss and a poor socket fit), and 3) the adjustable socket tightened by the user to a level that was deemed most comfortable by the user.

Data Analysis: The output of the RPT and BPT tests were the tracking error between the target and the user controlled cursor. Various postural sway metrics were calculated for the wobble test (Collins, 1995). A quadratic mixed effects model was created to determine the relationship between socket volume and scores on each of the tests.

RESULTS

All three tests showed better performance with better fitting socket conditions. The mixed effects model of the resisted pursuit tracking (RPT) test data showed a statistically significant relationship ($p < 0.05$) between socket volume and the score on the RPT test. While trends were observed, no statistically significant relationship was observed for the BPT and wobble tests (alpha = 0.05).

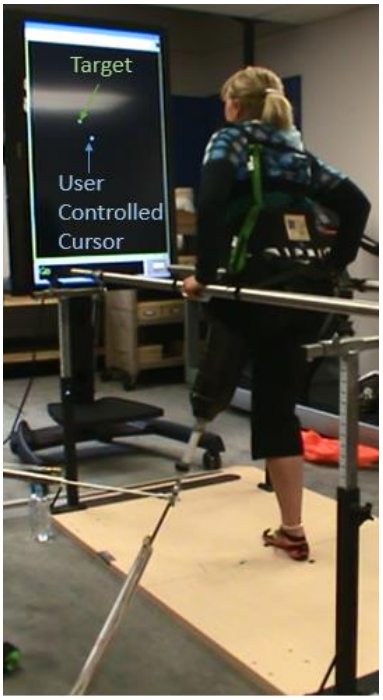

Figure 1 – A photograph of a test subject completing the RPT test.

DISCUSSION & CONCLUSION

The resisted pursuit tracking (RPT) test showed the ability to detect a relationship between increasing socket volume (i.e., decreasing quality of socket fit) and the score on the RPT test. This indicates that the RPT gives an objective and quantitative method for comparing sockets with different qualities of fit. The work presented here was focused on evaluating volume adjustable sockets. In the future, instead of changing socket volume, we intend to compare different socket designs including sub-ischial, elevated vacuum, 'Hi-Fi', osseointegration, etc. as well as test below-knee amputees. This will allow us to perform an objective evaluation of these socket designs to quantify how well they couple the prosthesis to the residual limb. In addition, it was clear that subject engagement had a substantial effect on the RPTs ability to differentiate between different socket volumes. Alterations to the test to mitigate this effect will be incorporated.

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The project depicted was sponsored by the Department of the Army under award number W81XWH-10-1-0902. The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014 is the awarding and administering acquisition office. The content of the information does not necessarily reflect the position or policy of the Government, and no official endorsement should be inferred.

ADVANCEMENTS IN MODULAR SOCKET INTERFACE DESIGNS - NASA ROBOTICS RESEARCH ENHANCES SOCKET INTERFACE CAPABILITIES

Jay Martin, CP, LP, FAAOP
Martin Bionics Innovations, LLC

INTRODUCTION

As the evolution of prosthetics component technologies continues, great advancements in capabilities and quality of life are being realized. However, one of the remaining critical aspects of enabling persons with limb loss to function to their full potential is the development of novel socket interface designs. With the increasing performance capabilities of prosthetic limbs, a result of greater forces on the body is realized. This requires changes to be made in clinical interface designs to maintain comfort and functional outcomes.

Research and development in conjunction with NASA and the DoD has lead to significant enhancements in design of modular clinical prosthetics interfaces. Instead of using a typical encapsulated socket, these new interfaces utilize compliant fabrics for the prosthetic fit.

New designs for transfemoral, hip disarticulation, and upper extremity prosthetic interfaces have been developed using the technology from the NASA program.

METHOD

These new interface designs effectively distribute the forces through integrated special fabric, versus rigid or semi-rigid materials of conventional socket systems, thereby allowing for the ability to increase loads and torques while simultaneously increasing user comfort and stability.

Extensive biomechanical research and development was conducted to find the optimal specific contouring of these specially selected materials about the body. Interface designs were then fabricated for prosthetic devices of various levels. Each of these designs provided predominantly fabric based contact about the body, versus conventional laminates or gels. Tests were conducted on various able-bodied and amputee subjects to determine comfort and stability outcomes, in various embodiments.

RESULTS

In each of the tests, subjects found the fabric-based devices to be preferable over their pre-existing prosthetics fabricated from conventional materials.

In addition, these novel compliant materials provide a significant reduction in heat and moisture buildup. The use of these materials results in incredibly lightweight interface designs, and provide enhanced comfort and functional outcomes, especially when in conjunction with the most capable prosthetic components.

DISCUSSION

The use of these prosthetic interface technologies have shown successful outcomes in practical clinical application. Their inherent modularity allows for them to be quickly and easily adjusted to accommodate for patient size fluctuations or preferences.

This presentation will discuss specific clinical case studies around the modular fabric-based interface designs use in upper and lower extremity prosthetics. It will additionally provide practical information on fitting and fabricating these interface designs.

CONCLUSION

The use of modular compliant fabric-based prosthetic interfaces allow for greater heat dissipation, volume accommodation, and comfort. Additionally, our testing has shown for greater skeletal stability through these socket designs.
As prosthetic interface designs integrate new materials, the functional and comfort outcomes of their users will be enhanced.

CLINICAL APPLICATIONS

Through educating clinical prosthetic practitioners how to perform these fittings, these and other designs will continue to evolve, allowing those who use prosthetics to gain greater experience and outcomes.

American Academy of Orthotists & Prosthetists
41st Academy Annual Meeting &
Scientific Symposium
February 18 - 21, 2015

Moisture Management and Secure Adherence

GK Klute, PhD[1, 2], K Bates, MS[1], JS Berge, MSE[1], W Biggs, CPO[1], C King, CP[3]

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[3]Arusha Control, Inc., Cumberland, MD.

INTRODUCTION

Lower limb prosthetic sockets and liners do little to alleviate perspiration accumulation in the inside of the prosthetic interface (liner). Under dry limb conditions, a secure adherence can often be provided. For the active individual, inadequate moisture management can be a significant impediment. The materials from which prostheses are made are nearly impermeable to moisture (Hachisuka et al., 2001) and of low thermal conductivity (Klute et al., 2007); properties that prevent evaporative and conductive cooling. More than just bothersome for many amputees (Hagberg and Branemark, 2001), sweat-related adherence problems can limit or inhibit mobility under demanding conditions.

This study compared a novel prosthesis, designed to expel accumulated perspiration by using negative gauge pressure to induce dynamic air exchange (DAE), with a widely-prescribed total surface bearing suction socket prosthesis (SUCTION) using a prospective, randomized cross-over experiment.

METHOD

Subjects: Five transtibial amputees provided informed consent to participate in this IRB-approved protocol (44±15 yo, 89±18 kg, 1.8±0.1 m, 14±15 years post-amputation, n=3 trauma, n=2 secondary to infection). All participants considered themselves moderately active community ambulators.

Procedures: Subjects were given a one-week acclimation period to each study prosthesis while their step activity levels were measured with a StepWatch3 (Orthocare Innovations). Subjects then performed a 30-min seated rest, 30-min treadmill walk at their self-selected speed), 30-min seated rest protocol in a laboratory environment (~20° C, ~30% relative humidity) while wearing thermally-insulative garments. Changes in residual limb skin temperatures were measured with thermistors and tare weights were used to measure accumulated and expelled perspiration. Afterwards, subject opinions about the prostheses were assessed with subsets of the Prosthesis Evaluation Questionnaire (PEQ; Legro et al., 1998). Three scales measuring ambulation, frustration, and residual limb health were scored on a scale from 0 to 100 where 100 represented the best outcome.

Data Analysis: A paired t-test was used to determine if differences in step activity levels were statistically significant ($p<0.05$). A linear mixed model was used to assess whether differences in residual limb skin temperatures were statistically significant ($p<0.05$). Accumulation and expulsion (DAE only) of perspiration and subjective experiences were not statistically analyzed.

RESULTS

No difference in step activity levels were observed between prostheses ($p=0.220$) during the week-long acclimation period. During the rest-walk-rest protocol, no differences in residual limb skin temperatures were observed between prostheses ($p=0.366$). The DAE prosthesis accumulated 1.09±0.90 g and expelled 0.67±0.38 g perspiration while the SUCTION prosthesis accumulated 0.97±0.75 g. As measured by the PEQ, subjects opined their residual limb was healthier while wearing the DAE (89±15) compared to the SUCTION (66±30), it was easier to ambulate while wearing the DAE (76±25) compared to the SUCTION (65±32), but wearing the DAE (49±32) was more frustrating compared to the SUCTION (58±40).

DISCUSSION

The total amount of perspiration (accumulated plus expelled) while wearing the DAE was 80% more than the SUCTION prosthesis. If the approximately 1 g of perspiration expelled by the DAE had remained between the skin and liner, it is unknown if that amount would have resulted in an insecure adherence. The time to loss of adherence under controlled conditions (e.g., activity intensity, environment temperature and humidity) would aid in defining perspiration limiting thresholds.

CONCLUSION

The DAE prosthesis was able to expel more than a third of the total perspiration, suggesting it may enable longer uninterrupted periods of perspiration-inducing activity for lower limb amputees. The questionnaire results suggest participants were receptive to both prostheses.

CLINICAL APPLICATIONS

Dynamic air exchange technology may improve the mobility, health, and comfort of ambulatory lower limb amputees.

ACKNOWLEDGEMENT

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Sub-Ischial Prosthetic Sockets Improve Hip Range of Motion and Performance for Individuals with Transfemoral Amputations

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INTRODUCTION

Persons with transfemoral amputation (TFA) represent approximately 20% of all persons with amputation in the general population (Owings et al. 1998) but the proportion of service members with transfemoral amputations is higher than the general population (31%) (Stansbury et al. 2008). These individuals are typically young, with excellent premorbid health and many wish to return to premorbid activity levels and have higher functional expectations (Pasquina et al. 2006) than the older, dysvascular amputee. Improvements in prosthetic componentry, including socket design and suspension, have critical impact on the functional abilities of individuals with TFA. Traditional designs include ischial containment sockets which limit hip range of motion and function (Tranberg et al. 2011). New sub-ischial designs, which incorporate vacuum suspension to maintain the socket-limb interface, may improve hip range of motion and overall function.

METHOD

The Brooke Army Medical Center Institutional Review Board approved this study and informed consent was obtained from subjects prior to participation. Six male service members between the ages of 18 and 45 with unilateral TFA and residual limb lengths of at least 4 inches are undergoing assessment in two socket and suspension designs: (1) Ischial containment sockets with cushioned gel liners and (2) Sub-ischial sockets with active vacuum suspension. All subjects wore the X3 knee (Ottobock, Duderstadt, Germany), an energy-storage-and-return foot and were given a minimum of 6 weeks accommodation time in each socket condition.

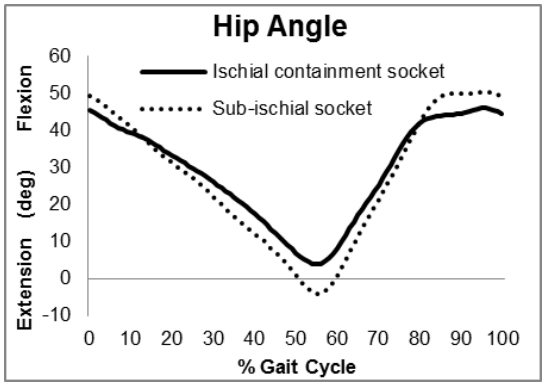
Testing took place in the ischial containment socket followed by the sub-ischial socket. Subjects underwent a series of range of motion, performance, and biomechanical tests. A 26-camera motion capture system (120 Hz, Motion Analysis Corp., Santa Rosa, CA) tracked trajectories of 57 markers secured to anatomical landmarks and body segments. Specifically, thigh and pelvic segments were tracked during active hip range of motion in the sagittal and frontal planes, a 5-time sit-to-stand test and at standardized walking speed. A T-test, which incorporates speed and agility with forward and backward running and side shuffling, was recorded for time.

Marker data were tracked and exported to Visual3D (C-Motion Inc., Bethesda, MD) for further analysis. Hip joint angles were calculated during the range of motion, performance task and 5 walking trials.

RESULTS

Thus far all subjects indicated that they preferred the sub-ischial to their ischial containment socket. One common theme was the ability to sit without the socket beneath the ischium.

Data from the first subject to complete the full testing protocol showed that the sub-ischial socket resulted in 10° greater active peak hip flexion, 13° greater active peak hip extension and 9° more hip abduction; sit-to-stand time improved by almost 2 seconds; hip range of motion increased 20.6°; T-test performance improved by 4 seconds (16%). Across 5 walking trials, hip range of motion increased 12.5° ± 1.2° with the sub-ischial socket and the hip was able to achieve extension during walking (Figure 1).



DISCUSSION & CONCLUSIONS

Speed, agility, and hip range of motion were expected to improve when subjects wore the sub-ischial socket with vacuum suspension due to the lower proximal trim lines. The inclusion of additional subjects will determine if greater hip range of motion during walking may improve overall walking ability and potentially lessen the need for gait compensations. High patient satisfaction with the sub-ischial socket supports further investigation of this new socket design.

CLINICAL APPLICATIONS

Sub-ischial sockets with active vacuum suspension are emerging as viable options for active individuals with TFA.

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Predictors of Success on the Prosthetics Certification Exam

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INTRODUCTION Many factors can potentially impact pass or fail performance of a certification examination. Nursing[1], nurse midwives, athletic training, physical therapy, several medical specializations, education, financial planning[2] and other professions[3] have conducted studies to assess whether specific variables predict performance on their respective certification exams. A literature search on predictors of success did not reveal any such studies specific to prosthetics and orthotics. The purpose of this study was to determine if significant differences existed in American Board for Certification (ABC) certification examination success or failure based on gender, Carnegie ranking of the institution from where the candidate received the degree, and whether the candidate was extending credential.

METHOD The USF Institutional Review Board approved this study. National Commission on Orthotic & Prosthetic Education (NCOPE) and the American Board for Certification (ABC) provided 158 de-identified records for this retrospective study. All candidates completed residency in 2011-2012 and were graduates of NCOPE-accredited programs.

Variables collected were: gender, institutions' Carnegie classification[4], credential extension, ABC prosthetics certification (yes/no), and ABC Written Multiple Choice, Written Simulation, and ABC Clinical Patient Management practical exam scores.

Institutions were grouped into four classification levels: Research Universities with very high research activity (RU/VH), Master's colleges and universities - larger programs (Master's L), special focus institutions – medical schools and medical centers (Spec/Med), and other. Such grouping further protected candidate confidentiality.

Data Analysis: SPSS v22 was used for statistical analysis. To determine if significant differences existed, Chi-square/Fisher's exact tests were used for categorical values. Independent *t*-test was used for 2-level independent variables and ANOVA for 4-level independent variable. Significance was set at $p \leq 0.05$*.

RESULTS The sample consisted of 101 male and 57 female candidates. By gender, the same percentage, 84.2% and 15.8%, passed and failed, respectively, achieving Certified Prosthetist status. Candidates from Spec/Med institutions had the highest pass rate (100%). Seventy three of the 158 candidates were seeking credential extension from CO to CPO and 67 of those succeeded. Only *credential extension* had a statistically significant relationship in *t*-tests and linear regression with obtaining prosthetics certification and with the three exams (see table).

	Credential Extension	
Exams	**t-test**	**Linear regression**
Written Multiple Choice	.000	.000
Written Simulation	.003	.006
Clinical Patient Mgmt	.010	.005

Summary of independent variable Credential Extension *p*-values Note: $p \leq .05$

DISCUSSION Only credential extension produced statistically significant results with prosthetics certification attainment and performance on the three prosthetics certification exams. This is plausible, as these candidates had familiarity with the exam process as a whole. Also, they could possibly draw upon orthotics clinical knowledge and apply it in a prosthetics setting. A study regarding Certified Financial Planning (CFP) certification exam (Grange et al, 2003) found a significant relationship between profession-specific licenses and success on the CFP exam.

CONCLUSION This study presented the first analysis of predictors of success on the ABC prosthetics certification exam. Collection of additional variables (i.e. pre-requisite GPA, etc.) will permit analysis of more robust information to better understand whether relationships exist between these variables and performance on the certification exam, and has potential to inform practice and policy in prosthetics education and certification.

CLINICAL APPLICATIONS As the prosthetic/orthotic practitioner population ages, educational requirements change and advance and as demand for P&O services increase, it is important to understand what factors contribute to attaining licensure. These data mark the first step to understanding this dimension of P&O training which upholds professional standards and ultimately protects patients. Additionally, it would help the prosthetics profession keep pace and become a leader in best educational and clinical practices in managing patients who utilize prosthetic technologies.

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PATIENT-CENTERED CARE: WHAT DO PATIENTS WANT FROM THEIR PROSTHETIST?

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INTRODUCTION

The notion of patient-centered care is a key component of the dialogue on healthcare reform in the United States (1). Patient-centered care seeks to change the dynamic of healthcare from a system that revolves around what physicians and other healthcare providers feel are important to a system that is centered on the patient's satisfaction with the care they receive and the outcomes produced. A key difference between the two approaches to healthcare delivery is that within a patient-centered healthcare system patients play an active role within the clinical decision-making process and the delivery of care is tailored to the preferences and needs of the patient. Understanding patient preferences, needs, and expectations is an important initial step to delivering patient-centered care.

Although patient-centered care is an integral part of current healthcare reform efforts, it is not known whether this approach to healthcare delivery reflects the desires and expectations of patients receiving O&P care. The design, delivery and fitting of a prosthetic device are highly individualized processes that seem amendable to a patient-centered approach. In order to deliver patient-centered O&P care it is important to understand the preferences and desires of O&P patients. Further, it is not known what impact patient-centered care may have on the business of providing prosthetic care.

METHOD

The Amputee Coalition developed a survey asking persons with limb loss about what they expect from their prosthetic provider, whether they have switched prosthetic providers and, if they have switched prosthetic providers, why they switched prosthetists. This survey was placed on the Amputee Coalition's website from February through June of 2014. The survey was advertised through the Amputee Coalition's electronic monthly newsletter – *Limblines* – and the Coalition's Facebook page, which has over 17,000 participants. At the conclusion of the data collection period, a total of 270 persons with limb loss completed the survey.

IBM SPSS Statistics version 20 was used to generate descriptive statistics and perform inferential statistical tests on survey data. Descriptive statistics were used to describe what survey respondents expect from their prosthetic provider, whether they have switched prosthetic providers and their reasons for switching prosthetists. Inferential statistical tests (e.g., chi-square and ANOVA) were performed on survey data to determine whether prosthetic provider expectations, behavior around changing prosthetic providers or reasons for changing prosthetic providers varied by key patient characteristics (e.g., age, race, sex).

RESULTS

Results from statistical analyses suggest that patients with limb loss expect to receive patient-centered care from their prosthetic provider. According to these data, about half of patients with limb loss will switch their prosthetic provider. Nearly half of those who switched prosthetists changed their provider more than once. The lack of receiving patient centered care was commonly cited as a reason for switching providers. Inferential statistical analysis of survey data show that these expectations and preferences for prosthetic care do not vary according to key patient characteristics (e.g., age, sex, cause of amputation).

DISCUSSION

Data collected from the Amputee Coalition's survey contain a number of limitations. However, the results from this preliminary study suggest that patients with limb loss expect to receive patient-centered care from their prosthetic provider and may change prosthetic providers if they do not receive patient-centered care. These results underscore the importance for prosthetists to provide patient-centered care to their patients with limb loss.

CONCLUSION

Patients with limb loss expect patient-centered care from their prosthetic provider. Furthermore, the absence of patient-centered approaches to prosthetic care was commonly cited by survey respondents as a reason for switching prosthetic providers.

CLINICAL APPLICATIONS

Prosthetists should develop care models that incorporate the patient as an active participant in their healthcare. Patient-centered care is an important factor in patient retention. Providing patient-centered prosthetic care may represent a key element that helps prosthetic practices remain viable within a competitive business environment. Thus, patient-centered O&P care may be good for patient outcomes and for those O&P practices that commit to this approach to care delivery.

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Muscle Activation Patterns during Therapist-Assisted and Robot-Aided Gait Training in a Patient with Incomplete SCI

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INTRODUCTION

Locomotor rehabilitation therapy (LRT) is designed to promote functional gait recovery in individuals with incomplete spinal cord injury (SCI). Multiple LRT approaches have been proposed, all of which show some potential for improvement of ambulatory function. However, no single method has been shown to be superior [Morawietz, 2013]. Therefore, this study was done to compare therapist-assisted (TA) to robot-aided (RA) LRT.

METHOD

Subject: The subject is an 18-year-old male with an incomplete SCI due to a C3-4 hyperextension and dislocation football injury. At the time of injury, he had no motor or sensory function below C4. Rectal motor and sensory function was absent five hours after the injury (ASIA A). A C2-4 decompression and fusion surgery was performed 12 hours after the injury. By 48 hours post stabilization he improved to C3 ASIA B tetraplegia with independent breathing. He progressed through therapy focused on an activity-based program. The subject was studied at 22 and 44 months after injury. At the first study he was classified as ASIA D.

Apparatus: For the first study, a Rifton Pacer Gait Trainer with hip positioner attachment providing partial body weight support and bilateral forearm platforms was used along with AFOs. One therapist stabilized the walker and one therapist facilitated reciprocal stepping patterns via continuous tactile cueing of the pelvis. The second study used an Ekso GT robotic exoskeleton with full-weight bearing and a front wheeled walker. An assistant stabilized the walker. The robotic exoskeleton was programmed to require voluntary hip flexion to initiate swing phase for each step and to provide assistance for knee extension via battery powered motors at the end of swing only if the subject was unable to complete it volitionally.

Procedures: Motion capture at 120 Hz was used to collect heel/toe marker movement and identify gait events. Electromyographic (EMG) data was obtained bilaterally at 2400 Hz from the iliopsoas, rectus femoris, hamstrings, tibialis anterior, and gastrocnemius, EMG data was rectified and passed through a 4th order, low-pass Butterworth filter with a 6 Hz cutoff.

RESULTS

Walking velocity was 19.5 cm/sec for the TA-LRT. For the RA-LRT, the initial walking velocity was 4.8 cm/sec and increased to 11.0 cm/sec at the end of the training session. Kinematic patterns of the hip, knee, and ankle were similar for both types of LRT.

Motor activation patterns were markedly different for the two types of LRT (Figure 1). During TA-LRT, the EMG had low level continuous activity lacking phasic muscle activation patterns. With RA-LRT, the EMG displayed phasic muscle activation patterns which were appropriate for all muscles studied.

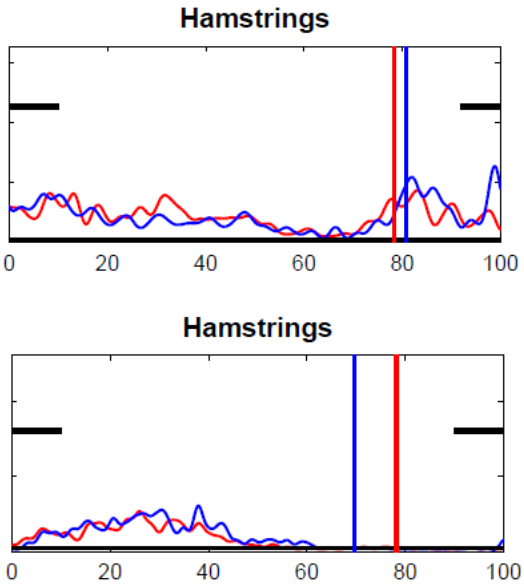

Figure 1.Hamstring muscle recruitment patterns during two gait cycles for (A) therapist-assisted LRT and (B) robotic-aided LRT. The recruitment pattern is more phasic for robotic-aided LRT.

Fatigue was the most striking difference between the two types of LRT. With TA-LRT, the patient was able to achieve 5 walking trials for a total walking distance of 25 m. In contrast, the patient was able to walk 38 trials for a total distance of 190 m with RA-LRT.

DISCUSSION

Requiring voluntary activation of muscles prior to activating assistance and assisting in movement only as needed, i.e. RA-LRT, resulted in similar kinematic and better muscle activation than when providing a fixed amount of assistance, i.e. TA-LRT. This should accelerate functional recovery.

CONCLUSION

A robotic-device that generates as normal as possible sensory input will increase phasic locomotor activity.

CLINICAL APPLICATIONS

Providing well timed assistance during LRT will produce better therapy outcomes.

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FPTH14

"SAGITTAL MISALIGNMENT AND IMBALNCE PATTERNS IN IDIOPATHIC SCOLIOSIS"

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INTRODUCTION

Idiopathic Scoliosis is a three-dimensional (3D) deformity of the vertebrae, spine, and rib cage (Lowe et al 2000). According to the Scoliosis Research Society (SRS) definition, it is diagnosed when the spine has more than 10 degrees of coronal curvature with rotation as seen on a posterior–anterior (PA) radiograph. Orthotic treatment is the most commonly used therapy, and works by providing mechanical actions of corrective forces on the scoliotic spine, rib cage, and trunk. In order to achieve more effective orthotic treatment and to identify a more accurate 3D biomechanical corrective concept of orthotic treatment, it is necessary to understand the complexity of scoliotic deformities. The sagittal aspect is relatively ignored in orthotic treatment compared to the coronal plane since it is not an official part of the SRS definition of scoliosis mentioned above. In the sagittal plane, the most commonly known deformity is thoracic hypo-kyphosis or lumbar hyper-lordosis on the posterior part of the torso and a tightening of the posterior structure in the spinal column (Dickson 1988) (Dickson et al 1984) (Burwell 2003). However, there is still a lack of understanding regarding detailed sagittal misalignment patterns and sagittal spinal imbalance, especially their relationship with coronal curve patterns. The purpose of this study is: (a) to define the sagittal misalignment and imbalance patterns of the scoliotic spine and trunk, and their relationship with the coronal curve patterns, and (b) to create new radiographic assessment tools for the sagittal plane of the spine, to be called the Sagittal Alignment Indices (SAIs), by using the data obtained in part (a).

METHOD

This is a retrospective study using a series of PA, standing, full-spine radiographs and lateral view, standing, full-spine radiographs of 100 patients that were randomly selected from the pool of patients seen at the scoliosis clinic with confirmed adolescent idiopathic scoliosis. These patients had completed their treatment, and ranged in age between 10 and 18 years old at the time of radiograph. These patients satisfied the conditions of the SRS inclusion criteria for adolescent IS orthosis studies (Richards et al 2005). Any radiographs, even if they meet the conditions, were excluded when: patients had leg-length discrepancies of more than 2cm, patients had any deformities of the lower limbs, patients had any surgical procedures on the lower limbs or spine, or when any of the radiographs displayed the use of breast shields.

RESULTS

Four distinct sagittal misalignment and imbalance patterns of the scoliotic spinal column and axis were found. Each of these patterns has a correlation with a common coronal curve pattern, such as a right thoracic curve, a left thoracolumbar curve, a left lumbar curve, and a double curve.

Based on these four distinct sagittal misalignment and imbalance patterns, SAIs were created.

Kyphosis Alignment Angle (KAA)	SAI
Lordosis Alignment Angle (LAA)	
Sagittal Balance Angle (SBA)	
Sagittal Sternal Angle (SSA)	
Pelvis Vertical Sacral Angle (PVSA)	

CONCLUSION

There is significant evidence that sagittal misalignment and imbalance exist in the spines and trunks of patients with IS. In addition, there are certain sagittal misalignment patterns that depend on coronal curve patterns.

DISCUSSION AND CLINICAL APPLICATIONS

This study will help improve orthotic treatment for IS by addressing the complexity of IS's deformities through identifying corrective forces applied in multiple planes, including the previously ignored sagittal plane. The SAI indices, combined with the overall coronal trunk symmetry indices (OCTSIs), which were created previously as radiographic assessment tools for the coronal plane, will be used to verify whether there exists a relationship between achieving overall trunk symmetry and spinal alignment in-orthosis and defining the appropriate biomechanical goals and primary parameters in orthotic treatment for IS.

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BIOMECHANICAL EVALUATION OF THERAPEUTIC FOOTWEAR IN ABLE-BODIED PERSONS

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INTRODUCTION

Therapeutic footwear and insoles have been widely used in clinical practice in managing foot deformities and ulceration. With an increasing number of new designs of therapeutic footwear on the market each year, both consumers and clinicians are interested in learning their potential biomechanical effects. Among the few studies on therapeutic footwear, majority of them are focused on either plantar pressure or gait kinematics and kinetics. Among some of the most popularly used therapeutic footwear, Orthofeet® (Orthofeet Inc., NJ USA) have some distinct features such as ergonomic sole and tie-less lace design (integrates a lace and straps). However, there lacks scientific evidence showing whether the Orthofeet® therapeutic footwear will offer biomechanical benefits such as reducing the plantar pressure and impact positively on the gait kinematics and kinetics. The purpose of this study was to investigate the effects of two types of Orthofeet® therapeutic footwear in comparison to generic footwear on plantar pressure and lower extremity kinematics and kinetics in a healthy population during walking.

METHOD

Twenty healthy volunteers (twelve men and eight women; height: 171.5 ± 8.4 cm; body mass: 69.1 ± 10.7 kg; age: 33.1 ± 6.2 yrs) without foot disorders and pains participated and walked at self-paced speed across a walkway three times for each of the four footwear conditions (two therapeutic footwear: orthofeet biofit, orthofeet dress; two generic footwear: Danskin® Now and participants' own walking shoes). In-shoe plantar pressures were collected using F-scan (Tekscan Inc. MA, USA) and gait kinematics and kinetics in the sagittal plane were obtained using an optical motion analysis system (VICON Inc. Oxford, UK) and two AMTI force plates (American Mechanical Technology, Inc., Watertown, MA, USA). Joint kinematic and kinetic data in the sagittal plane were obtained using Visual3D (C-Motion, Inc. Germantown, MD, USA). Gait kinetics and kinematics were focused on lower extremity in sagittal plane including ankle joint peak dorsiflexion, peak plantar flexion, range of motion, 1st and 2nd peaks of knee flexion, 1st peak flexion and peak extension of hip joint. The peak ankle, knee, and hip joint torques in the sagittal plane were normalized with respect to the body mass and reported in group average and standard deviation. Foot mask included eight anatomical zones and three combined zones (forefoot, mid-foot and hind foot). Within each region of interest, peak pressure and pressure-time integral were obtained. Repeated measures ANOVA was conducted for measured variables.

RESULTS

Therapeutic footwear showed significantly larger ankle dorsiflexion during the late midstance and significantly smaller ankle plantar flexion during push-off than generic shoes. No significant effects of footwear on kinematics were revealed in joints beyond ankle. Similarly, larger ankle plantar flexor torques were shown when wearing therapeutic footwear and orthofeet dress showed significantly higher value compared to Danskin® Now (1.43 ± 0.24 Nm/kg v.s. 1.38 ± 0.24 Nm/kg). Therapeutic footwear altered the plantar pressure distribution with increased peak pressure and pressure-time integral (PTI) under the big toe, slightly reduced peak pressure and PTIs under 1st metatarsal, reduced peak pressure and PTIs under the medial heel. Participants' own athletic shoes provided slightly distinct outcome measures yet comparable performance when compared to therapeutic footwear.

DISCUSSION AND CONCLUSION

The current study extensively investigated the biomechanical effects of two Orthofeet® therapeutic footwear and two generic footwear (Danskin® Now footwear and participants' own walking shoes) via evaluating both plantar pressure and gait kinematics and kinetics in the sagittal plane. The outcomes of the study indicated that Orthofeet® therapeutic footwear had detectable biomechanical effects compared to generic footwear, especially the Danskin® Now, such as redistributing the plantar foot pressure, reducing both peak pressure and PTIs especially under the medial heel while increasing peak pressure under the big toe. Participants' own athletic shoes provided slightly distinct yet comparable outcome measures compared to therapeutic footwear. Our results indicate that therapeutic footwear offer biomechanical benefits over generic shoes and athletic footwear might be considered as a substitute to therapeutic footwear when cost and cosmetics are of concerns.

CLINICAL APPLICATIONS

The current study had laid down some pilot work for future clinical trials focusing on evaluating long-term effects of the Orthofeet® therapeutic footwear. In addition, the outcomes of the study might be useful and helpful for both clinical practitioners and consumers when prescribing/selecting therapeutic footwear.

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A BRACE DESIGN COMPARISON FOR THE PEDIATRIC PATIENT WITH CHARCOT MARIE TOOTH DISEASE

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INTRODUCTION

Charcot Marie Tooth (CMT) is the most frequently seen hereditary neuropathy with an estimated prevalence of 17-40 per 100,000 individuals affected by the disease. The typical patient with CMT shows symptoms of the disease within the first two decades of life, and experiences a slow progression of symptoms as the individual continues to age (Pareyson 2004).

The clinical presentation of individuals with CMT varies greatly, even within any one of the 70 different types of the disease. Common symptoms include weakness, decreased muscle size, and sensory impairment. Distal weakness of the lower extremities can affect balance, endurance and efficient clearance during swing phase. The muscle imbalance causes rigid contractures of the foot and ankle which eventually lead to inefficient gait patterns, increased fatigue, (Hoellwarth JS et al; Yagerman 2012) and possibly pain.

The literature on orthotic management for patients with CMT is extremely limited, with even less research on pediatric patients. This creates a significant challenge for orthotists treating growing children with CMT

CASE DESCRIPTION

A female patient was first seen by neurology at age three for evaluation of gross motor delay, abnormal waddling crouch gait, wide base of support, and difficulty clearing toes. The patient was seen at a multidisciplinary neuromuscular clinic by age four with a confirmed diagnosis of CMT type 2A (MFN2 deficiency related HMSN II peripheral neuropathy). The patient demonstrated progressively worse foot and ankle alignment, as well as decreased balance and strength. Physical therapy was initialed and the patient was also evaluated for day and night-time orthotic management.

MATERIALS AND METHODS

Two separate pairs of custom day-time orthoses were fabricated for the patient as well as a pair of positional night-time orthoses to prevent further deformity and loss of range of motion. The first pair was a custom lightweight polymer PLS/SMO (PAFOs) design made by CasecadeDafo™. The second pair was made with a carbon fiber shank thermoformed into a polymer SMO and proximal calf cuff (CFAFOs). Sagittal and frontal plane photographs were taken of her gait, and 6 minute walk tests were performed in both sets of orthoses. Due to the patient's age, the mother completed the Activities-specific Balance Confidence (ABC) Scale for the patient's performance in both sets of orthoses. All tests were repeated with the patient barefoot.

RESULTS

The results indicated that the CFAFOs allowed the single subject to walk a longer distance as compared to the PAFOs and barefoot. Similar findings were observed in the ABC scores, which indicated that the subject was more confident that she would maintain her balance while wearing the CFAFOs compared to PAFOs or barefoot. Finally, improved lower extremity kinematics were seen in the split frame photographs.

	ABC SCORE	6 MINUTE WALK TEST
Barefoot	49.375%	239 meters
PAFOs	61.25%	391 meters
CFAFOs	70.625%	412 meters

DISCUSSION

Based on the findings, the CFAFOs proved to be the more appropriate and preferred design for this four-year-old patient with CMT. The patient also preferred the CFAFOs because she was able to "run faster."

CONCLUSION

While the common treatment for patients with peripheral neuropathies such as CMT is to use a light weight carbon PLSAFO, it is important to control the progressive foot changes of the pediatric patient, while also giving assistance in clearance and energy return. A hybrid design appears to both control the tri-planar tendencies of the young patient's foot and give energy return, as demonstrated in the increased distance obtained during the 6 minute walk test.

CLINICAL APPLICATIONS

Clinicians have many options when treating patients with peripheral neuropathies. When evaluating the specific needs of the pediatric patient, clinicians should consider custom hybrid designs which give benefits from both the customized fit and the lightweight properties of carbon fiber.

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WALKING SURFACE AMELIORATES EQUINUS GAIT IN CHILDREN WITH IDIOPATHIC TOE WALKING

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INTRODUCTION

Idiopathic toe walking (ITW) is diagnosed when persistent or habitual equinus gait persists beyond the age of three years with no sign of neurological, orthopedic or psychiatric diseases (Englebert et al., 2011, Hirsch et al., 2004). Prolonged toe-walking can result in muscle contracture and skeletal malformation. Ankle-Foot Orthoses and similar orthotic designs are commonly prescribed to correct toe walking. Alternative or concomitant therapies aimed at the heretofore unknown etiology of ITW could be more efficient and effective. Because toe walking occurs in many other conditions, such as cerebral palsy, autism spectrum disorders, and muscular dystrophy, and because these conditions have differing potential for orthotic intervention, implications of potential treatments are compounded. The aim of the current study was to investigate novel therapeutic/treatment method based on terrain during barefoot walking.

METHOD

Both children with ITW and typically developing children (TD), aged from 4 to 10 years old, participated in a barefoot gait analysis over three 4-meter walkways. Each of the walkways was covered with a different surface providing a different tactile stimulus: smooth, even vinyl tile, compliant carpet, and loose pea gravel. Ten trials were collected at a comfortable self-selected walking speed on each of three walkways following a random sequence. Kinematics were collected at 100 Hz with a seven-camera 3-D motion analysis system. Temporal-spatial parameters were recorded along with HR32, a novel outcome measure designed to distinguish a defined aspect of the toe-walking pattern: early heel rise. HR32 was measured as the difference between the heel marker vertical coordinate in a static flat-footed trial and the vertical coordinate at 32% of the gait cycle, when heel rise normally occurs in this population. Five 2 x 3 factorial ANOVAs with repeated measures were conducted on gait velocity, cadence, step length, step width, and HR32.

RESULTS

Thirty participants, 15 children with Idiopathic Toe Walking (ITW) and 15 typically developing (TD) children, completed the study. Children walked slower ($p<0.001$) and with shorter step length on gravel ($p<0.001$). They also had significantly higher cadence on vinyl tile ($p<0.001$). Step width was not significantly different across all surfaces. Children with ITW had significantly higher HR32 than TD children ($p<0.001$). Notably, the gravel surface controlled toe walking in children with ITW. Out of 838 analyzed steps across all children in the ITW group, none showed initial contact with the toe or forefoot. Heel Rise was significantly later for children with ITW on gravel than on either other surface (Table 1). Furthermore, HR32 was within normal limits for 45% of those steps.

		Carpet	Vinyl Tile	Gravel	*P*-value		
Velocity (m/s)	TD	1.11	1.15	0.74	Group	0.724	
	ITW	1.11	1.12	0.71	Surface	<0.001	*
Cadence (steps/ min)	TD	125	130	109	Group	0.099	
	ITW	133	138	114	Surface	<0.001	*
Step Length (m)	TD	0.54	0.53	0.41	Group	0.081	
	ITW	0.5	0.49	0.37	Surface	<0.001	*
Step Width (m)	TD	0.12	0.11	0.11	Group	0.693	
	ITW	0.12	0.11	0.13	Surface	0.147	
HR32 (mm)**	TD	20	14	12	Group	<0.001	*
	ITW	34	35	17	Surface	<0.001	*

Table 1 Surface Effects on the Gait Pattern, TD vs. ITW (TD n=15, ITW n=15). *statistical significance ** interaction

DISCUSSION

Children with ITW showed substantially less toe-walking on the gravel walkway. This important result might indicate that at least some component of this population chooses an equinus gait pattern due to altered sensory processing, either through the plantar surface of the foot or through related force, pressure, or vibration.

CONCLUSION

The results suggest that walking on a gravel surface should be further explored as a possible method for treating ITW,

CLINICAL APPLICATIONS

Practitioners who worth with equinus gait should consider sensation when developing therapies. In particular, plantar foot texture should be considered as an element of orthosis design for children with ITW and associated sensory processing-related disorders of gait.

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A Novel Shear Reduction Insole Effect on the Thermal Response to Walking Stress, Balance, and Gait

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INTRODUCTION

Shear stresses have been implicated in the formation of diabetes-related foot ulcers. Our bench testing of a novel dynamic foot orthoses (DFO), found an average 270% reduction in shear stiffness at various regions of the DFO during the simulated gait cycle. The aim of this study was to evaluate the effect of DFO on thermal response to walking, balance, and gait in subjects with diabetes at risk for foot ulcer.

METHOD

Methods: Twenty-seven subjects with diabetes and peripheral neuropathy were enrolled. Subjects walked 200 steps in both DFO and standard insoles. Spatio-temporal gait and balance were assessed using a validated wearable sensors technology (LEGsys™, Biosensics. LLC, Cambridge, MA, USA). Thermal foot images were taken at

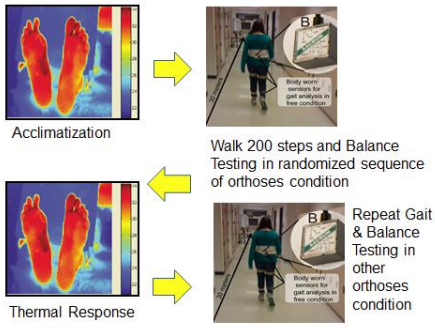

Figure 1. Gait & balance assessed using wearable sensors. Thermal imaging was conducted with Fluke Ti25 thermal imager.

baseline following five minute temperature acclimatization, and immediately after walking using Infra-red Camera (Fluke® T-i25). Testing order was randomized and a five minute washout period was used between trials. Sudomotor function was assessed by measuring electrochemical sweat conductance with a SudoscanTM,(Impeto Medical , Paris, France).

***Data Analysis*:** Comparison across walking task (single task and dual task) for each walking condition (type of footwear) was done with repeated measures ANOVA 2×2 test, and pairwise main effect or interaction comparisons were done using a Sidak adjustment. All calculations were made using SPSS® version 21 (SPSS, Chicago, IL, USA) or Matlab (MathWorks, v7.4).

RESULTS Walking in both insoles increased foot temperatures; however, significant ($p<0.05$) increases was observed in standard insoles only. The DFO significantly reduced forefoot (64.1%; p=0.008) and mid-foot (45%; p=0.046) temperature increases compared to standard insoles (SCI) (Figure 2). We also observed significant negative correlations with sudomotor function and baseline temperatures (r=0.53-0.57). For both single-task and dual-task conditions, there was a trend for improvement in all gait parameters. DFO demonstrated 10.4% less double support time during gait initiation compared to standard insoles (p=0.05). During dual-task, we observed a noteworthy 32% reduction in gait variability with DFO (p=N.S.).

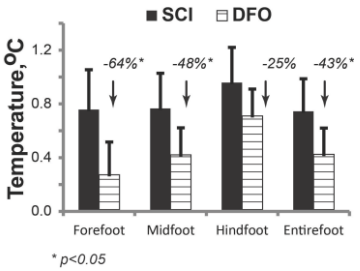

Figure 2. Depicts temperature changes in foot region using standard insoles (SCI) and dynamic foot orthosis (DFO) shear reducing insoles.

DISCUSSION

We found that a novel shear-reducing insole significantly reduced temperature increases over baseline in the forefoot (64%) and midfoot (48%) after walking 200 steps compared to standard insoles.

CONCLUSION

In conclusion, we found significant reductions in forefoot and midfoot temperature increases after known walking stress using a novel shear-reducing insole when compared to standard insoles. We also found sudomotor function demonstrated significant correlations with the thermal response after walking. Future work should focus on the efficacy of the DFO for reducing foot ulcers. Future footwear studies should also consider measuring thermal and sudomotor function changes.

CLINICAL APPLICATIONS

Shear stress-reducing insoles appear to hold the promise of preventing foot ulcers. In fact, studies have shown that shear-reducing insoles tend to prevent foot ulcers in high-risk patients with diabetes more effectively than traditional insoles

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Bench Test Validation - Dynamic Posterior Leaf Spring Ankle Foot Orthosis

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Introduction

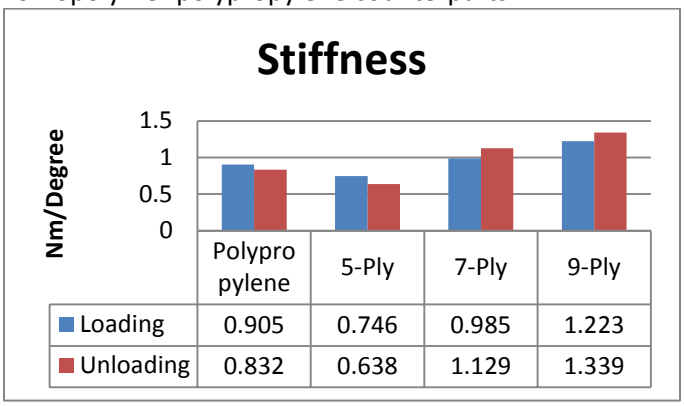
The posterior leaf spring ankle foot orthosis (PLS AFO) is a unique lower limb orthosis used to assist dorsiflexion during swing phase, ensure toe clearance, and limit falls. The design of the orthosis has changed over time[1] with use of different materials, fabrication techniques, and trim lines. In this study, a new material consisting of a carbon-infused polypropylene composite was tested against the standard homopolymer polypropylene. The PLS design followed a previous iteration[2] in the use of a flat blade PLS spring segment which incorporated a material doubler inserted during molding.

Method

Nine orthoses were fabricated with three varied ply discontinuous carbon-fiber infused polypropylene PLS inserts (three orthoses per carbon ply content) and three homopolymer polypropylene orthoses served as the control. Each orthosis was tested in a motorized testing device that measured resistance to torque as the orthosis was cycled through dorsiflexion and plantarflexion. The motorized device with an inline torque sensor (Transducer Tech Inc., USA) and optical encoder developed in an earlier study[2] was used to move the AFO in the prescribed range of motion. The motor was controlled by a motor drive under speed mode in which both speed and direction of the motor rotation were modulated.

Results

The stiffness value in this study is a representation of resistance to rotation moment per angular displacement. Our results showed that both 1/8" 7-ply and 3/16" 9-ply carbon-infused polypropylene spring insert AFOs outperformed 3/16" homopolymer polypropylene AFOs in stiffness. The 3/16" 5-ply carbon-infused polypropylene PLS AFO proved to be less stiff yet restricted range of motion better than the 3/16" homopolymer polypropylene PLS AFO. Furthermore, 1/8" 7-ply carbon-infused polypropylene AFOs demonstrated greater stiffness while allowing greater range of motion than 3/16" homopolymer polypropylene AFOs. The increased stiffness of the carbon-infused polypropylene composite materials will produce a smaller index of hysteresis by allowing less deformation under increased torque thus providing greater dynamic energy return than their homopolymer polypropylene counterparts.



	Polypropylene	5-Ply	7-Ply	9-Ply
Loading	0.905	0.746	0.985	1.223
Unloading	0.832	0.638	1.129	1.339

Conclusion

The research results followed the proposed hypothesis: PLS AFOs fabricated with carbon pregnated polypropylene composite demonstrated more dynamic mechanical properties, as indicated by increased stiffness and decreased index of hysteresis than homopolymer polypropylene orthoses, thus decreasing energy loss and providing a rigid toe lever at pre-swing. The 9 Ply carbon infused polypropylene PLS AFO demonstrated a 35.14% increase in stiffness over the corresponding homopolymer polypropylene orthosis and a 21.81% reduction in hysteresis for the broad expanse of the test results. Limitations existed in the study and further research with human subjects within a clinical gait laboratory is recommended to match bench testing to potential improvements in locomotion.

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Management of Skin Temperature and Perspiration Using a Modified Liner

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INTRODUCTION

Common prosthetic liner materials insulate the residual limb[1], resulting in elevated socket temperatures and increased perspiration. Heat and perspiration are common complaints leading to a decreased quality of life reported by amputees[2]. A proprietary phase-change material (PCM) has the ability to store and release thermal energy. In an effort to better manage the thermal environment of the prosthetic socket, silicone used for prosthetic liners has been modified with PCM to increase thermal conductivity and heat capacity. Initial attempts to evaluate the performance of the PCM liner included socket bench top testing and pilot testing with a small number of study participants. Results from the bench top testing and pilot testing indicated a benefit associated with the PCM liner. In addition, patient anecdotal comments advocate that the PCM liner provided a more comfortable temperature environment and less perspiration inside the liner. The purpose of this work is to report results from a larger crossover study evaluating the PCM liner to a standard silicone liner.

METHOD

Subjects: Eight unilateral transtibial amputees participated in this study.

Apparatus: Temperature was measured using T-type thermocouples. The amount of moisture on the skin was measured by wiping the skin and liner surface with a laboratory towel. The towel was then weighed in a zip-lock bag on a digital scale to determine the change in weight from the calibration weight. The zip-lock bag was used to minimize water loss through evaporation.

Procedures: The study procedures were reviewed and approved by an IRB. A randomized crossover design was used to evaluate the change in temperature and moisture buildup during activity between a standard silicone liner and a silicone liner with PCM added. Group A (n=4) began testing wearing a standard silicone liner and Group B (n=4) started the study wearing the PCM liner. The starting skin temperature was recorded. After completing the activity (riding a stationary bicycle for 25 minutes at a self-selected speed) subjects in Groups A and B crossed over to use either the PCM or standard liner respectively. Continuous temperature data was collected by thermocouples that were placed on the skin surface (posterior calf), between the liner and socket, on the outside surface of the socket, and in the testing room (environment was maintained at 80°F). The thermocouples were carefully placed so when the amputee subject donned the prosthesis, the temperature sensors overlapped one another. During the bicycle ride, a metronome was set to match the participant's self-selected pace to keep them on cadence during the entire activity. Skin moisture was measured immediately after doffing the liner post-activity by wiping the limb and liner and determining the change in weight of the towel. After a 1 hour rest period, the groups changed treatments and the procedures were repeated. The metronome cadence documented during the first activity session was used during the second ride to ensure consistent cadence between the two bicycle rides.

Data Analysis: Data was plotted on graphs that were color-coded to indicate differences between each patient and between each liner material. A one tailed, paired t-test was performed on the data.

RESULTS

Initial pilot results found trends in the data: 1) Donning either liner initially reduced the skin temperature. 2) Activity increased the skin temperature. 3) The PCM liners demonstrated lower skin temperatures, especially during activity. 4) Temperature associated with the PCM liner was relatively stable post activity.

Similar results were found for the work reported here. A significant decrease ($p<0.05$) in temperature change was found when subjects wore the PCM liner compared to the standard liner during activity. In addition, a significant decrease ($p<0.05$) in perspiration was found when wearing the PCM liner compared to the standard liner. Perspiration values were similar to those reported previously by Klute et al.[1]

DISCUSSION & CONCLUSION

Overall, the results from the testing indicated incorporating PCM into the liner can significantly affect the environment inside the liner. The difference in temperature between the two liners is clinically significant as suggested by Peery[3]. The results support anecdotal claims made by amputees that a PCM liner creates a more comfortable temperature environment and less perspiration inside the liner. Regulating the temperature in the socket and reducing the amount of perspiration can lead to improved comfort, health and quality of life for amputees.

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Thermal Management of the Residual Limb Via a Liner Cooling System

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INTRODUCTION

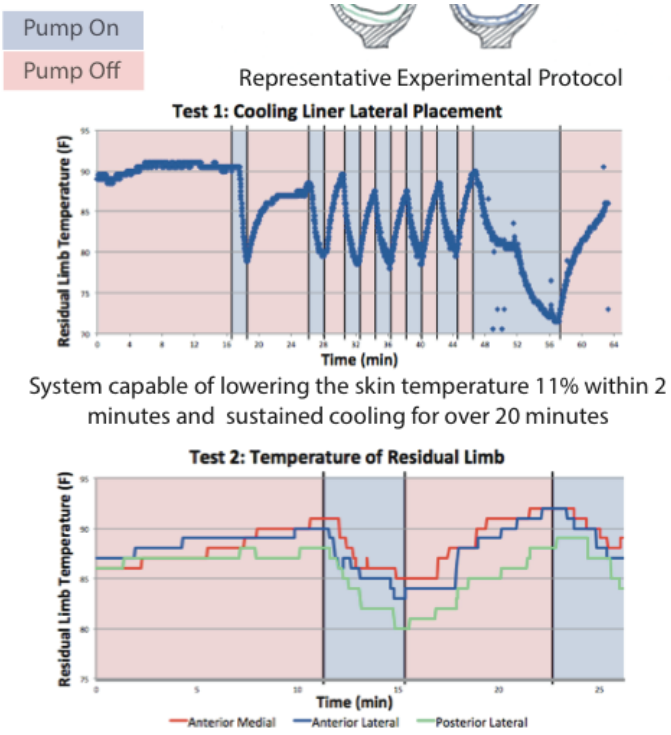
Sweat and heat are two major complaints in regards to socket comfort. Not only can these conditions cause discomfort, but they can lead to decreased skin health and maceration in some cases. The prosthetic socket, often coupled with a gel liner, acts as a thermal insulator. This compounds the problem of amputees having decreased skin surface area to dissipate heat, especially in the case of higher level or multi-limb loss cases. To address this problem, the team developed a process for fabricating a cushion liner that incorporates coolant tubes to reduce the temperature of the internal socket environment.

METHOD

The team developed a process for constructing a non-custom silicone cushion liner with coolant tubes imbedded 1-2 mm from the internal surface. Utilizing a reservoir of ice water and a pump, cold water was circulated through the liner. Two tests were performed, one with a bilateral trans-tibial amputee wearing a traditional liner on one limb, and the cooling liner on the other. The pump was cycled on and off while subject exercised at a self selected speed on an elliptical. Temperature data was collected for both liners utilizing temperature probes taped to the residual limb. The second test was performed with unilateral trans-tibial amputee, also exercising on an elliptical. Temperature measurements were taken with both a conventional liner and the cooling liner.

RESULTS

In both short term tests, the skin temperature dropped between 6-11% when the pump was cycled on. Both subjects stated that they felt a significant decrease in the temperature inside the socket when the pump was cycled on. Subjectively, the subjects also noted a decrease in sweat in liner upon removal. Both subjects stated that they would use the system under conditions when they might be hot (either from environmental temperatures or exercise).



DISCUSSION

The preliminary data and tests indicate that the system does result in a decrease in temperature that is noticeable by the user.

CONCLUSION

The system is proof of concept that a convective cooling system can effectively reduce temperatures in the socket, while not negatively impacting comfort, range of motion, or prosthetic suspension.

CLINICAL APPLICATIONS

Refinement of this system could lead to use in the general population, providing increased comfort, longer wear time, and decreased incidence of skin breakdown.

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FPTH14

Influence of Longitudinal Stiffness Modification on Impact Forces within the Transtibial Prosthesis

Boutwell, E.V.[1,2], Stine, R.L.[1,2], Gard, S.A.[1,2]
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INTRODUCTION

Previous studies have investigated the effects of reduced-stiffness components in comparison with more traditional components, but have not reported changes in GRFs (Miller & Childress, 1997; Gard & Konz, 2003; Berge, 2005). However, gait is a complex activity in which active modification of impact forces may be achieved through kinematic or neuromuscular adjustments. The purpose of this study was to deliver a controlled, consistent impact to the prosthetic-side limb while minimizing active user adaptation to systematically evaluate the effect of a wide range of prosthesis stiffness values on force generation.

METHOD

Subjects: 14 subjects with transtibial amputations (mean age: 49 ± 16 years, mean mass: 81.2 ± 15.9 kg) were recruited to participate in this study. Subjects were required to have at least six months of experience with a prosthesis, be 18-80 years of age, and weigh <125 kg. The Northwestern University Institutional Review Board approved this study and informed consent was obtained from all subjects prior to participation.

Apparatus: Impacts were delivered using a modified gym apparatus (Total Gym, San Diego, CA) with (1) a winch-controlled rolling platform, and (2) a force plate (AMTI, Watertown, MA) to record forces (Figure 1). The prosthetic side limb was extended during testing, and subjects were translated upwards 5 cm and dropped to generate forces of approximately body weight.

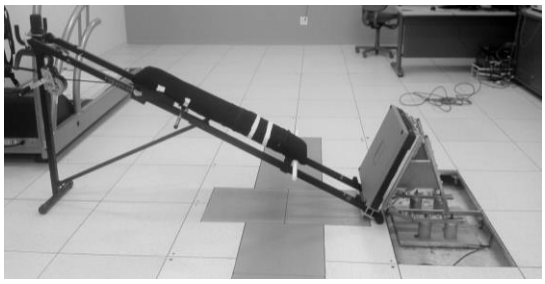

Figure 1. Sudden Loading Evaluation Device (SLED).

Procedures: Subjects wore their current socket and suspension system, and were provided with a standardized experimental prosthesis consisting of a shock-absorbing pylon (SAP) and foot/shoe. Longitudinal stiffness was varied by swapping out the spring within the SAP. A NORMAL (manufacturer-recommended), a SOFT (50% NORMAL) and a MEDIUM (75% NORMAL) stiffness as well as a RIGID pylon were tested for each subject. Impact testing was performed for each stiffness condition.

Data Analysis: Cortex (MAC, Santa Rosa, CA) was used to collect force plate data. MATLAB (MathWorks, Natick, MA) was used to identify loading peaks, and SPSS was utilized to perform statistical analysis (IBM Corp., Armonk, NY).

RESULTS

No significant differences were found between stiffness conditions for either peak force magnitude or peak timing (Figure 2).

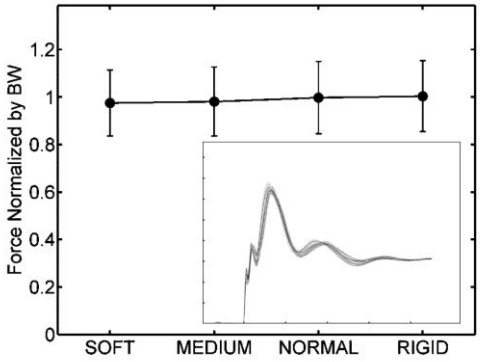

Figure 2. Mean impact peak magnitudes +/- 1 S.D. for 14 subjects Inset: a typical force profile over time.

DISCUSSION

The lack of significant change in forces indicates that the experimental prosthetic stiffness conditions were not sufficient to alter the passive mechanical stiffness of the prosthetic-side limb. This finding explains the results of previous gait analyses that have determined no shock absorption benefit with reduced stiffness components. We believe this finding may be explained by the low stiffness of soft tissue at the residual limb/socket interface, which may dominate the behavior of the prosthetic-side limb system.

CONCLUSION

Longitudinal stiffness modification does not influence total limb stiffness in a transtibial prosthetic-side limb.

CLINICAL APPLICATIONS

It is important to consider the possible interaction of reduced-stiffness prosthetic components with other prosthesis and anatomical limb characteristics.

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Influence of Longitudinal Prosthetic Stiffness Modification on Ground Reaction Forces during Transtibial Gait

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INTRODUCTION

Lower-limb shock-absorbing prosthetic components, including feet, pylons, and gel liners, are often characterized by reduced longitudinal stiffness, the effects of which are not well understood, particularly during walking. Decreasing the stiffness of a prosthesis should reduce the ground reaction force (GRF) loading peak and increase the time to reach this peak from force onset, commonly used metrics of shock absorption. Previous studies have investigated the effects of reduced-stiffness components in comparison with more traditional components, but have not reported changes in GRFs (Miller & Childress, 1997; Gard & Konz, 2003; Berge, 2005). The purpose of this study was to systematically evaluate the effect of a wide range of longitudinal prosthesis stiffness values on gait biomechanics.

METHOD

Subjects: 12 subjects with unilateral transtibial amputations (mean age: 49 ± 18 years, mean mass: 84.8 ± 21 kg) were recruited to participate in this study. Subjects were required to have at least six months of experience with a prosthesis, be 18-80 years of age, weigh <125 kg, and be able to walk at least 10m without assistance. The Northwestern University Institutional Review Board approved this study and informed consent was obtained from all subjects prior to participation.

Apparatus: Gait data were acquired using a twelve-camera real-time motion capture system (MAC, Santa Rosa, CA) and six force platforms (AMTI, Watertown, MA) embedded within the laboratory floor.

Procedures: Subjects wore their current socket and suspension system, and were provided with an experimental prosthesis consisting of a shock-absorbing pylon (SAP) (Endolite TT Pro, Miamisburg, OH) and a standardized prosthetic foot and shoe. Longitudinal stiffness was varied by swapping out the spring within the SAP. A NORMAL (manufacturer-recommended), a SOFT (50% NORMAL) and a MEDIUM (75% NORMAL) stiffness as well as a RIGID pylon were tested for each subject. Gait analyses were performed for each stiffness condition at both freely-selected and fast self-selected walking speeds.

Data Analysis: Cortex and OrthoTrak software (MAC, Santa Rosa, CA) were used to process data and calculate kinematic and kinetic data. MATLAB (MathWorks, Natick, MA) was used to identify loading peaks, and SPSS was utilized to perform statistical analysis (IBM Corp., Armonk, NY).

RESULTS

Few significant differences were found between stiffness conditions at freely selected walking speeds; a statistically significant difference was found in peak force magnitude between the SOFT and NORMAL conditions during fast walking ($p = 0.021$) (Figure 1). No changes in kinematics or time to loading peak were observed.

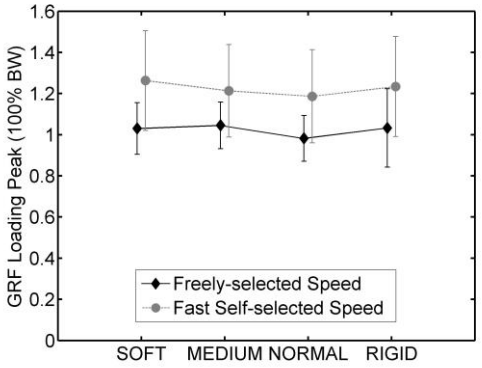

Figure 1. Mean peak GRF loading peak magnitudes for 12 subjects during gait. The error bars denote +/- 1 S.D.

DISCUSSION

No clinically significant changes were found between stiffness conditions at freely selected walking speeds. While some changes were observed at fast speeds, the question of how the prosthetic-side limb system is accommodating the change in prosthetic stiffness remains. Two possibilities exist: (1) that subjects are altering their neuromuscular strategy to change the stiffness of their residual limb/knee joint, or (2) that the experimental stiffness conditions are not sufficient to change the net limb stiffness. In the future, these possibilities may be investigated by incorporation of EMG analysis of the residual limb and analysis of an *in vivo* impact in which active adaptation is minimized.

CONCLUSION

Longitudinal stiffness modification does not influence ground reaction forces at self-selected walking speeds. At fast walking speeds, low stiffness resulted in an unexpected *increase* in loading peaks.

CLINICAL APPLICATIONS

Prosthesis components in which longitudinal stiffness has been reduced *separately from any other factor* are unlikely to enhance prosthetic shock absorption.

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COLD SENSITIVITY POST AMPUTATION: CASE STUDY OF A NOVEL SOLUTION AND PROPOSED FUTURE RESEARCH DESIGN

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INTRODUCTION

Cold intolerance is a well-documented sequelae post hand injury and amputation. Symptoms include pain, aching, numbness, weakness, stiffness and color change; the pathophysiology is unclear. Research suggests rates of 51% of upper limb amputees experience some level of cold intolerance. In many of these cases ADL, work and leisure activities are negatively impacted. Furthermore, self-reported cold sensitivity is associated with decreased quality of life and perceived disability. Therapeutic interventions to date have achieved some success including pharmacological approaches to improve vascularization of the affected limb, psychological conditioning and for prosthetic users, liners and covers of various types.

METHOD

A novel approach to prevention of cold intolerance symptoms is presented here in a single case study. Research to explore the viability and success of this approach further is proposed. The Cold Symptom Severity Scale, with a prosthetic user appendix and an 11 point pain rating scale in which 0 indicates no pain and 10 corresponds to maximum pain, are utilized.

RESULTS

The patient is a 25 year old male who sustained a left non-dominant wrist disarticulation secondary to a wake boarding accident at age 17. He is an avid outdoorsman who enjoys a wide variety of activities including snow skiing. Pain resulting from cold intolerance while skiing would force him to cease the activity after 4 hours with discomfort starting between 2-3 hours. Pain scale rating of 6 and 8 was reported when skiing without a prosthesis and with his prosthesis (without heat), respectively. Retrospective CISS score was 24 and 28, without and with his prosthesis, respectively (max intolerance score 100). In addition, the prosthetic user appendix indicated that prosthetic wear time was reduced by 75% and pain increased by 75% in cold weather conditions. A battery powered heated material was integrated into his body powered prosthesis. Post intervention CISS and pain scores were 0, as indicated in table 1 below.

Measure/Condition	*Score*	*Range*
CISS/ Prosthesis without heat	28	0-100
CISS/ Prosthesis with heat	0	0-100
Appendix:/No Heat Prosthesis	16	0-20
Appendix: /Heated Prosthesis	0	0-20

Table 1. CISS and Prosthetic User Appendix scores for cold weather conditions with and without heat.

DISCUSSION

Given the prevalence of cold intolerance among the amputee population, further research regarding the broader application of this technology is proposed. Using a modified version of the Cold Intolerance Symptom Severity questionnaire including a prosthetic user appendix, a minimum of 12 patients will be assessed pre and post implementation of a heated material. In addition, scores on the Disabilities of Arm, Shoulder and Hand questionnaire (DASH) pre and post intervention will provide measurement of perceived disability. Based on results of this case study, it is hypothesized that the heated prosthesis will result in reduced scores on both the CISS, prosthetic user appendix and the DASH, indicative of improvement in both cold intolerance and perceived disability.

CONCLUSION

Given the dramatic pain relief experienced by the patient presented, further research into the broader applicability and viability of integrated and/or external heating solutions for prosthetic users is warranted. This prosthetic technological application may provide a clinical solution to the longstanding problem of cold intolerance experienced by amputees.

CLINICAL APPLICATIONS

This novel approach to reducing pain symptoms caused by cold intolerance in prosthetic wearers may improve prosthetic tolerance, wear time and function.

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Mechanical Evaluation and Comparison of Two Intra-Prosthetic Load Cells: An Analysis of Force Measurements

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INTRODUCTION

The practice of clinical prosthetics, which has since its inception relied on qualitative assessment and observational gait analysis on part of the practitioner to ensure a proper fit of a prosthesis to the patient, has thus far resisted the movement toward technological integration in healthcare (Gard, 2006). This is due, in part, to the lack of accessible and/or user-friendly tools that practitioners could use to bring technology, and quantitative analysis, to practice. The current state of healthcare in America and especially in prosthetics is making the need for accurate, cost-effective, and easily-used modes of proving the success of prosthetic interventions more of a necessity now than ever.

Two prosthetic alignment systems that have become available recently are the Intelligent Prosthetic Endoskeletal Component System (iPecs™), originally of College Park Industries, and the Smart Pyramid™ Compas™ system, a product of Orthocare Innovations. Both systems are intra-prosthetic load cells designed to measure both forces and moments that occur within a patient's prosthesis during gait. Although these systems can be categorized similarly they differ greatly in design, user-interface, and intended purpose.

It is safe to assume that during the development of these devices and in the time since the aforementioned companies have tested the accuracies of these respective systems, however an independent and unbiased evaluation and comparison has not been found. The purpose of this study is to mechanically evaluate the force outputs of iPecs™ and Smart Pyramid™ for accuracy and compare results between both systems.

METHOD

An EnduraTec digital universal testing machine was used to apply a directed force to each of the two load cells in their frontal and sagittal plane and also along their vertical axis while being recorded by the respective system. The protocol was adapted from the AOPA Foot study. 10 vertical axis trials were taken at 600, 800, 1000, 1200, and 1400 Newtons on each system. The load was applied to each system at 200 N/s.

The data from each system was processed and maximum values were taken from each trial for comparison.

The means of maximum load values taken from the EnduraTec tester and from each system were compared using percent difference. Testing for significance was not appropriate due to the small sample size at each force level.

RESULTS

The percent differences of each system compared to the EnduraTec are in Figure 1 below. The differences for vertical force of the iPecs™ are less than 3.6% different and less than 1% different at 800, 1000, and 1400N while the same differences for the Smart Pyramid™ are between 6.6% and 7.9% different.

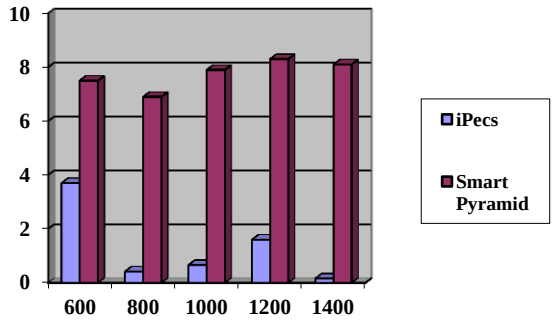

Figure 1. Percent Differences between EnduraTec tester and load cells. Testing levels in Newtons are on the X-axis while percent differences are on the Y-axis.

DISCUSSION

The vertical force measurements for the iPecs™ were found to be reasonable accurate especially in higher loads. The vertical force measurements for the Smart Pyramid™ were found to be above a reasonable limit of accuracy.

CONCLUSION

The iPecs™ is a valid and reliable system to use during the dynamic alignment of a prosthesis.

CLINICAL APPLICATIONS

There are many differences between the two systems mentioned in this study. Although the vertical force output was found to be more accurate in the iPecs™, the Smart Pyramid™ Compas™ system has its place in clinical prosthetic practice. Mainly, the iPecs™ was designed for research and can be used in clinical practice whereas the Smart Pyramid™ was designed almost exclusively for clinical practice. Benefits and drawbacks of each system including user interface and onboard capabilities will be presented.

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Assessment measures for evaluation of outcomes in transtibial amputees resulting from trauma: A systematic review

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INTRODUCTION

Amputations secondary to high-energy injuries to the lower extremity are common challenges faced by military and civilian orthopaedic surgeons given improved survival rates from associated major trauma. Many therapeutic controversies remain to be answered including clinical thresholds for limb salvage and the efficacy of tibio-fibular synostosis. High-quality clinical trials are required to guide clinical decision-making, yet outcome assessment remains controversial. A lack of consensus on domains to be measured and controlling for the quality of prosthetic rendering pose methodological challenges to researchers and clinicians alike. We conducted a systematic review of the literature in order to summarize which domains of health, socket fit, and prosthetic alignment are used to describe outcomes for lower extremity amputees secondary to trauma.

METHOD

Procedures: A search of Pubmed, Cochrane, and Embase was conducted using keywords and major subject headings. Initial search results were screened by title and abstract for subsequent full text review. The selections were based on whether the study assessed clinical outcomes following transtibial amputation following trauma. Experimental and observational comparative studies were included, as well as case-series. Study characteristics and results were extracted using standardized data forms. The number, frequency and validity of instruments used were compiled.

RESULTS

Titles and abstracts of 1,885 articles were screened and full text review ultimately resulted in 273 included articles. Given the heterogeneity of studies, descriptive statistics and qualitative summary were performed. A conceptual model was constructed to capture and organize the causal and temporal relationships between fit, alignment, and outcome (Figure 1). The assessment measures used in the articles were classified based on how they fit into the conceptual model.

1. Socket Fit (n=68)
2. Alignment (n=19)
3. Prosthetic componentry (n=68)
4. Gait: Biomechanical measures (n=75)
5. Comfort/Pain (n=17)
6. Function: General quality of life (QOL) (n=75); Disease-specific QOL (n=83)
7. Performance (n=59)
8. Satisfaction/Other (n=57)

Of the 273 articles, 32 assessed the validity of one or more instruments. Two approaches were used to assess fit and alignment: questionnaires and technology-based assessments. Of the 68 articles that used questionnaires to assess prosthetic fit, 37 used a questionnaire designed specifically for the study as opposed to a published or validated tool; the most commonly used standard questionnaire was the PEQ (n=10). Four validated tools are commonly used to capture patient satisfaction with a prosthesis: the OPUS, the PEQ, the TAPES, and the Socket Comfort Fit Score. Prosthetic alignment was assessed in 19 of 273 articles. Eight of these 19 articles used gait analysis and ground reaction forces to capture differences due to alterations in alignment.

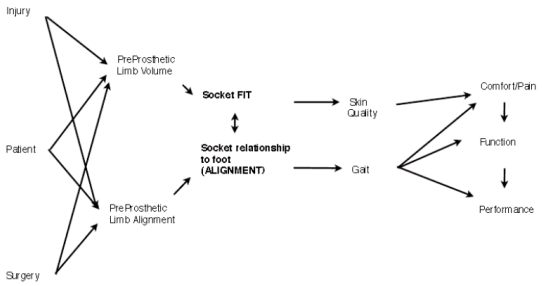

Figure 1. Conceptual Model

DISCUSSION

We found a large number of different tools used across studies, making results difficult to compare. Prosthetic fit is a complex and dynamic concept that includes two primary considerations that are the foundation for the proposed conceptual model: the fit and comfort of the socket and its alignment relative to the foot.

CONCLUSION

In order to distinguish effects attributable to an intervention versus that of prosthesis rendering, validation of a clinically objective scoring system to assess socket fit and alignment is necessary

CLINICAL APPLICATIONS

This work will contribute to the understanding of currently available assessment tools as well as provide guidance in development and validation of clinically objective assessment tools for socket fit in transtibial amputees resulting from trauma.

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Traumatic Lower-Extremity Amputations: An Epidemiologic Study using the National Trauma Data Bank

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INTRODUCTION

Trauma-related amputations are the second most common cause of limb loss in the United States — the first being dysvascular conditions such as diabetes (Dillingham et al., 2002). Resources expended on re-amputations and post-surgical complications result in a high degree of financial burden for U.S. citizens and the healthcare system. Despite the public health impact of traumatic amputations, distributions of various lower limb amputations and their relative frequency of complications and reoperations have not been described. We used the 2012 National Trauma Data Bank (NTDB) to elucidate this gap in knowledge.

METHOD

Subjects: 1,533 subjects who underwent a lower-extremity amputation secondary to trauma were gathered from the NTDB. The NTDB draws from 900 trauma centers from around the U.S. and contains over three million incident trauma cases. *Procedures*: We conducted a secondary data analysis of the 2012 NTDB Research Data Set, using means and frequencies to characterize our patient population and describe the distribution of lower limb amputations. *Data Analysis*: Multivariable regression models were fit in order to identify which variables significantly influence length of hospitalization, rate of reoperation, and adverse surgical complications.

RESULTS

A total of 1,533 patients underwent a lower-extremity amputation secondary to a traumatic lower limb injury, representing 0.18% of all NTDB trauma admissions. 81.2% were male and 18.8% were female. 67.7% were White. The 1,533 patients had 2,500 amputation-related procedures performed. Table 1 shows the incidence of amputations, re-amputations, and proximal extension procedures at the four most frequent levels. The most frequent diagnostic codes for all lower limb amputations were traumatic amputations of the leg below the knee (6.3%), open fractures of the tibia and fibula shaft (4.7%), and closed femur fractures (4.5%). 26.5% of amputees experienced major post-surgical complications. The most frequent major complications included pneumonia (5.6%), acute kidney injury (4.4%), and deep vein thrombosis (4.1%). Table 2 provides the incidence of major complications, average length of hospitalization, and percentage of patients needing assistive care in a nursing or rehabilitation facility following discharge. Predictive factors associated with major post-surgical complications included Injury Severity Score (ISS) ($p<0.0001$), age ($p=0.01$), presence of a neurovascular injury ($p=0.03$) and compartment syndrome ($p=0.009$). Risk factors for amputation among those with an open tibia/fibula fracture included ISS, age, location of the fracture (proximal greater than distal), and presence of compartment syndrome (all $p<0.0001$).

Amputation Level	Frequency (%)	Re-amputations (%)	Proximal Extension (%)
Above Knee	32.7	21.2	2.0
Through Knee	6.1	18.4	25.4
Below Knee	45.9	26.5	11.8
Through			

Amputation Level	Length of Hospitalization (days)	Major Post-Surgical Complications (%)	Care Following Discharge (%)
Above Knee	22.5	32.6	64.7
Through Knee	22.9	34.9	63.6
Below Knee	20.1	22.2	61.7
Through Foot	17.4	15.3	46.8

Table 2. Hospitalization Characteristics

DISCUSSION & CONCLUSION

We report a high rate of complications and reoperations among trauma-related lower limb amputees. Consistent with the literature, we found that injury severity is a predictor of complications and length of hospitalization (MacKenzie et al., 2002); however, we also identified additional predictors for post-surgical complications. Future therapeutic studies should focus on modifiable risk factors for re-amputation and surgical outcomes.

CLINICAL APPLICATIONS

This work will contribute to the sparse epidemiologic literature on traumatic lower-extremity amputations

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and provide prognostic information for patients with limb threatening injuries.

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Evidence-based Recommendations for Trial Fittings of Microprocessor Controlled Hydraulic Prosthetic Knee Joints in Limited Community Ambulators

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INTRODUCTION

A systematic review of the literature on the benefits of microprocessor-controlled prosthetic knees (MPK) to limited community ambulators (MFCL-2) with a transfemoral amputation (TFA) has recently been presented (1). Use of hydraulic MPKs by these individuals may result in similar safety and functional benefits as established in higher functioning individuals. However, it remains unclear how to predict whether an amputee with MFCL-2 mobility will or will not benefit individually from using an MPK.

METHOD

The outcome measures used in the clinical trials turned out to be sensitive to determine success or failure of MPK fitting. The study results were related to changes in outcome measures established and accepted as clinically meaningful in comparable conditions to develop recommendations for MPK trial fittings in the MFCL-2 population.

RESULTS

The walking speed and Amputee Mobility Predictor (AMP) scores while using the non-microprocessor controlled knee (NMPK) may help identify candidates for MPK trial fittings. Individuals who walk between 60 m (195 ft) and 95 m (310 ft) in the 2MWT on their NMPK may benefit from MPK use in activities of community ambulation (e.g. on slopes and stairs). Subjects who walk more than 95 m (310 ft) in the 2MWT on the NMPK may additionally benefit from an MPK in indoor ambulation and activities of daily living (ADL). Improved safety of prosthesis use may be demonstrated by a reduction in completion time of the Timed up and go test (TUG) of more than the reported minimal detectable change (MDC) of 3.6 sec, preferably under the threshold of 19 sec indicating an increased risk of multiple falls in transtibial amputees. The Activity-specific Balance Confidence (ABC) scale may be used as a secondary safety related outcome measure with scores >67 indicating no increased risk of falling. Function and mobility may be assessed using the 2MWT and the AMP with an increase in walking distance of ≥12 m (40 ft) and AMP scores of ≥3.4 indicating a clinically meaningful improvement as compared to NMPK use

DISCUSSION

Trial fittings with MPKs are common practice in several European health care systems (e.g. Germany, Austria, France, Italy) to determine whether a person with a TFA does or does not benefit individually from MPK use. Several performance-based and self-reported outcome measures with established MDCs or cutoffs appear to be suitable for clinical decision making. As the MDC for amputees in the 2MWT of 34.3 m (112.5 ft) has been determined in a higher functioning sample with different amputation levels it seems to be justified to accept an increase in walking speed of .1 m/s as clinically meaningful as has been established for pre-frail and frail elderly subjects, patients after hip fracture, and stroke survivors.

CONCLUSION

Subjects with an TFA and MFCL-2 mobility may benefit from MPK use in safety, function, and mobility. Trial fittings with a MPK are a means to determine whether an individual does or does not benefit from MPK use.

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DISCLOSURE

All authors are full-time employees of Otto Bock HealthCare, a manufacturer of hydraulic MPKs.

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Further Evaluation of 1200+ C-Leg Trial Fittings in Germany

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INTRODUCTION

Trial fitting is a standard procedure conducted prior to the prescription of C-Leg. In Germany approval requires demonstration of the utilization functional benefits offered by C-Leg [Kuhr 2008; Wetz 2005]. First results on an evaluation of 1200+ C-Leg trial fittings were presented earlier [Hahn, 2014]. We refine the statistical approach including multiple logistic regression modelling.

METHOD

Data on 1223 C-Leg trial fittings conducted between May 2006 and June 2010 were analyzed retrospectively. Subjects with age below 21ys and those rated mobility grade 1 (here: MOBIS) were excluded from this analysis.

Subjects: 83% of the subjects were male, mean age 55.6±15.1. Mean age at amputation was 38.1 ±20.6. Amputation etiology includes trauma [44%], vascular disease [24%], tumor [14%], infection [6%], combat trauma [4%], malformation [2%] and others [6%]. In 13.4% of the total population amputation etiology was not specified. *Apparatus*: Two customized questionnaires for the subject and for the CPO were used to document whether the subject showed significant functional benefit. CPOs were encouraged to supply video documentation. *Procedures*: Subjects likely to respond to C-Leg test fittings were invited. Subjects presented themselves on their prior prosthesis for baseline evaluation. After adaption of a test prosthesis using the same shaft, product introduction and gait training subjects were re-evaluated. Most trials (90%) were conducted within one day. *Data Analysis*: Rates for responsiveness were evaluated. Kendall`s tau was used to investigate correlations of age, mobility grade and/or amputation etiology with respect to the capacity to show individual functional benefits, To quantify effect sizes the Logit multiple regression model was used.

RESULTS

Responder rates for functional benefits were 83% for increase in “safety”, 95% for “relieve of the sound leg”, 94% for “divided attention”, 95% for “gait pattern harmonization”, 93% for “variable gait speed”, 88% for an “overall reduction of effort” and 23% for a “reduction in walking aids”.

Stratification for Age, Mobility Grade (MOBIS) and amputation cause (vascular disease (VD)) showed to either not to correlate (safety, sound. leg, gait harmonization) or weakly correlate: divided attention - MOBIS, τ=0.161; p<0.001 variable cadence: - MOBIS τ=0.251, p<0.001; - Age τ=-0.159; VD τ=-0.141, all p<0.001; reduction of effort: – MOBIS τ=-0.094, p=0.048 and reduction of walking aids: – MOBIS τ=-0.23; - age τ=0.209, all p<0.001. All p were Sidak adjusted.

A logistic multiple regression model was used for effect size quantification The calculated probabilities for predicting an individual’s potential of exhibiting a functional benefit based on age, MOBIS and/or VD range from 0.7% (gait harmonization) to 9% (variable cadence).

About 50% of subjects rated MOBIS 2 at baseline were rerated MOBIS 3 after trial fitting (95% CI [45% , 54%]).

DISCUSSION

The rate of responsiveness is comparable to those reported by e.g. Berry 2009 or Drerup 2008. No or only weak correlations could be found with respect to age, mobility grade and amputation etiology. The multiple regression showed, that age, mobility grade and/or amputation etiology possess very little power to predict individual functional benefit. The MOBIS reclassification after test fitting suggests that technology to a large extend influences mobility grade rating.

CONCLUSION

As to the difficulties to predict whether a subject will exhibit individual functional benefits by broad demographic classification criteria the individual assessment of this potential seems to be key.

CLINICAL APPLICATIONS

The general use of mobility grade classification to exclude subjects from C-Leg fittings is not supported by these data.

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Performance Differences in Energy Storing & Shock Absorbing Prosthetic Feet in High Functioning Transtibial Amputees. A Randomized Control Trial

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INTRODUCTION

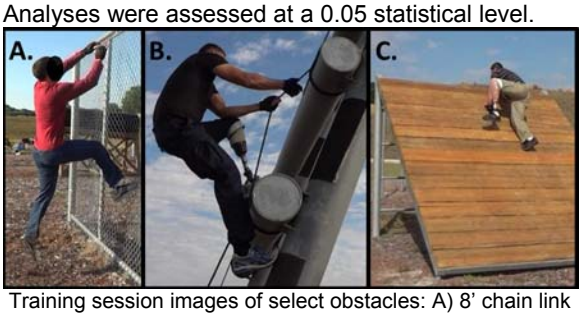
There are ≈ 378,000 Americans with transtibial amputation (TTA) and ≈2000 amputees from recent war in the middle-East. Military TTAs tend to be high functioning (e.g. Medicare K4 level) and use prostheses functionally beyond basic ambulation. Energy storing prosthetic feet (ES) have been studied for preference, bio-mechanical and -energetic differences. TTAs prefer ES feet, and biomechanically, they increase ankle motion over non-ES feet and return energy in terminal stance. ES feet increase gait speed suggesting basic walking may be insufficient to fully determine ES feet benefits in high-functioning patients. Unlike ES feet, multi-function feet, such as vertical or torsional shock absorption combined with ES, are poorly studied.

Military TTAs currently have increased return to duty rates but assessments to substantiate their physical capability are elusive. Military equivalent obstacle courses (OC) are one means to assist in determining eligibility for return to duty and for differentiating abilities between prosthetic feet and those with TTA and non-amputees. This study's purpose was to determine differences in functional abilities between ES feet with and without vertical and torsional shock absorption and between TTAs and non-amputees.

METHOD

The study was approved by the USF IRB and listed in a federal clinical trial registry. A randomized, double blind, 3-period cross-over experimental design was used. A non-amputee control group was also studied. K4 level prosthetic users with unilateral TTA for ≥1y were recruited. Additionally, subjects had to be ≤45y of age and be medically cleared to participate. TTAs had to be either active duty military, first responder, a veteran or an accomplished civilian athlete. Non-amputees were local SWAT team members. TTA subjects' preferred prostheses were fitted with all three study feet (Ossur Ceterus and Variflex, Endolite Elite Blade) and TTAs were trained by SWAT personnel to complete a 17-task, military equivalent OC. Subjects accommodated with each foot for 1wk (3wks total). Subjects completed the OC and tested with each foot (double-blinded) in a randomized order over the course of a week with a rest day between each of the 3 tests. Total completion time, per-obstacle completion times and perceptive measures were assessed. Laboratory biomechanical and energetic measures were assessed for each foot with a VICON motion capture system and COSMED metabolic system at self-selected walk/run speeds(SSWS/SSRS). SWAT controls completed the same assessments a single time.

Data were examined for normalcy and outliers. Repeated measures ANOVA was used with normally distributed data and non-parametric alternatives were used with categorical or abnormally distributed data. Analyses were assessed at a 0.05 statistical level.



Training session images of select obstacles: A) 8' chain link fence. B) A-Frame. C) Angle wall.

RESULTS

TTA's(n=14) mean age (31.4y±5.9) was significantly(p=0.002) younger than controls(n=14; 38.5y±5.1). The TTA BMI was 28.4±6.7kg/m^2 compared to controls: 26.3±2.9kg/m^2(p=0.28). While 66.7% of TTAs rated themselves as 'highly active', only 35.7% of controls rated themselves as 'highly active'(p=0.13). Self-reported activity (years & # bouts/week) was not different between TTAs and controls however duration/bout was (p=0.02).

Prosthetic feet were aligned to specification and were not significantly different sagittally or coronally between conditions (verified via LASAR tool;p>0.05). Ceterus made prostheses significantly heavier (p<0.05) than the other two feet. Mean OC completion times(total) were similar between prosthetic feet: Variflex[425s±144], Elite-Blade[419s±130] & Ceterus[444s±220]; as were median RPE values; p>0.05. Controls' OC time (287.2s±58) was less than TTA as were median RPE values(p<0.05). In individual OC tasks, 4/17, with blended functional requirements (ie upper limb, slalom step) were not uniformly different between groups. Similar trends between controls & TTA were found in laboratory measures however Elite-Blade decreased O_2 uptake at SSWS & SSRS(≈2-4%;p≤0.05).

DISCUSSION & CONCLUSION

High functioning TTAs can complete a military equivalent OC however performance is different (i.e. impaired) compared to non-amputees. All 3 prosthetic feet tested are suitable to complete these rigorous tasks however, Elite Blade may be preferred and offer a bioenergetic advantage in sustained, linear activity. Further, the heaviest foot with increased functional features tended to not be preferred relative to lighter-weight alternatives.

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*Presenters

Effects of the Genium Knee in Transfemoral Amputees using Continuous Scale Physical Functional Performance-10 (CS-PFP10) Assessment

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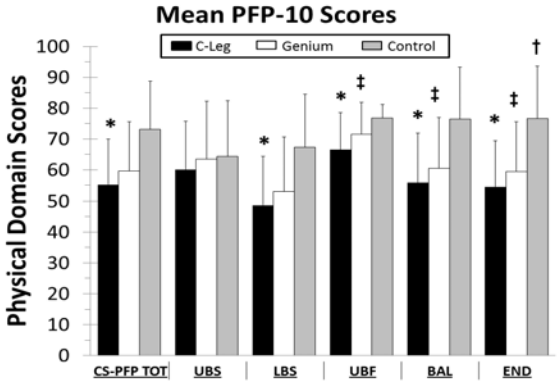
INTRODUCTION Functional studies of the ≈350,000 Americans with transfemoral amputation (TFA) are limited. Obstacle courses simulating home and community barriers and *ad-hoc* measures are the extent to which functional benefits of microprocessor knees (MPKs) have been evaluated. Home barriers have included traversing over rugs and around trash cans. Simulated community barriers have included uneven terrain, ramps and stairs. In these simulations, C-Leg use tended to improve function compared to polycentric knees and to some extent, single axis and hydraulic knees. The aforementioned studies had numerous methodologic issues including small samples, high group variance, lack of control of components, lack of randomization and use of outcome measures lacking psychometric rigor. Improved methodologic quality and selection of outcome measures are clearly indicated. Presently, the Genium knee system has been commercialized and preliminary data show gait improvements, however there is no data on advantages from a functional evaluation perspective available at present. Therefore, this study sought to improve methodologic quality over prior MPK functional studies and to determine if Genium provides advantages in functional abilities compared to the C-Leg.

METHOD The study was approved by the USF IRB and listed in a federal clinical trial registry. A randomized, 2-period cross-over experimental design was used. A non-amputee control group was also studied. Unilateral TFAs (≥K3), who used C-Leg currently for ≥1y were recruited. Subjects were 18-85y and free of medical comorbidities. Non-amputees were also healthy, independent community ambulators of a similar age range. TFAs' preferred sockets either retained C-Leg or were fitted with a Genium (randomization dependent) and all TFAs were fitted with the same study foot. Component alignment was set to specification (LASAR verified). Subjects were provided training for each component and accommodation tested prior to data collection. After data collection, knee mechanisms were crossed-over and the process repeated.

CS-PFP10 was administered via standardized procedure (i.e. certified test site, script dialogue, trained rater; all reported elsewhere). CS-PFP10 scores 10 ADLs in time, distance, and mass. Raw data reflects physiologic functional domains. Testing requires ≈30min. Raw data (time, distance, mass) are converted to summary scores with a validated algorithm in licensed software. Scaled from 0-100, summary scores include CS-PFP total score (CS-PFP TOT) and 5 physiologic domain scores: upper body strength (UBS) & flexibility (UBF), balance & coordination (BAL), lower body strength (LBS) & endurance (END).

Data were examined for normality. Paired *t*-tests were used for between-knee comparisons. Independent samples *t*-tests to compare TFA and controls when data (interval & ratio level) were normally distributed. Otherwise, Wilcoxon's Signed-Rank test for median differences was used (SPSS). Effect size(ES) was calculated using accepted methods and interpretations for Cohen's *d*. The *a priori* significance level was $p \leq 0.05$.



Values = mean±SD. * = $p \leq 0.05$ between C-Leg vs controls. ‡ = $p \leq 0.05$ Genium vs C-Leg. † = $p \leq 0.05$ Genium vs controls.

RESULTS 20 TFAs (age: 46.5y±14.2; BMI: 26.4±4.2kg/m^2) and 5 controls (age: 57.2y±15.7; BMI: 23.0±3.0kg/m^2) completed the study. Body mass was greater in TFAs(p=0.01). Most TFAs lost their leg to trauma. Alignment was consistent between knees.

UBF score improved (7.0%, p=0.01, ES=0.45) when subjects used Genium compared with C-Leg. BAL and END scores also improved with Genium use [(7.6%; p=0.03, ES=0.28) & (8.4%; p=0.02, ES=0.32) respectively]. Finally, CS-PFP total score also improved 7.4% (p=0.03, ES=0.28) with Genium use.

Controls scored higher than TFAs in all domains. No statistically significant difference was found between controls and TFAs when using Genium except in END (22.4%; p=0.05). Controls scored higher in 4/5 domains (except UBS), compared to TFAs when using C-Leg. The smallest difference in this comparison was UBF (13.4%; p=0.01) whereas the largest was END (28.9%; p=0.01).

DISCUSSION & CONCLUSION There were no significant differences in UBS between controls and TFAs. Genium use improved total CS-PFP scores likely due to improved confidence, willingness to lift and carry greater mass and move faster in activities from UBF, BAL and END domains. In LBS, UBF, and BAL domains, C-Leg use resulted in scores lower than controls. END was the only domain where Genium use significantly improved function compared to C-Leg, while both conditions were still lower than controls. In total CS-PFP, controls had significantly higher scores than TFAs using C-Leg. Regardless of knee condition, TFAs did not equal or surpass controls in any functional domain, suggesting room for improved TFA functional performance.

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*Presenters

Where to Amputate based on Probabilities the Prosthetic Components will Fit

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INTRODUCTION

Traditionally, surgeons performing amputation surgery intend to leave the residuum as long as possible but this practice may inhibit prosthetic componentry options. As prosthetists become more involved in the healthcare team, he/she's advice may be sought by surgeons performing amputation about desirable residual limb lengths.

The amount of space needed for prosthetic components (component clearance) will be dependent on more than prosthetic foot build height. There will need to be additional allowances for the socket thickness, distal attachment plate, alignable components, and suspension design. The plethora of available prosthetic technology makes for a near infinite number of possible component selection combinations and this makes a straight calculation impractical. However, advanced mathematical modeling based on predictive variability can calculate the probabilities a successful combination could be fit.

The purpose was to calculate the probability a successful combination of prosthetic components could be achieved at a given component clearance using a random Monte Carlo simulation. These results will be a first step to better inform surgeons.

METHOD

A random Monte Carlo simulation was used to assign a probabilistic distribution to model parameters (e.g. data will be normally distributed with a mean and standard deviation) and reiterated 10,000 times (π times the minimum iterations). Each iteration pseudo-randomly uses a value consistent with the defined probabilistic distribution function, calculates an output, and builds a database of possible outcomes.

The model used here calculated component clearance based on male and female anthropometric variability (NASA, 1978), gender probability, residuum length probabilities (Childers et al., 2014), component build height variability, and probability a foot within an L-code would be chosen (Levinson, 2011).

Component build heights were acquired for fifty prosthetic feet with L5972, L5980, L5981, and L5987 associated L-codes, suspension components (shuttle locks, vacuum pumps, etc.), lamination thickness (direct measurement of twenty sockets), attachment plate thicknesses, and pyramid receiver heights.

The probability a random combination of components would fit anyone was calculated by subtracting predicted residual limb length and total component build height from the total shank/foot length. The percentage of outputs with positive values indicated the likelihood of success.

Component clearance was calculated by isolating the build height data organized by foot Lcode.

RESULTS

There was a 74.3% chance a random component combination would fit anyone with an amputation, regardless of the prosthetic foot being used. There were 89.8, 81.6, 56.6, and 56.6% chance a random component selection with a L5972, L5981, L5980, & L5987 code foot (respectfully) would result in enough clearance. The probability a selected component combination would fit increased with component clearance (Figure1).

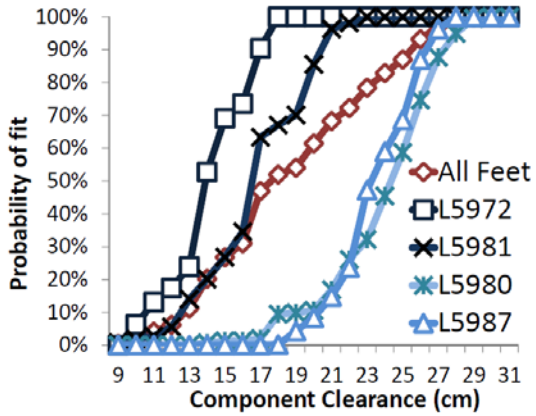

Figure 1. Probability of fit based on component clearance. For example, an amputation 27 cm from the bottom of the heel would yield a 95% chance any component combination with a L5987 foot would fit.

DISCUSSION

Residual limb length optimization will be the tradeoff between biomechanical advantages of a longer length and potential functional advantages of prosthetic components that require higher build heights. This work demonstrated the relationship between component clearance and the probability those components will fit. Future work can model the relationship between residual limb length and biomechanical advantage and then calculate an optimal amputation length.

CONCLUSION AND CLINICAL APPLICATION

A transtibial amputation that leaves at least 27 cm of component clearance will ensure a high likelihood the person will not be limited by component build heights.

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The Effects of Umbrellan® Technology on Night Time Phantom Limb Pain

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INTRODUCTION

The purpose of this study is to determine if Umbrellan® technology which is used in Medipro® Relax Night Care Socks (RNCS) is effective in reducing night time phantom limb pain. Phantom limb pain is prevalent in amputees and can affect their day to day life as well as their sleeping habits. It is reported that 80% to 85% of amputees will have significant phantom limb pain at some point after amputation. (Ehde et al. 2000), (Knotkova et al. 2012), (Sherman et al. 1988), (Weeks et al. 2010).

METHOD

Subjects: Ten participants were recruited from Scheck and Siress. Eight out of ten finished the study. The inclusion criteria included being at least eighteen years of age with lower extremity amputation, and experiencing night time phantom limb pain.

Procedures: Participants were asked to wear the RNCS with Umbrellan technology on a predetermined schedule. This time line consisted of the participant wearing the sock for three weeks, not wearing the sock for three weeks and then wearing the sock for a second time for three weeks. Medipro® donated ten socks to be used during this study.

Research tools: Participants were asked to fill out a daily log during the nine weeks of wearing and not wearing the sock. They were also asked to fill out three questionnaires both prior to and after wearing the sock. The universal numeric rating scale (NRS) was used to determine intensity of phantom limb pain. (Hawker et al, 2011).

Data Analysis: Microsoft Excel software was used to analyze the data.

RESULTS

Daily Log Results: The average pain when wearing the sock for the first time was 1.98. The average pain when not wearing the sock was 2.27. The average pain when wearing the sock for the second time was 1.69. Six out of the eight participants had decreased pain when wearing the sock for the second time when compared to not wearing the sock. One out of the eight participant's pain remained consistent when wearing the sock for the second time when compared to not wearing the sock. One out of the eight participants had a 0.01 increase in pain when wearing the sock for the second time when compared to not wearing the sock.

Questionnaire Results: Eight out of the eight participants (100%) had decreased pain at nine week post-sock questionnaire when compared to pre-sock questionnaire.

DISCUSSION

Quantitative data from the daily logs did not show a significant decrease in pain when using Umbrellan® technology. However, Qualitative data from the questionnaires did show a meaningful reduction in pain when wearing the RNCS. There are many factors that may have influenced the study. Many participants reported having trouble keeping the sock on when they slept. Others reported not following protocol consistently.

Scheck and Siress funded ten additional socks to bring the total participants to twenty for future analysis. Additional research in the future would include more control of outside factors as well as wearing the sock for a longer period of time.

CONCLUSION

The Medipro® RNCS with Umbrellan® technology is efficient in decreasing night time phantom limb pain when the appropriate candidate uses it a majority of the time.

CLINICAL APPLICATIONS

This has clinical application because 80% to 85% of patients will encounter phantom limb pain sometime after amputation. Practitioners can offer this sock as an effective treatment.

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SELF-REPORTED COGNITIVE CONCERNS IN PEOPLE WITH LOWER LIMB LOSS

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INTRODUCTION

Traditionally, loss of a limb has been viewed solely as a musculoskeletal impairment. However, a recent review by Coffey et al. (2012) describes a common association between lower limb loss (LLL) and presence of cognitive impairment (CI). This association was typically reported in persons with comorbid dysvascular conditions, such as diabetes. Previous studies assessing CI in people with LLL rarely include persons with traumatic LLL or examine how experiences with CI differ between populations with different etiologies of amputation. Further, no identified studies assessed cognitive difficulties from the perspective of people with LLL (Coffey, 2012).

Therefore, the purpose of this study was to compare self-reported cognitive difficulties between persons with LLL and normative values for the US general population to estimate the prevalence and severity of cognitive concerns in this population. Presence of cognitive concerns by etiology was also examined to assess how perceived cognitive difficulties were influenced by etiology of amputation.

METHOD

Subjects: Adult prosthetic limb users with unilateral LLL from dysvascular or traumatic causes.

Apparatus: Paper or electronic survey that included the NeuroQoL Applied Cognition General Concerns (NeuroQoL AC-GC) instrument (Cella, 2012), an 8-item survey that measures perceived difficulties with cognitive processes (e.g., memory).

Procedures: Participants were recruited to take a one-time survey in their home or prosthetic clinic.

Data Analysis: Data were compared to US population norms (i.e., a T-Score of 50) using one-sample t-tests. Data were then compared by etiology using t-tests to assess differences between groups.

RESULTS

1086 people with LLL participated in this study.

Table 1. Participant characteristics

		Mean	SD
Age at survey (yrs)		54.9	13.4
Years since amputation		11.8	13.9
		N	**%**
Gender	Female	319	29.4%
Education	≤ High school	319	29.4%
	> High school	762	70.2%
LLL Level	Transfemoral/KD	383	35.3%
	Transtibial/Syme's	703	64.7%
Etiology	Trauma	602	55.4%
	Dysvascular	484	44.6%

RESULTS, CONT.

People with LLL reported significantly more perceived difficulties with cognition (mean NeuroQoL AC-GC score=45.9, SD=8.4, median=44.6) than the population norm (mean NeuroQoL AC-GC score=50, SD=10, median=46.6). Subgroups defined by age and etiology were statistically significantly different from the norm ($p<0.025$), but not significantly different from each other ($p>0.05$). There were no statistical differences in scores between age groups.

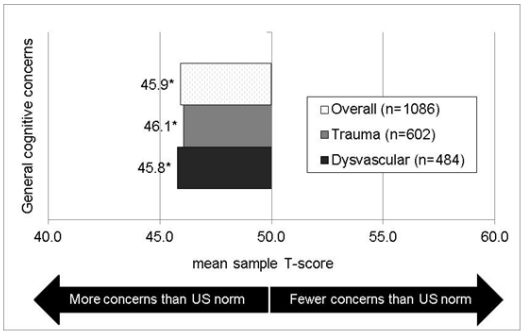

Figure 1. Mean Neuro-QoL AC-GC T-scores for individuals with lower limb loss, overall and by etiology. The T-score of 50 represents the norm sample mean.

DISCUSSION

Overall, NeuroQoL scores are approximately 0.4 SD lower in people with LLL compared to the US general population. One-half SD has been demonstrated as an acceptable estimate for meaningful difference across outcome measures (Norman, 2003). Additionally, people with LLL from dysvascular causes did not report more perceived difficulties with cognition than those with traumatic etiology, indicating that increased incidence of cognitive concerns is not solely associated with dysvascular comorbidities, but is common to many people with LLL.

CONCLUSION

People with LLL report significant concerns with cognitive function that do not differ by etiology.

CLINICAL APPLICATIONS

Prosthetic care often requires patients to learn new skills and/or follow complex instructions. Presence of CI in people with LLL may require prosthetists to modify how information is communicated to patients with CI to ensure optimal prosthetic care is provided. NEURO-QoL may be used in prosthetic clinics as a screening tool for perceived cognitive difficulties.

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Development of a Quantitative K-Level Classification Method

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INTRODUCTION

The Medicare Functional Classification Level, or K Level, is required by third-party payers to categorize amputees based on their potential functional ambulation ability (*HCFA Common procedure Coding System HCPCS 2001*, 2001). Suitable components are prescribed based on an amputee's K level. However, Medicare has not established a method to determine K levels. Classification is currently based on patient-reported questionnaires (Stepien et al., 2007) or in-clinic evaluations that do not adequately capture real-world function (Hafner and Sanders, 2014). The subjectivity of current methods can result in discrepancies in patient's classifications (Gailey et al., 2002), a factor that has become a significant problem with the increases in Medicare audits.

Activity monitors can measure real world function, including step count. Accelerometer-based monitors have been shown to accurately count steps in amputees, particularly for walking faster that 0.75 m/s (Ramstrand and Nilsson, 2007). One such activity monitor, the Fitbit® One™, is wireless, lightweight, low cost, readily available commercially and its data can be accessed by both patients and clinicians.

Of particular interest for this study was distinguishing between K2s and K3s given the frequency these prosthetic components are prescribed. A key differing characteristic is that K3 amputees have the ability to walk with variable cadences, while K2 amputees do not. Cadence is calculated as the number of steps per minute. The purpose of this study was to develop and begin to evaluate a quantitative method for classifying K2 versus K3 levels based on real-world step activity.

METHOD

Subjects: 13 unilateral amputees were recruited for this IRB approved study. 11 subjects (7 male, 4 female; 47 ± 13 yrs; 68.8 ± 3.1 in; 194.8 ± 53.2 lbs) were classified as K3 by the prosthetist and 2 subjects (males; 66 ± 11 yrs; 70.5 ± 3.5 in; 210 ± 12.7 lbs) were classified as K2. Of the K3s, 5 were above knee and 6 below knee. Both K2s were below knee.

Apparatus: All step activity was recorded via a Fitbit® One™ attached near the ankle of the prosthesis.

Procedures: First, subjects came to the clinic for an assessment visit where they were equipped with a Fitbit® One™. Walking speed was determined via a 10-meter walk test. Then, subjects were sent home with the Fitbit® One™ for a 7 day observation period. Subjects were instructed to perform their regular daily activities, wearing the device at all times that they were wearing their prosthesis. Once the Fitbit® One™ was returned, minute-by-minute step count data were extracted from the device via FitaBase, a cloud-based, fee-for-service data aggregation platform.

Data Analysis: For each subject, self-selected walking speed was calculated from the 10-meter walk test. From the 7-day observation period, the total number of steps taken and cadence at each minute were calculated. The number of occurrences of each cadence was calculated, and then cadence was binned (bin 1 = 0-10steps/min; bin 2 = 11-20 steps/min, etc.). A Weibull pdf was fit to each histogram, and the scale parameter (measure of distribution's spread) was calculated to quantify each subject's ability to walk at different cadences.

RESULTS

All subjects walked at or above 0.75 m/s, with K2s walking slower than K3s (0.81 ± 0.08 vs. 1.19 ± 0.21 m/s). K2s took fewer total steps during the 7-day observation than K3s (19,912 ± 11,554 vs. 34,423 ± 25,609 steps). K2s had a lower scale parameter than K3s (29.1 ± 3.3 vs. 36.4 ± 7.3) (Figure 1).

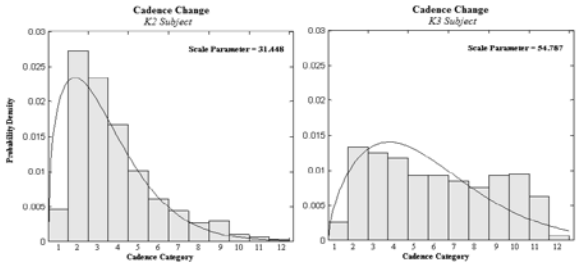

Figure 1: Cadence change histograms with Weibull pdf for an example K2 and K3 subject. Larger scale parameter (wider spread) indicates subjects walked at variable cadences.

DISCUSSION

The results suggested that step count-based measures recorded via a Fitbit® One™ can be used to objectively differentiate between K2 and K3 level amputees. The small K2 sample size made it difficult to fully evaluate the method, but future work will recruit more K2 subjects to strengthen the findings.

CONCLUSION

This study introduced a method to objectively classify K2 and K3 level amputees based on their total number of steps and frequency of cadence change over a week long observation period of daily activities.

CLINICAL APPLICATIONS

The method presented in this study may provide a low cost, objective, clinically viable way to effectively classify K2 and K3 level amputees.

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FPTH14

Investigation of Center of Pressure during Double Support in Males with a Unilateral Transfemoral Amputation

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INTRODUCTION

The kinematics and kinetics of able-bodied ambulation produce a smooth progression of the center of mass (CoM) and center of pressure (CoP) throughout the gait cycle (Orendurff *et al.*, 2004). During the double support phases, body weight is accepted and transferred from trailing to leading limb, and the smoothness of the transfer is influenced by the trailing limb. Persons with a transfemoral prosthesis lack the local muscle control at the joint closest to the ground (the foot/ankle complex), and therefore, when the prosthetic limb is the trailing limb the control of this transfer is at the proximal hip joint (Hof *et al.*, 2007). The lack of muscle control also reduces fine motor movements, potentially influencing the transfer of CoP. The purpose of this descriptive and exploratory study was to investigate the effect of walking with a transfemoral prosthesis on the path and velocity of total CoP during double support phase.

METHOD

Subjects: This was a retrospective study of clinical data acquired from two males, age 30 and 33, with a unilateral transfemoral amputation. The two males used their own above-the-knee prosthesis with a microprocessor knee and dynamic response foot. Both subjects walked without an assistive device and had no reported comorbidities.

Apparatus: CoP data was collected using the 2' by 16' Zeno Walkway (ProtoKinetics, Havertown, PA), a 16-level pressure sensing mat sampling at 60 Hz.

Procedures: Subjects were instructed to walk across the mat at a comfortable, self-selected walking speed. Five trials ambulating across the mat were collected for each subject.

Data Analysis: ProtoKinetics Movement Analysis Software (PKMAS), Excel (Microsoft Corporation, Redmond, WA), and MatLab (The MathWorks, Inc., Natic, MA) were used to process and calculate the gait data, as well as perform statistical analysis.

RESULTS

For weight transfer from prosthetic to sound limb and sound to prosthetic limb, minimal difference was observed for the overall anterior/posterior and medial/lateral CoP displacement. However, for weight transfers from prosthetic limb to sound limb, there was increased velocity of the anterior/posterior (CoPX) and medial/lateral (CoPY) center of pressure during the first 20 percent of double support (Figure 1). This early double support phase anterior/posterior velocity during weight transfer from prosthetic to sound limb is significantly greater than the early double support phase velocity during weight transfer from sound to prosthetic limb for both subjects ($p \leq 0.001$).

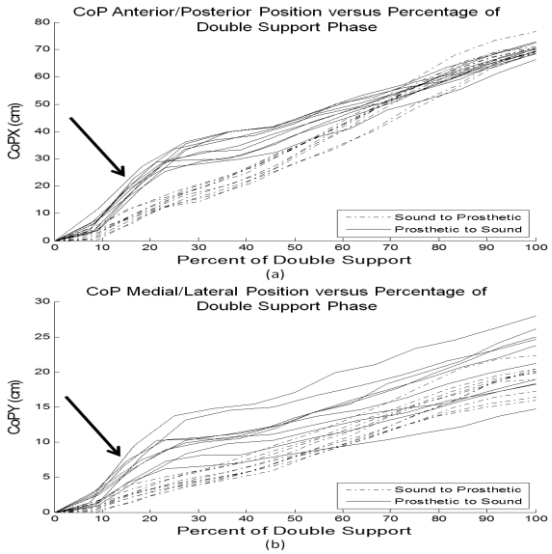

Figure 1. One subject's anterior/posterior (a) and medial/lateral (b) CoP position versus percent of double support phase. Arrow indicates increased velocity during early double support when transferring from prosthetic to sound limb.

DISCUSSION & CONCLUSION

This is part one of a pilot investigation, and the results show an increase in total CoP X and Y velocity during the initial 20% of double support when transferring off the prosthetic limb. The increased CoP velocities affect sound limb joint moments and are potentially related to the increased sound limb loading reported in previous studies (Hansen *et al.*, 2006; Snyder *et al.,* 1995*)*. CoP velocity may be influenced by mechanical properties of the prosthetic foot, such as effective foot length and stiffness. Part two of the study investigates the effect of two different prosthetic feet (SACH versus Carbon Fiber) on CoP path and velocity.

CLINICAL APPLICATIONS

The results of this research study will increase our understanding of the effect of prosthetic foot choice on sound limb loading, and will assist clinicians with prosthetic foot selection for their patients with a transfemoral amputation.

ACKNOWLEDGEMENTS

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Variable Stiffness Prosthesis to Improve Amputee Coronal Plane Balance

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INTRODUCTION

Lower limb amputees exhibit a higher prevalence of falls compared to age-matched non-amputees (Miller, 2001). One reason may be that both household and community environments are replete with uneven terrain. In the home, objects left on the floor, uneven flooring, and loose cords are common causes of falls (CDC, 2011). Many outdoor falls are precipitated by uneven surfaces in sidewalks, curbs and streets (Li, 2006).

The purpose of this research is to determine if a controlled stiffness ankle (CSA), whose coronal plane rotational stiffness can be varied independently of sagittal plane stiffness, can improve the coronal plane balance of lower limb amputees.

METHOD

Intervention: A prototype prosthesis whose coronal plane stiffness can be varied using a motor-driven screw mechanism is shown in Figure 1. The effective stiffness is changed by moving a cart contact point along two carbon fiber cantilever beam springs. A commercial low profile foot is used for the keel. Control functions are performed by two Arduino Pro Mini microcontrollers. The build height requires 70mm between the foot and socket pyramid adapters and the ready-to-use weight is 1120g. A 25% change in ankle stiffness (from 400Nm/rad to 300Nm/rad) can be accomplished in 0.45 sec.

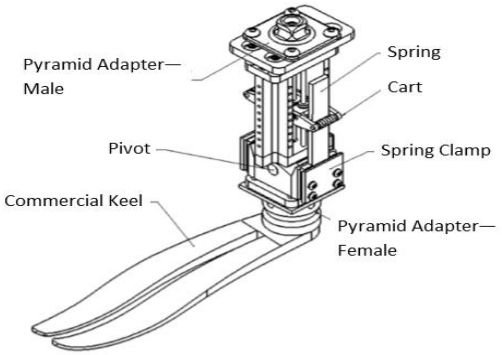

Fig. 1. Schematic of the controlled stiffness ankle.

Coronal plane bench tests demonstrated the stiffness could be adjusted to envelope four commercial feet (VariFlex Evo, Ossur; categories 5, 6, 7, 8).

Subjects: 3 transtibial amputees provided informed consent to participate in this IRB-approved protocol to measure the response to a step on uneven terrain (56±19 yo, 75±11 kg, 1.8±0.05 m, 8±5 years post-amputation, n=2 trauma, n=1 secondary to infection).

Procedures: We built an instrumented walkway with a central force plate that could be rotated to fixed angles in the coronal plane. We then conducted an experiment where each subject walked at their self-selected speed and stepped on each terrain condition (0°, +15°, -15° coronal angle) in random order over five repeated trials at two different coronal stiffness settings (stiff and compliant). A 12-camera motion capture system was used to measure coronal ankle angle and step width.

RESULTS

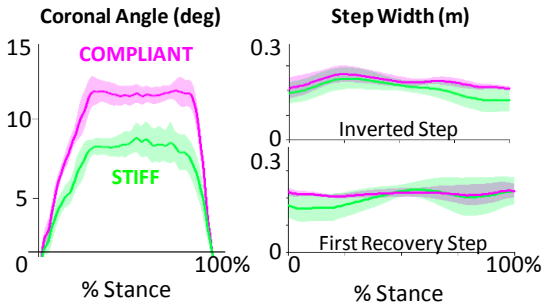

Fig. 2. Amputee (n=3) coronal ankle angle during a step on inverted terrain and step width during a step on inverted terrain and the first recovery step afterwards.

Amputee coronal ankle angle during a step on inverted terrain was greater for the compliant condition (see Fig. 2). Amputee step width during a step on inverted terrain was greater for the compliant condition and continued to be greater through half of the first recovery step (see Fig. 2). Results for stepping on everting terrain were similar.

DISCUSSION

The compliant CSA condition allowed greater ankle angle conformance to terrain and greater step width. Further development of a control system that automatically adapts the stiffness for different terrains appears warranted.

CONCLUSION

Initial human subject tests suggest the potential for this CSA to improve the coronal balance of lower limb amputees.

CLINICAL APPLICATIONS

This technology may reduce lower limb amputee risk of falls and fall-related injuries.

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Use of Computer Aided Design and Additive Manufacturing in the Rehabilitation of Wounded Warriors at Walter Reed National Military Medical Center

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Introduction

Computer Aided Design and Additive Manufacturing in various print medias and metals facilitate the design and manufacture of custom devices to enhance the rehabilitation of Wounded Warriors utilizing both upper and lower extremity prosthetic devices. The versatility of the process allows for the design of specialized devices that would otherwise be unfeasible or to time and cost intensive to produce using traditional manufacturing processes. Allowing the clinician, Wounded Warrior, and patient to work in conjunction with each other facilitates the design process.

Methods

Working with the 3-D Medical Applications Center at Walter Reed, an idea would be taken from conception to manufacturing, often with multiple iterations as designs were tested and modified based on observation of function and patient feedback.

Designs could start as sketches, physical models, or simply descriptions from patients/practitioners. If a new device was required to interface with an existing part (e.g.-a pyramid adaptor or terminal device) measurements or a 3-D scan of the existing device would be taken to ensure that the custom device would interface with the existing device.

The Medical Applications Center then designs parts using 3-D modeling software. After reviewing the digital model with the prosthetist/patient, the design is printed in the appropriate media (titanium, hard plastic, rubber). The device is then tested with the patient and further adjustments are made if needed.

Results

Wounded Warriors at Walter Reed have benefited from the introduction of this technology. Custom 'shorty' feet for training bilateral trans-femoral amputees have been produced, lowering the patient's center of gravity and allowing for a more natural rocker motion, both of which facilitate initial ambulation. 'Mechanics' feet were also produced for a bilateral trans-femoral amputee. This basket shape allows patient a great deal of motion on the ground under his car. A 'pilot's' foot has allowed a unilateral trans-tibial amputee to more safely operate the rudder and brake foot controls on a general aviation aircraft. Upper extremity terminal devices have been made to allow a patient to manipulate a hockey stick and to safely hold a hand gun with his prosthesis. Terminal devices have also been made to allow a patient to participate in indoor rock climbing. Adaptors to existing hook type terminal devices have been made to allow patients to grasp a "Mushroom" terminal device to propel a wheelchair. Adaptors have also been made to hold toilet paper to allow for independent toileting, and a sandwich holder to facilitate eating.

Discussion

CAD and Additive Manufacturing allow for the production of highly specialized devices to facilitate rehabilitation, increase independence, and enhance the Wounded Warrior's daily life. With multiple limb loss, especially upper extremity, it is even more important to provide as much independence for activities of daily living as possible. Having the clinician, 3-D Design team and patient all working together resulted in a better design outcome.

Conclusion

The use of additive manufacturing technologies allows us provide highly specialized adaptive devices in a quick and cost effective manor.

Clinical Applications

As additive manufacturing technology becomes more accessible and cost effective, it can be incorporated into multiple facets of patient care, from improved manufacturing techniques to development of devices for specific needs.

Reactivity Effect of Observation in Prosthesis Gait Assessment

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INTRODUCTION

The aim of this research was to challenge the current process of gait assessment in prosthetics. This pilot study explores the idea that prostheses users walk differently in their daily lives than they do during prosthesis fitting sessions. The Hawthorne - or more generally - reactivity effect states that people will act differently when they are aware of being observed (McCarney, et al, 2007). Presence of a reactivity effect in prostheses users would imply that, aware of observers, they will not walk their habitual stride. Conscious efforts to "walk normally" may prompt a gait that is perceived as normal, yet is considerably different from their normal pattern (Brackett, et al, 2007). This could create a large problem when a prostheses user's walk during a fitting session is the basis for prosthesis alignment and adjustment. Based on past reactivity research (Bussmann and Stam, 1998) it was hypothesized that the mere presence of a prosthetist or researcher affects the amount of limping, as signified by upper body sway angle and double support durations in lower limb prostheses users. If this is the case, prosthetics gait assessment could be less accurate than commonly assumed.

METHOD

A single subject was recruited who was comfortable walking on prosthesis and was familiar with the research facility. To create a situation that allowed the analysis of "unobserved" gait, the subject had to be deceived about the true purpose of the study. First, a sensor unit containing a tri-axial accelerometer, a magnetometer, and gyroscope (G-Walk, BTS Bioengineering, Milano, Italy) was attached to the subject's waist with a belt. The subject was then sent through an empty hallway to a different laboratory, unaware that data was being collected (Condition A). In the second lab, the subject underwent a gait assessment by a group of prosthetics students (Condition B). Figure 1 illustrates the protocol.

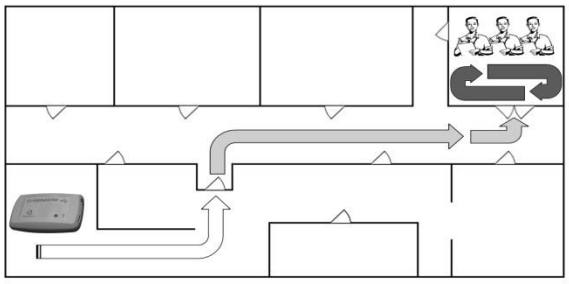

Figure 1: Subject's pathway from the first lab (white arrow) through the hallway (light grey) into the second lab (dark)

In post-processing, step data were manually sequenced and the variables of body sway and double support time were compared across conditions by t-test, using statistical software (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp).

RESULTS

The participant in this study was a 57 year old male, (88kg, 1.77m), who used a trans-femoral prosthesis on his right leg. Fourteen steps were recorded during condition A and sixteen steps on each side were taken at random from condition B.

A significant difference was found in the right (the prosthetic leg) step time in double support. Other variables were not significantly different (Table 1). The subject walked 0.12m/s faster and took 18 cm longer strides while he knew he was being watched.

Variable (double support phase)	Unobserved (Cond. A)	Observed (Cond. B)	Absolute difference	Percentage difference	p
Right step (% of gait cycle)	13.6	11.8	1.8	14.2%	0.014*
Left step (% of gait cycle)	10.1	10.2	0.1	1.0%	0.089
Left-right average (% of gait cycle)	11.85	11.0	0.85	7.4%	0.061

Table 1: Differences in double support time

DISCUSSION & CONCLUSION

The finding of a significant difference between the two conditions suggests that the subject was affected by the observers' attention. Every variable studied had changed a noticeable amount from the control to the observed trial, most of which may be attributed to the change in gait speeds. The shorter double support time in the prosthetic leg stride could mean that limping was reduced in the presence of observers. Double support times were much less symmetric when walking unobserved, with a bilateral difference of 3.5% compared to 1.6% when observed.

CLINICAL APPLICATIONS

The results of this case study provide some indication that clinical gait assessment procedures in prosthetics have an undesirable reactivity effect on the walking pattern of prosthesis users. In clinical practice such an effect could lead to the misalignment and maladjustment of lower limb prostheses.

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Biology of Biomechanics

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Introduction:

Assessing outcomes for extra-corporal orthotics, prosthetics and robotics clinical and technological intervention is fairly straight forward: just ask. Of course, the resulting subjective interpretation or ratings might not fully capture or accurately reflect the underlining biological issues involved in physical restoration and rehabilitation of individuals with desensitized or missing limbs. This poster presentation suggests a reproducible, consistent and (most importantly) predictable method for testing or proving that any one technological invention modality is preferable to any other. It also suggests that this clinical training and testing protocol be used to more objectively measure treatment outcomes. To these ends, we need to find answers to the following three questions:

- **What makes a mechanical device biological?**
- **What is the essential role of applied or clinical biomechanical engineering in rehabilitation science?**
- **How can we physically measure clinical efficacy of a biomechanical device?**

The answers to these questions lies in the understanding of how biomechanics and neural mechanisms interact to facilitate correlation of normal body imagery skills with normal sensory perception skills and the acquisition of sensori-motor skills associated with control and manipulation of the supportive or replacement O&P or robotics device.

Method

In 2006, an experimental neurocorrelagraphic device was developed to measure contingent sensori-motor function. The device consists of accelerometers, load cells, foot switches and a manually activated timing switch. Information from this device is fed into a PC for display and analysis

The neurocorrelagraphic display indicates kinetic and kinematic activity on the vertical axis; the sound leg in red and the orthotics insensate leg or prosthetics leg in blue. Time in seconds is displayed on the horizontal axis. Manual activation of the hand switch is indicated by timing markers appearing on the graph relative to both vertical and horizontal axes. For cyclic or repetitive training and/or extreme measuring accuracy (to within 5 ms.), both axes can be compressed or expanded. Haptic (tactile) sensory input generated primarily from the body-machine interface is initially augmented with acoustical as well as inclusive optical (graphic) input. Acoustical input consists of three separate and distinct tones; a low frequency that indicates the approach to threshold calibration, a pleasant frequency that indicates exact threshold calibration and an unpleasant frequency when the set point calibration is reached or exceed.

Discusion

If we choose to take an “active and voluntary” or enactive and volitional approach to physical rehabilitation, we need to define the essential biological issues involved. Simply stated, an individual who is successfully rehabilitated think or conceive of themselves as whole and normal, they perceive or experience physical sensations of wholeness and normality and they acquire sensori-motor skills that allow them to purposefully, meaningfully and voluntarily interact with their environment.

Conclusion

The neurocorrelating effect of this mental visualization or conceptualization provides physically measureable evidence of enhanced sensori-motor skills, normal body imagery skills and normal sensory perception skills associated with the practical application and optimal utilization of an O&P or robotics device. It is the inclusive role and arguably the ethical obligation and responsibility of the clinical orthotist/prosthetist to biomechanically create, implement and clinically evaluate such an accurately perceptible active and voluntary device.

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EFFECT OF OPEN CALCANEUS CARBON COMPOSITE AFO ON GAIT OF AN INDIVIDUAL WITH SPINAL CORD INJURY

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INTRODUCTION

Ankle foot orthoses are often prescribed for individuals with Incomplete Spinal Cord Injury to provide support for weakened musculature, specifically to address excess plantar flexion during initial contact, stabilize the joint for effective push-off during late stance, and prevent toe-drag during swing. (LER Article 14, 16). Traditional AFOs that encompass the calcaneus prevent this "normal" biomechanical process. The purpose of this case study was to investigate the effect on gait wearing bilateral custom solid ankle plastic rigid AFO (SAAFO) versus bilateral rigid Dynamic carbon composite AFO (Allard ToeOFF® AFO) with open calcaneus (RDCC AFO).

METHODS

Subject: 27 year old female who sustained an Incomplete T12 Spinal Cord Injury due to a horse riding accident at the age of 15.

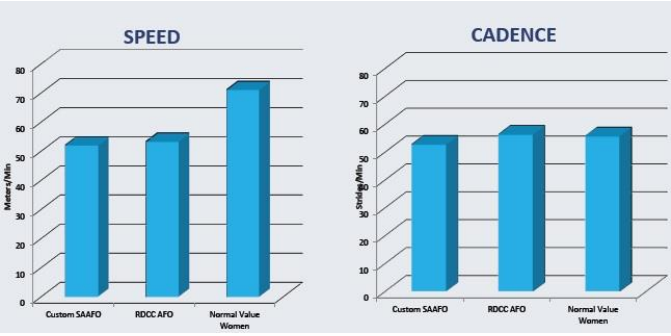
Procedures: Subject was tested in 2 different conditions: 1) Bilateral Custom Solid Ankle AFO and 2) Bilateral rigid dynamic carbon composite AFO with an anterior tibial shell and open calcaneus.

Research Tools: BTS G-WALK Portable Gait Analysis System placed at the L5 vertebral level3.

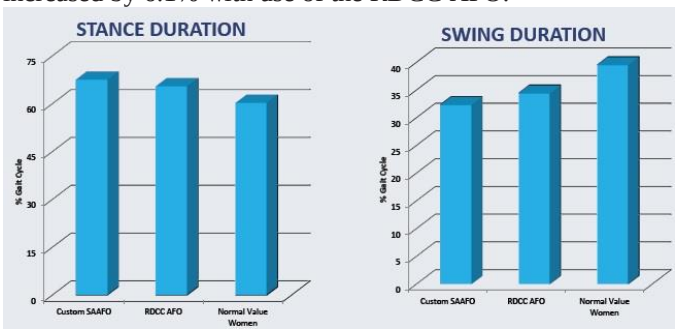
Data Analysis: Averaged temporal-spatial data from 3 walk trials in each condition and then compared averaged data between two conditions.

RESULTS

Overall, the subject performed better in all temporal spatial measures using the RDCC AFO with her performance trending toward normal values for women. Subject's speed increased by 2.4% and cadence increased by 6.38% while utilizing the RDCC AFO.



Stance duration decreased by 3.2% and swing duration increased by 6.1% with use of the RDCC AFO.



Double limb support decreased by 13.6% and single limb support increased by 6.6% with use of the RDCC AFO.

The patient was very confident in the RDCC AFO and did not look as though her gait was affected at all – she appeared to be walking without the need for AFO's. The patient is young and is opposed to donning anything that will limit her ability to dress professionally and ultimately limit shoe choices for her career as an attorney. In addition to affecting gait, compliance issues are also important to the patient.

DISCUSSION

Comparing objective measured values provides guidance for providing the orthotic design with maximum functionality for the patient. The DRCC orthotic intervention provides the maximum function for this patient with an increase in speed and cadence, a decrease in stance phase duration and double limb support while increasing swing phase duration and single limb support. These temporal spatial values tend to indicate more stability and comfort in walking. The RDCC AFO design incorporates a relatively stiff forefoot, restricting dorsiflexion and includes an anterior tibial shell that provides a mechanism whereby forces caused by loading the toe lever can be comfortably distributed to the leg which appears to normalize gait parameters in this patient model. This study has the obvious limits of a case study and gait parameters measured but can give guidance to practitioners in recommending AFO interventions for patients with SCI.

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DISCLOSURE

Thank you Allard USA for use of ToeOFF AFO's (RDCC AFO).
Thank you to my patient for her participation

MAXIMIZING FUNCTIONAL OUTCOMES UTILIZING OBJECTIVE GAIT ANALYSIS
A CASE STUDY: CHARCOT-MARIE-TOOTH ORTHOTIC TREATMENT INTERVENTIONS

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INTRODUCTION

Charcot-Marie-Tooth (CMT) is one of the most common inherited neurological disorders, affecting approximately 1 in 2,500 people in the United States. The neuropathy of CMT is a slowly degenerative process with symptoms often starting in adolescence or early adulthood and typically results in weakness of dorsiflexors, plantarflexors and the intrinsics of the feet. CMT is not considered a fatal disease and people with most forms of CMT have a normal life expectancy however they typically require physical therapy, orthotic intervention and assistive devices to maintain mobility during their lifetime[1]. Identifying maximal functional outcomes is often limited to visual gait analysis and subjective patient commentary and it can be difficult to know if an adjustment or change of design has made a difference to function. Utilizing a portable computerized gait analysis system, we are able to quantify measures of gait modify our components, designs and gait training to maximize functional outcomes of orthotic intervention.

METHODS

A single female patient with a 15 year history of CMT affecting bilateral lower extremities was tested in 3 different bilateral conditions. The custom fit dynamic carbon composite AFO designs included 1) without adjustment; 2) with increased rigidity without adjustment; 3) same rigidity as condition 2 with an adjustment to customize the orthosis for the heel height of the shoe. Temporal-spatial and pelvic motion was collected utilizing a BTS G-Walk Portable Gait Analysis System placed at the L5 vertebral level[2]. Speed, percent of double limb support, and pelvic kinematics were compared across the conditions and to normal values for women.

RESULTS

Speed and percent double limb support were closest to normal values when the patient ambulated with the orthoses that were more rigid, custom fit, customized for heel height and manufactured fully of carbon composite. Pelvic range of motion in 3 planes shows that orthotic interventions with more rigid profiles reduce pelvic motion primarily in the transverse plane.

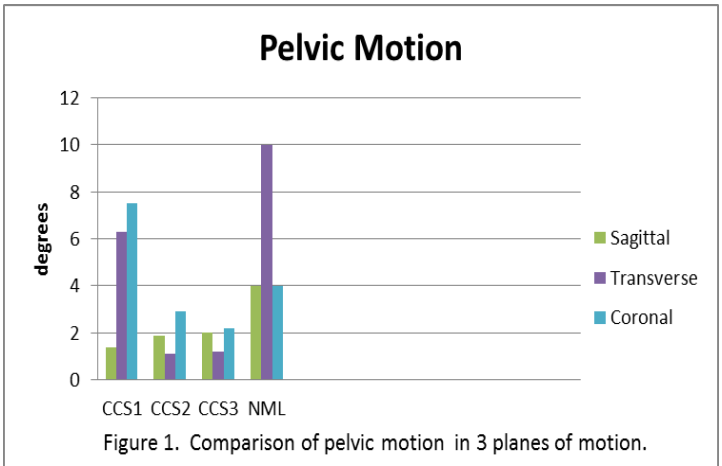

Figure 1. Comparison of pelvic motion in 3 planes of motion.

DISCUSSION

Comparing objective measured values provides guidance for providing the orthotic design with maxium functionality for the patient. Utilizing the G-Walk system functional outcomes due to changes in orthotic design and customization can be measured and documented. The orthotic intervention that provides the maximum function for this patient allowed for increased speed and decreased pelvic motion, which happened to be the more rigid design customized for heel height. By utilizing a portable computerized gait analysis system changes in gait function can be monitored over time and with changes to orthotic intervention as well as physical therapy treatments.

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DISCLOSURE

Vincent DeCataldo, BOCPO, NJ LPO is employed by Allard USA manufacturer of dynamic carbon composite AFOs.

ACKNOWLEDGMENTS

Thank you to Virginia Mamone and Orthopedic Motion, Inc.

PEDIATRIC PARTIAL FOOT PROSTHESES: A NEW TREATMENT OPTION

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INTRODUCTION

Documentation of pediatric partial foot amputation (PFA), prosthetic intervention and effectiveness of treatment is insufficient. However, recommendations regarding pediatric prosthetic intervention advise downsizing, sequenced complexity and a modular design that does not interfere with an increased activity level.[2] In the general population PFA is the most common amputation surgery with 2 per 1000 affected.[4] Transmetatarsal or mid-tarsal amputations account for approximately 24% of PFAs.[3] In the pediatric population 40% of amputations are attributed to trauma.[8] Lawn mowers and household accidents account for the majority of the partial foot amputations in the pediatric population[8.] Current pediatric treatment options mimic those for adults with the extent of the intervention proportional to the extent of tissue lost.[3] More recently it has been recommended that any amputation involving the metatarsal heads or proximal structures requires a prosthetic intervention that extends proximal to the ankle.[6] A prosthesis utilizing a custom fit rigid dynamic carbon composite (DCC) ankle foot orthosis structure to aid in the restoration of gait has been proposed for the adult PFA patient. [7] By extending above the ankle the prosthesis aids in the progression of the center of pressure along the foot and restores the biomechanics of walking.[6]

METHODS

A prosthetic design for treating the pediatric partial foot amputee that restores gait function by addressing the biomechanical deficits is proposed. A custom fit rigid DCC with carbon anterior shell AFO customized with a toe-filler type socket with wedging, lifts and posting are the components of the proposed prosthesis. Until recently there was not a custom fit option for providing a reliable custom fit rigid DCC structure in which to fabricate a custom prosthesis for the pediatric population. The new custom fit rigid DCC is a prefabricated full carbon foot plate, rigid lateral strut and carbon composite anterior shell. The footplate is rigid with a tapered rocker built into the distal section with a flexible posterior section and a rigid stable midfoot. This design aids in restoring gait by allowing for a controlled plantarflexion moment at initial contact, a stable midstance and a controlled tibial advancement through terminal stance, while maintaining a 3rd rocker rollover and providing propulsion at terminal stance. This system is combined with a custom molded toe filler type prosthesis that is aligned with wedges, posts and lifts to maximize functional outcomes. This system addresses the biomechanical deficits of the PFA and the DCC is designed to have varying degrees dynamic function by style and size. The ability to customize the socket, alignment and interface helps to protect the skin of the residuum while the dynamic function can be customized for functional needs.

RESULTS

The pediatric prosthetic design is proposed based on the outcomes of the adult treatment option with similar outcomes expected. This prosthetic design has been used with adult PFA patients since 2010 the anecdotal results are positive. Patients report increased mobility and decreased skin breakdown.

DISCUSSION

Research on specific effects on gait function utilizing the proposed PFA DCC design need to be conducted. Preliminary data regarding use of the DCC AFO in the pediatric population indicates that a dynamic response carbon AFO, similar to the rigid DCC design, provides improved function in running, jumping and walking performance while Gross Motor Function Measure was also improved. [1] Similar outcomes are expected with a PFA DCC prosthesis due to the similarity of the gross structure and function of the rigid DCC design.

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DISCLOSURE

Vincent DeCataldo, BOCPO, NJ LPO is employed by Allard USA manufacturer of dynamic carbon composite AFOs.

Standing balance in people with trans-tibial amputation due to vascular disease: A scoping review

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INTRODUCTION

Balance control is an essential part of motor activities. The presence of a transtibial amputation (TTA) could limit the ability to control balance due to the loss of structures below the knee as compared to healthy individuals. However, depending on the cause of amputation balance control might be affected differently. Pre-existing sensory deficits, i.e. diminished sensation at the residual limb and the intact leg, in people with TTA due to vascular disease (diabetes, PVD) (TTA-vascular) could reduce the feedback coming from the lower extremities and further alter the deficit of balance control in this population as compared to people with TTA due to trauma (TTA-trauma). The literature on balance control in people with TTA-vascular is limited. The purpose of this paper is to review literature and determine if balance control in people with TTA-vascular is altered as compared to people with TTA-trauma and healthy individuals.

METHOD

Procedures: An electronic search of articles was made from Feb to Mar 2014 on PubMed, Google Scholar, Science Direct, COCHRANE and CINAHL. Key terms used: amputee, vascular, balance and prosthesis.
Data Analysis: Articles were included if they had participants with TTA-vascular, focused on balance and were peer reviewed.

RESULTS

An initial electronic database search yielded 40 articles. Upon review, 6 articles were selected. A common aim of the studies was to measure static balance by having the participants stand still on force platforms under eyes open and closed conditions. Typical parameters measured included: weight distribution, center of pressure (CoP) maximal excursion and overall postural sway (standard deviation of CoP). One of the studies made use of the composite equilibrium score from computerized dynamic posturography testing.

Four of the 6 studies (Nadollek et al., 2002, Kanade et al., 2008, Isakov et al., 1992, Quai et al., 2005) investigated weight distribution in people with TTA-vascular. These studies did not include TTA-trauma. In general, participants with TTA-vascular stood with more weight on the non-prosthetic side.

CoP excursions were investigated by 3 studies (Quai et al., 2005, Nadollek et al., 2002, Kanade et al., 2008). During both eyes open and eyes closed, participants with TTA-vascular have significantly increased anterior-posterior (A-P) CoP excursion compared to people with TTA-trauma and healthy individuals. The A-P CoP excursion occurred more toward the non-prosthetic side in both individuals with TTA-vascular and TTA-trauma.

The 2 studies (Hermodsson et al., 1994, Isakov et al., 1992) investigating sway found participants with TTA-vascular to have significantly more sway than people with TTA-trauma and healthy individuals during both eyes open and closed testing conditions. Mohieldin et al. (2010) measured composite equilibrium score and found people with TTA-vascular have lower scores than people with TTA-trauma and healthy individuals.

DISCUSSION

Limited evidence exists on the balance control of people with TTA-vascular. However, all studies in this review had a similar conclusion; balance control is impaired in TTA-vascular population. Further, the inherent sensory deficit in people with TTA-vascular compromises their balance control more as compared to people with TTA-trauma. The postural adjustments (CoP movement, sway and weight distribution) found in this population are greater than those seen in people with TTA-trauma and healthy individuals. Diminished peripheral feedback could have caused weight distribution asymmetry in this population. However, other factors like residual limb pain, prosthesis alignment, socket discomfort and lack of confidence could also have affected weight distribution. Excessive loading of the non-prosthetic side could lead to secondary complications like osteoarthritis or amputation. Increased CoP excursion or sway in TTA-vascular could be one way of increasing proprioception from the lower extremities. However, more likely, the increased postural sway and/or CoP excursion reflects poor balance control.

CONCLUSION

People with TTA-vascular present with impaired balance control while standing still. Limited evidence suggests that balance control is affected greater in people with TTA-vascular than in people with TTA-trauma. Further research is warranted to determine if balance control in TTA-vascular differs from people with TTA-trauma during dynamic activities like walking or running.

CLINICAL APPLICATIONS

Prosthetists should be aware that people with TTA-vascular present with impaired balance control which differs from TTA-trauma. This difference may need to be taken into account when designing the prosthesis.

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MODELING TECHNIQUES FOR PERSONS WITH TRANSFEMORAL AMPUTATION

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INTRODUCTION

People with transfemoral amputation (TFA) experience impairments in ambulation, such as lateral trunk lean, hip hiking, and circumduction. These gait deviations may lead to excessive center of mass (COM) movements reflecting detrimental changes in gait quality and postural stability when walking. Position of the COM can be estimated from the weighted averages of body segments (Dempster, 1967) and is typically centered behind the umbilicus. COM position may be altered in people with TFA because of mass asymmetries between the prosthetic and intact limbs.

Currently, there is no consensus on the best modeling approach for persons using a prosthesis, and methods for estimating COM position from prosthetic-side mass distributions are often not reported (Kent, 2011). The magnitude of difference in COM outcomes between modeling methods for persons with TFA is needed to inform methodological decisions in quantitative gait analysis and to more accurately measure biomechanical outcomes in this population. Therefore, the goal of this study was to compare COM parameters derived using anatomical and component-specific models in people with TFA to better quantify observed gait deviations.

METHOD

A traditional, anatomical model was first created using mass distributions equivalent to the non-prosthetic side. Two component-specific (PRX) models were then created using a range of prosthetic-side weight distributions based on available componentry and estimates of the residual limb mass. These models demonstrated the effects of heavy (Heavy-PRX) and light (Light-PRX) prosthetic limb weights on COM outcomes.

Subjects: Four adult participants with unilateral TFA attended a single testing session at the University of Washington Human Motion Analysis Lab. All participants used a microprocessor-controlled prosthetic knee.

Apparatus: 3-D marker position data was collected at 120 Hz using an 8-camera Qualisys Motion Capture System (Gothenburg, Sweden). Kinematic data was processed using Visual 3D motion analysis software (C-Motion, Inc., Rockville, MD).

Procedures: Walking was assessed on a flat, firm surface. Biomechanical outcomes, including COM displacement in the medial-lateral direction and peak inclination angle during single limb support (SLS) on the intact side were derived with each model (Anatomical, Heavy-PRX, and Light-PRX).

RESULTS

Preliminary results in four participants suggest that COM parameters were affected by the model applied, Differences were observed between the Anatomical and the Light PRX models and were generally greater in magnitude for inclination angle than displacement parameters (Figure 1).

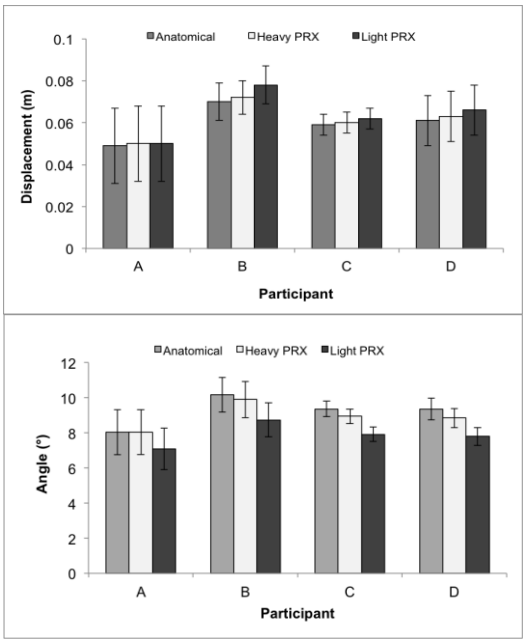

Figure 1. COM displacement in medial-lateral direction (Top) and peak inclination angle during SLS on intact side (Bottom) estimated with Anatomical and PRX models. Participants are ordered from lightest (A) to heaviest (D).

DISCUSSION & CONCLUSION

Participants' COM shifted upward and laterally toward the intact limb with the PRX models. This shift was more pronounced when there was a greater difference in weight distribution between the prosthetic and intact limbs (i.e., heavier individuals, Light-PRX model) Comparisons of the Anatomical and PRX models resulted in potentially important differences in COM outcomes. After analysis of additional participants, this study might suggest that it is less critical to use a component-specific gait model if COM excursion is a primary outcome of interest. However, if inclination angle is to be used as an indicator of postural stability, the model selected may have a greater effect on the data obtained.

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MOTOR LEARNING AND PERFORMANCE IN USERS OF UPPER EXTREMITY PROSTHESES

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INTRODUCTION

Many users of upper limb prostheses receive minimal training in using the devices for activities of daily living, even though they are capable of performing skillful motor control. Utilizing concepts in motor learning may be useful to understand how persons use prostheses for skilled tasks. Studies that evaluate motor learning can take advantage of two unique processes: an incidental phase of learning 'how to do' something without awareness and an explicit recall of the task. By studying incidental processes, we can understand how motor learning affects device usage without awareness of task constraints.

The goal of this study is to understand the behavioral aspects of upper extremity prosthesis users who are learning how to use devices for motor control. We hypothesized that implicit motor learning would be impeded in prosthesis users due to lack of familiarity with the prosthesis when compared to INTACT subjects performing the same task.

METHOD

Subjects: Twenty healthy subjects (11 female, 9 male, mean age: 24.6, SD: 7.1, all right-handed) completed the study. Ten subjects wore a fictive amputee model system (FAMS) affixed to their right hand. Ten control subjects used their right hand (INTACT).

Apparatus: Edinburgh handedness inventory, wooden board with moveable pucks, video camera

Procedures: FAMS subjects were fit with a FAMS socket that encompassed the subject's entire forearm and hand. The distal end of the socket used a hook-style terminal device, actuated by shoulder extension through a figure-8 harness. Subjects were seated in front of a task board and computer screen. We developed a modified multi-finger sequencing task (MFST). A visual display prompted participants to move the pucks in a repeated sequence of 7 movements, unknown to the subjects. All subjects performed 8 trials in each of the 6 blocks. A washout period between the 5th and 6th blocks was implemented. Subjects were instructed to perform the task as quickly but accurately as possible. Subjects were video recorded to assess accuracy.

Data Analysis: Time and accuracy of task completion were compared between groups. Sequence recall was recorded both initially and 24 hours following the study. Paired 2-sample t-test was used to evaluate statistical significance between groups.

RESULTS

Time to completion for FAMS and INTACT subjects decreased from Block 1 to Block 6, however accuracy remained consistent. FAMS subjects consistently showed more error with movements related to the puck and terminal device (such as dropping it or tapping it into the space), which never improved across blocks. In both groups, 9/10 subjects acknowledged recognition of a sequence, however only 1/10 FAMS subjects could recall the sequence compared to 5/10 INTACT subjects. INTACT subjects could recall more of the 7-move sequence than FAMS subjects.

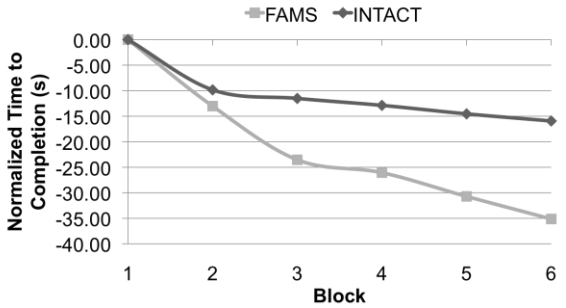

Figure 1. Normalized average time to completion.

DISCUSSION

Both FAMS and INTACT subjects show a decrease in latency, attributed to motor learning, but whether the sequence was explicitly encoded is inconclusive. The normalized time to completion suggests that FAMS users have a greater capacity for motor learning compared to INTACT subjects, likely due to adaptation to the prosthesis. However, FAMS users also have a high propensity for task related errors during motor learning that do not improve. Future studies can explore what effects explicitly knowing the sequence would have on FAMS users and the neurobehavioral outcomes of these processes.

CONCLUSION

Upper extremity amputees demonstrate motor learning in using their devices, but may require additional training to optimize device usage.

CLINICAL APPLICATIONS

Understanding motor learning in upper extremity amputees is important in the success rate of upper extremity device acceptance. Additionally, occupational therapy techniques can be designed in such a way to maximize potential of the patient.

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"ASSESMENT OF FORCES APPLIED FROM UNILATERAL TRANSFEMORAL RIDER TO MOTOCROSS FOOT PEGS"

"Caldwell, G.G. Brennan, B.M."
"Eastern Michigan University"

INTRODUCTION

In the world of Orthotics and Prosthetics we see patients face a broad variety of challenges on a daily basis just to make it through every day activities. When activities of daily living like grocery shopping or getting the mail pose a challenge, it may seem that recreational activities they once participated in may be out of reach. Contrary to this sentiment, in recent years there are hundreds of individuals that have shown that this couldn't be further from the truth and recreation is within reach. New devices entering the market place have allowed patients to regain useful function in extreme ways that were unheard of 20 years ago. Sports such as skiing, wakeboarding, and even motocross are now within reach of the motivated amputee. The devices that make this possible are much different from the devices used in normal everyday life and experience forces that are above and beyond what a normal prosthesis will see in daily use. Understanding these forces and how they affect the prosthetic user and the prosthesis itself is important to being able to further their use. With the ultimate goal of prosthetic use being full functionality, striving to get the utmost from these devices is a goal worthy of pursuing. Therefore gaining quantitative data on extreme recreational use is a worthy goal that will help patients return to the recreational activities that define quality of life.

A particular example of this is an amputee in his who has returned to the sport of motocross racing. New advances in prosthetic knees and other componentry have allowed him increased function and competitiveness in riding. However there are very few studies that pertain to competing in recreational sports while using a prosthesis and virtually none for the sport of motocross riding. Gathering data to show the forces involved in recreational use is an essential aspect that has been over looked in designing components and will help provide increased functionality for the patient during recreational use.

METHOD

Subjects: 1 male Unilateral Transfemoral amputee, age 43, amateur motocross rider, participates at high levels nationally in competitions

Apparatus: Pressure sensing film strips, motocross track, dirt bike, appropriate prosthetic componentry used by the subject during normal riding use.

Procedures: Film strips will be placed in soles of boots while riding and peak forces will be measured over a consistent course consisting of straight jumps and no turns for several trials. Data will then be collected by evaluated the pressures indicated by the film.

Data Analysis: Data will be analyzed by evaluating the results obtained from the pressure sensing film strips located in the soles of the subjects boots. Results will be converted from color data from the film strips into numerical data reflecting the forces through the rider's leg and prosthesis in the form of a pressure measurement at the foot. This data will then be used to compare the side using a prosthesis as opposed to the contralateral side. This data will then be used to determine if the rider is favoring a certain side while riding.

RESULTS

This project is in progress as we are working through the IRB approval process and will move to data collection procedures very shortly.

DISCUSSION

Moving forward we are planning on taking the project one step further after this assessment to using electric strain gauges. Instead of peak forces this will give us real time data at moments in time. Once the peak forces are understood, it will give us a better base of knowledge to selecting testing equipment appropriate for the task at hand. This assessment using pressure film will provide the base needed for further observational studies to build on.

CONCLUSION

Currently we are still in the process of IRB approval, material selection, and implementation of data gathering procedures. At this point in time we cannot make a definite conclusion as to what we will find. By the time of the symposium we will have completed data gathering, analysis and will have findings ready for display.

CLINICAL APPLICATIONS

There are many clinical applications that can be furthered from gathering data in this manner that will result in improved patient outcomes in recreational use. Gaining information on the forces being experienced by the prosthesis and unaffected side will provide knowledge that can then be used to select proper components to allow the patients to perform to their maximum potential.

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Gait Analysis of the Kinetics and Kinematics of K1, K2 & K3 Foot Performance in Comparison to Normative Data

Justina Shipley, CO, BOCP, Med, FAAOP, Thacher Karner, BS, Holley Furrow, PT

Shriners Hospital for Children Shreveport, Louisiana

INTRODUCTION

"Gait kinetics and kinematics during ambulation were analyzed for a right unilateral trans tibial pediatric amputee at a self-selected comfortable walking speed with the Bioquest K2 foot, College Park Venture® K3 foot, and a K1 SACH foot. Results were variable and indicated the need for a continuation of the case study to discover the differences between the feet with long term use.

METHOD

This study consisted of a single subject gait analysis comparing kinetics and kinematics during ambulation of prosthetic feet with different K levels. The subject was outfitted with reflective dots and surface EMG's by the prosthetist and the physical therapist. The gait analysis was performed; the analysis was done with a Vicon Nexus Motion capture system. The analysis included three trials with each type of foot. The reflective dots on the prosthesis were adjusted each time the prosthetic foot was exchanged. The study also used the Subjective Functioning Questionnaire which was completed after the gait analysis of each of the feet. The subject was allowed to keep the foot from the study that was most preferred.

RESULTS

K2

275946417.c3d Right 7/22/2014	
Assistive Devices	None
Orthoses	(R) K2
Opposite Foot Off	16 %
Opposite Foot Strike	50 %
Foot Off	68 %
Single Support	35 %
Step Length	69 cm
Stride Length	130 cm
Cycle Time	1.3 s
Cadence	90 steps/min
Velocity	98 cm/s
GDI	70.4

275946415.c3d Left 7/22/2014	
Assistive Devices	None
Orthoses	(R) K2
Opposite Foot Off	18 %
Opposite Foot Strike	50 %
Foot Off	71 %
Single Support	32 %
Step Length	54 cm
Stride Length	116 cm
Cycle Time	1.3 s
Cadence	95 steps/min
Velocity	88 cm/s
GDI	79.8

K3

275946431.c3d Right 7/22/2014	
Assistive Devices	None
Orthoses	(R) K3
Opposite Foot Off	16 %
Opposite Foot Strike	47 %
Foot Off	67 %
Single Support	32 %
Step Length	67 cm
Stride Length	121 cm
Cycle Time	1.3 s
Cadence	93 steps/min
Velocity	99 cm/s
GDI	70.1

275946426.c3d Left 7/22/2014	
Assistive Devices	None
Orthoses	(R) K3
Opposite Foot Off	21 %
Opposite Foot Strike	52 %
Foot Off	66 %
Single Support	31 %
Step Length	76 cm
Stride Length	133 cm
Cycle Time	1.3 s
Cadence	90 steps/min
Velocity	97 cm/s
GDI	76.2

SACH

275946408.c3d Right 7/22/2014	
Assistive Devices	None
Orthoses	(R) SACH
Opposite Foot Off	18 %
Opposite Foot Strike	48 %
Foot Off	67 %
Single Support	30 %
Step Length	66 cm
Stride Length	121 cm
Cycle Time	1.4 s
Cadence	89 steps/min
Velocity	88 cm/s
GDI	76.9

275946406.c3d Left 7/22/2014	
Assistive Devices	None
Orthoses	(R) SACH
Opposite Foot Off	20 %
Opposite Foot Strike	52 %
Foot Off	70 %
Single Support	32 %
Step Length	67 cm
Stride Length	124 cm
Cycle Time	1.4 s
Cadence	85 steps/min
Velocity	89 cm/s
GDI	79.8

50 normal subjects age 5 to 16 years	
Assistive Devices	None
Orthoses	None
Opposite Foot Off	11 %
Opposite Foot Strike	50 %
Foot Off	62 %
Single Support	38 %
Step Length	57 cm
Stride Length	112 cm
Cycle Time	0.9 s
Cadence	140 steps/min
Velocity	129 cm/s
GDI	>100

DISCUSSION

The study was designed to show that there were functional advantages for wearing a foot designed for more active individuals in a pediatric setting. Cost of the terminal device was also considered. There is a significant difference between the costs of a K2 level foot in comparison to a K3 level foot but there was little difference in the functional results of the study between the two devices. The results of this study support previous research. Future studies can be performed on long term use of each type of foot that would also include a larger subject base.

CONCLUSION

Motion analysis results showed that walking with an energy storing foot was associated with a smoother gait and suggests the increase of the biomechanical efficiency when compared to a SACH foot. The patient felt as though the K2 foot moved better for him. He liked the energy storing qualities and commented about how it gave him more bounce. He liked the K3 foot as well but had concerns about durability. He felt that both the K2 and the K3 feet were more cosmetic then the K1 foot. He decided to keep the K2 foot.

CLINICAL APPLICATIONS

A single case study can be used as a pilot program to indicate the need for further research on a topic. In this instance the case study has shown that there are implications that would encourage further research involving long term use of each lower extremity terminal device for the purpose of comparison. Research using pediatric subjects is limited; this case study indicates that there is a need for more research to establish best practices for foot choice in this population; not only for biomechanical advantages but

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Shriners Hospital for Children Shreveport, Louisiana

also cost effectiveness of the device in comparison to its functionality.

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Efficacy of the Non Invasive Halo in Cervical Spine Trauma
Internal Decaptitation- A Case Study

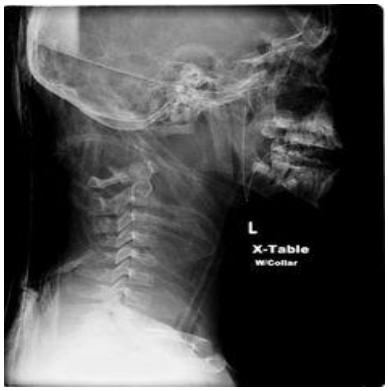
Authors: *Jackie Valdez BS, ABC C.O. FAAOP Director of O&P Education Trulife*
William Holt, CO, BOCPO

Introduction

This course is an introduction to the Non Invasive Halo and the clinical outcomes for cervical spine trauma. We will cover pathologies and discus specific cervical fracture types. We will also review and discuss a patient study on a patient who sustained an internal decapitation.

Methods

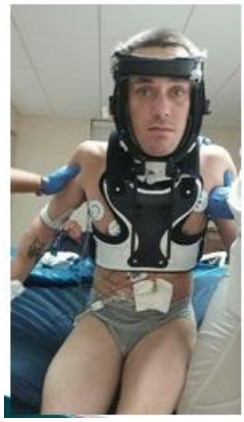
The course will include a formal presentation and videos as well as a review and discussion of the case study. This course combines practical and theoretical knowledge, reviews evidence and allows opportunities to consolidate learning through the use of videos, and open forum.

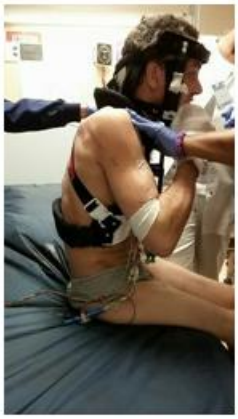


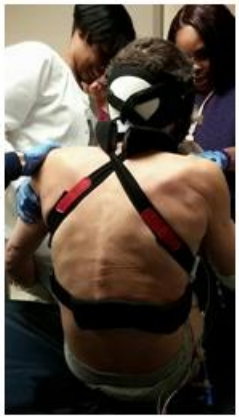
Results

After 12 weeks in the NIH the neurosurgeons ran a series of CT scans and were astounded by the results. The doctors reported it was unbelievable that there would be a complete healing of the fractures. There was a 100% success in the treatment of the Hangman's fracture.

The doctor's believe that a little bit of movement in the cervical area attributed to the complete healing of the fracture (Wolff's Law).







Discussion and Conclusion

Education plays an important role for patients and caregivers for best outcomes with this approach. Without compliance, benefits to the patient could be compromised.

Attendees will have an in depth review of the cervical spine and specific fracture types protected by the application of the Non Invasive Halo. A fascinating case study of an internal decapitation with the use of a NIH will be reviewed and discussed.

Dominant vs non-dominant hand influence on the neurophysiology of upper extremity praxis motor control

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INTRODUCTION

Neural control for complex movement has been extensively addressed in the neurosciences. One specific aspect of motor control has been the neural control of "praxis" movements, which are defined as symbolic pantomimes or actual tool or communicative gesture movements. It is clear from prior studies that left parietofrontal networks are engaged in performing tool-use pantomime and communicative gestures for right hand dominant individuals. While left hand individuals tend to engage bilateral parietal regions while performing praxis movement. It remains unclear how limb loss affects lateralization of skilled movement in motor planning and execution. We hypothesize that RHD individuals that have lost their dominant hand will maintain lateralization of motor planning and execution in the left parietal area of the brain when performing praxis movements.

METHOD

Subjects: 20 intact subjects, 10 left-hand dominant and 10 right-hand dominant, each wearing a prosthosis on their right arm. 4 right-hand affected amputee subjects, all right-hand dominant

Apparatus: Edinburgh Handedness Inventory; Electrocorticography (EEG), Electromyography (EMG)

Procedures: Each participant was instructed to perform two tasks. For the amputee group, the tasks were performed with both the sound side and affected side with the prosthesis donned. For the intact group, the subjects performed the motor tasks with their unaffected left arm while the fictive amputee modeling system device was on the right arm. First, participants were told to reach out and rotate forearm ("Rotation") which emulates tool use. They were naïve to the nature of the task. Next, they were shown a three minute video of an individual using a screwdriver. Finally the participants were asked to pantomime using a screwdriver ("Tool Pantomime"). Both movements have similar kinematics. The participants were instructed to perform each movement about every 10 seconds.

Data Analysis: The magnitude of regional activation at 18-22 Hz was compared between subjects. ANOVA and 2 sample t-test was used to evaluate statistical significance between subject groups and tasks

RESULTS

While performing simple or tool pantomime tasks with the left hand, the amputee subjects showed comparable neural activity during motor planning and execution for all regions of the brain as the right hand dominant individuals. Compared to the left hand dominant subjects, increased neural activity was observed for the amputee subjects in the parietal and occipital regions during motor planning and execution. While performing simple and tool pantomime tasks with the right affected hand, amputees exhibited increased activity in the occipital regions compared to both right and left hand dominant individuals during motor planning. Amputees also exhibited faster rebound to baseline after movement onset while performing simple and tool pantomime tasks with their right affected hand compared to intact individuals.

DISCUSSION

During motor planning and execution, activity over parietal regions for amputees was increased compared to left hand dominant individuals, but did not differ compared to right hand dominant individuals. These neural patterns suggest that although the dominant hand had been amputated, hemispheric lateralization is still maintained. It was also noted visuomotor regions of the brain had increased activation for amputees while performing tasks with their prosthesis compared to all intact individuals. More study is needed to understand the activation observed when a device is used.

CONCLUSION

Regardless of the task performed, neurophysiological function indicates that hemispheric lateralization of hand dominance is maintained in chronic amputees even when the dominant hand is amputated in right hand dominant individuals.

CLINICAL APPLICATIONS

The overall goal of this study is to understand the neurophysiological aspects of upper extremity amputees who are learning how to use their device for praxis motor control. There are significant advantages of studying this process. First, this work suggests that functional restoration of the amputated limb with prostheses may utilize similar brain areas to when their limb was present. Second, with a better understanding of how prostheses can be incorporated into a subject's body schema, novel occupational therapy approaches can be designed to facilitate usage and acceptance. This work has important implications, as wearers of these devices may be able to shed the stigma of being disabled and become further re-integrated into society. Additionally, this type of research may aid the development of neural prosthetics by showing how the central nervous system "encodes" a prosthetic device during praxis motor control.

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Effects of a concurrent task on walking on an unpredictable foam surface in people with lower limb loss: a pilot study

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INTRODUCTION

Lower limb loss (LLL) profoundly alters the sensory afferents and motor efferents critical to walking. These impairments may manifest as postural instability, particularly in challenging situations like walking over irregular surfaces (Lamoth, 2010). In situations where the ground is unstable or moving unpredictably, persons with LLL may compensate for limited sensory feedback from the prosthesis by relying on cognitive control to maintain postural stability. Such interactions between cognition and walking can be examined with a dual-task paradigm, where walking is assessed both with (dual-task) and without (single-task) a concurrent task.

Prosthesis users report the need to concentrate on walking (Miller, 2001), but previous studies do not consistently demonstrate walking dual-task walking deficits. A reason for this discrepancy between self-report and measured outcomes may be that experimental walking conditions are not as challenging as the complex environments people with LLL encounter in their daily lives (Morgan, 2014). Assessment of walking on challenging terrains is needed to better understand the effects of concurrent cognitive tasks on walking in people with LLL.

METHOD

Subjects: A 50 year-old male with transtibial amputation (TTA) and comorbid diabetes, a 66 year-old male with transfemoral amputation (TFA), and a 19 year-old female with no amputation.

Procedures: Participants walked at a self-selected pace over two level surfaces, one predictable (firm) and one unpredictable (foam with variable compliance). On each surface, walking was measured under single-task and dual-task conditions, with the auditory Stroop test used as the cognitive task.

Data Analysis: Walking was quantified using speed, step width, and step time asymmetry. Cognitive task response accuracy was also measured.

RESULTS

All participants walked more slowly and with wider steps on the unpredictable surface compared to the predictable surface. Adding a concurrent cognitive task did not affect walking speed for individuals with LLL on either surface. However, on the foam surface, both participants with LLL demonstrated increased step width and step time asymmetry in dual-task compared to single-task condition.

On the cognitive task, participants with LLL increased accuracy over time, while the control participant's accuracy was 100% for all conditions.

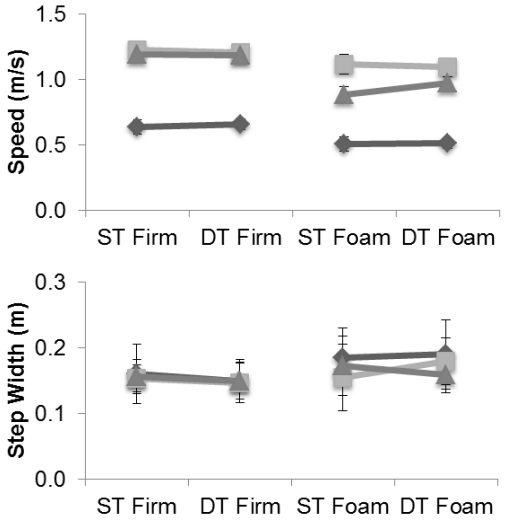

Figure 1. Changes in speed and step width across single- and dual-task conditions. ◆ = TTA, ■ = TFA, ▲ = Control

DISCUSSION

Overall, addition of a cognitive task similarly affected walking performance for all participants on the firm surface. In contrast to the control participant, participants with LLL demonstrated increased step width, an indication of postural instability, during dual-task walking on the foam surface. Results also suggest that the cognitive task chosen may be too challenging for some participants, particularly those with cognitive impairment.

CONCLUSION

These preliminary findings suggest that people with LLL may rely on cognitive resources to maintain postural stability on unpredictable surfaces, where the absence of sensory afferents and motor efferents reduces the ability to regulate postural stability automatically.

CLINICAL APPLICATIONS

We developed a novel protocol to assess cognitive contributions to walking over an unpredictable foam surface. This protocol may be used to enhance our understanding of the mobility challenges faced by people with LLL and to investigate their potential use of compensatory cognitive control during walking.

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American Academy of Orthotists & Prosthetists
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Evaluating Obstacles and Applicability of 3D Printed Prostheses in Developing Countries

Yonadav Diamond, Frank J. Fedel
Eastern Michigan University

INTRODUCTION

Approximately 30 million people are in need of orthotic and/or prosthetic care in Africa, Asia, and Latin America (WHO 2011). Several obstacles to establishing reliable and effective O and P care in developing countries exist, including inadequate training programs for health professionals, lack of access to materials, cultural barriers/differences, and costs of facilities and machinery (Tarp and Hjertholm, 2000). Additionally, a lack of understanding of cultural considerations and poor preparation are major impediments on various foreign aid projects (Williamson 2009). Often, there is not adequate time spent considering all of the potential obstacles that may present themselves between project conception and project implementation. Furthermore, it is essential to patient well being that there is adequate and appropriate follow-up by health professionals.

Traditional methods of casting, modification, and fabrication are often too costly and time consuming for countries with limited budgets. However, with 3D printers, a new opportunity for affordable manufacture of prostheses has opened up (Kurman and Lipson 2013).

METHOD

While there are several models of open-source 3D printed prosthetic hands available online, and many articles which speculate on the use of this technology in poorer nations, there is no explicit overview of what it would take to actually implement this technology and what issues would have to be overcome.

The first objective of this project is to estimate the time, cost, and process involved in the printing and assembly of the Cyborg Beast (e-NABLE) prosthetic hand using a Printrbot Simple (Printrbot, Lincoln, CA), a low-cost 3D printer. The second objective is to map and frame this procedure while considering constraints associated with its use in developing countries.

RESULTS

In addition to the actual assembled Cyborg Beast prosthesis, a framework will be created from which development workers and O&P professionals can consider potential 3D printed prosthetic-related projects in developing countries.

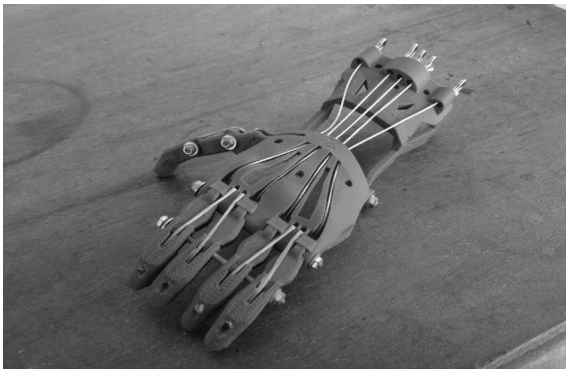

Image 1. Cyborg Beast Prosthetic Hand

DISCUSSION

With the increasing effectiveness of 3D printing and its decreasing cost, this technology may potentially emerge in developing countries and become more pertinent to prosthetic care. While 3D printing provides this opportunity, it is essential that prosthetists are guiding forces in its applications. If we are to expect this technology to be used for the patient's best interests it is necessary that prosthetists be involved in project organization, implementation, and follow-up. This work would be done in conjunction with NGOs, local government, prostheses manufacturers, fitters, and clinicians.

CONCLUSION

A guideline for applications of 3D printed prostheses will help lead future endeavors in developing countries.

CLINICAL APPLICATIONS

Armed with data relating to cost and time, as well as a framework to begin asking relevant psychosocial and logistical questions, clinicians and development workers interested in using 3D printing abroad will be able to work more thoughtfully and efficiently.

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3D Printer for Orthotic and Prosthetic Devices

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Faculty Mentor: Frank J. Fedel MS, C.E.S.

INTRODUCTION

3D printing has the potential to change the way we manufacture orthotic and prosthetic devices. This technology utilizes additive, rather than reductive techniques, such as CNC, carving, milling, etc. to fabricate parts. The latter all start with a mass of material and "reduce" it down to the desired part. Additive manufacturing, however, starts with a clean slate and builds the part from scratch, synthesizing material in the process and constructing in layers. This allows the designer to have more control over the outcome, including the interior, which saves materials and results in a more efficient process.

While 3D printing uses an unconventional process, additive and reductive manufacturing are not that different. Both utilize a computer aided design (CAD) process, where a digital rendering is planned, controlled, and executed using a computer. The computer generates a series of commands, which it provides to machines that fabricate the part. This allows the user to remotely monitor fabrication, which ultimately saves time, money and resources. Computer aided design and manufacturing (CAD/CAM) has been shown to be effective in orthotics and prosthetics for years now, since the advent of scanning and carving for prostheses and orthoeses. Where CAD/CAM carving reduces the number of steps and materials required to produce patient devices, 3D printing inherently takes this one step further, resulting in a final product. CAD/CAM carving has eased production and increased patient care, and 3D printing is poised to become the next wave of technology in orthotic and prosthetic fabrication.

METHODS

This project consisted of creating a dedicated orthotic and prosthetic prototype printer that employs additive technology. Designed from the ground up to create devices for patients, this project helps lay the groundwork for others to follow.

The planning stage involved formulating a design and parts list for the printer. This meant utilizing information collected from others in the community to limit the pitfalls after construction. Then, assembling a parts list to order parts and procure funding. Once everything is collected, detailed building notes will be presented.

One of the greatest challenges of this project will be getting the various pieces of the puzzle to communicate with one another effectively—the physical printer, to the firmware, to the software, to the computer, and vice-versa. Once this is solved, the printer will be ready to start building orthoses and prostheses.

The final step in the process is to tune the hardware and software so that it can be most effective in construction of devices. Temperature, heating, cooling, layer height, infill, speed, etc. all play into how a printed part appears, functions and lasts, so optimizing these are crucial to producing an effective patient device.

RESULTS

Upon successful completion of this project, there will be a low-budget "guide" for other practitioners to employ 3D printing in their offices. The technology exists to change the way we treat our patients, decreasing costs and increasing care at the same time.

Furthermore, physically demonstrating the products of 3D printing will increase the possibilities and acceptability in the minds of practitioners. The availability of this technology is ever-increasing, but allowing practitioners and students to hold devices in their hands, and visualize how they will work on patients, helps them to formulize how the technology may fit into practice.

DISCUSSION

Inherently, there are pros and cons to 3D printing. These will be discussed over the course of the presentation. Most of the limitations currently lie in the setup and cost, two components that this project aims to significantly address. Conversely, 3D printing provides qualities that will appeal to clinicians. It produces a replicable, quality product, fast turn-around, decreased production costs, and the ability to provide cutting edge care to patients.

CONCLUSION

I believe in the technology of 3D printing and I also believe that it isn't going anywhere. It is on this faith that I set out on this project, to build a low-budget socket printer that could be used in an average sized. This project will help to integrate 3D printing technology into the field and allow other students, practitioners, and patients to see the applicability, which will snowball new ideas. As a field, we are in constant transition, and 3D printing is the next major stepping stone in how we provide our services to patients.

CLINICAL APPLICATIONS

Clinical applications of 3D printing are unlimited. The custom nature of the field of orthotics and prosthetics lends itself to one-off manufacturing and the advent of new materials used in printing increases the applicability.

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3D Printer for Orthotic and Prosthetic Devices

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Evolution of the Test Socket: Historical Methods and the Emergence of 3D Printed Sockets

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INTRODUCTION

Fitting amputees for their definitive socket involves finding the proper fit to ensure patient safety and comfort. The first step in this is forming a "test socket" 4). The test socket uses a clear plastic to allow practitioners to see areas of pressure and relief as well as adjustments for optimal patient fit (4).

Historically, plaster casting has dominated the field of prosthetics as the most commonly used method to capture an individual's limb shape (1). This requires the cast to be filled with plaster, modified, and a plastic encasement to be created by the technician (1).

Scanning of limbs has become more popular in recent years as it creates little mess and is a simple, fast process to capture the limb shape (1). After scanning and modifying the STL file, many companies use foam carvers to create a positive mold of the individual's limb that requires little technician labor (1). Following this, plastic must be pulled over the foam piece again and fabricated by the technician (1).

A new method of test socket fabrication that is making waves has emerged through 3D printing. This process has the ability to bypass using a positive mold (3). 3D printing can print the socket directly from the scans taken of the patient limb (3). However, the last study to assess 3D printed sockets was done in 1998 and determined that the test socket could be completed in 26 hours for a cost of $1,560 (2). 3D printed test sockets need more current literature supporting it's time, cost and space requirements.

3D printing may have more appeal for the technology driven field, but there are several factors to consider when deciding which fabrication system is the best for a particular facility. Some of these factors include price of machine, price of materials, size, time to fabricate, and location.

METHOD

Subjects: No human subjects will be used in this study. This project looks to compare the efficiency of 3D printers and foam carvers for the use of test sockets.

Apparatus: Observable data collection will focus on time, cost, space, and ease of use.

Procedures: This study will be observational in exploring the variables considered when a business is looking to invest in a carver or a printer. The sample businesses that are evaluated will be convenience samples due to location and willingness to participate.

Data Analysis: All information regarding the varied methods of socket fabrication will be recorded and compared in an unbiased way. This study does not aim to support or refute 3D printing technology but merely show how it compares to foam carving in its current state.

Delimitations: This study does not compare the socket strength or durability as it is not a review from a material science point of view. It also uses a sample locations of convenience from companies that use foam carving or 3D printing.

RESULTS

This project will report on the amount of time and cost it takes to create a test socket for a trans-tibial amputee using one of two methods. The first method being a scanned limb that is rectified using a foam carver and the second is the test socket created by 3D printing

DISCUSSION

As technology for 3D printing continues to grow and evolve, we must keep evaluating its ability to produce more cost effective test sockets. This look at the current literature show very little information on the exact cost and time of creating a 3D printer since 1998 (2). It is time to re-evaluate the process and determine if it has yet surpassed the efficiency of plaster casting or foam carving.

CONCLUSION

Creating test sockets has historically been performed with plaster casting (1). It is now moving toward the limb being scanned and the socket being created through foam carvings and more recently 3D printing (1). Although there is no one method with a clear advantage, each one should be considered carefully before choosing which one should be used at your clinic.

CLINICAL APPLICATIONS

This research can be useful in the clinical setting when comparing which method of creating test sockets will be more time, cost, and space efficient. It can be useful for businesses who are expanding or starting up to decide what strategy is best for them.

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Self-assessed balance confidence in patients with transtibial amputations using the Modified Cheetah prosthesis

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INTRODUCTION

The Modified Cheetah (MC) is a lightweight, high energy return transtibial prostheses with medial/lateral stability that was developed at Davidson Prosthetics (Puyallup, WA). It is fabricated by attaching an Ossur Cheetah blade to a transtibial carbon fiber socket using direct lamination. The blade is split medially for M/L stability, and a foot shape is fabricated using high density foam securing the prosthesis in the shoe.

Anecdotal reports from users of the MC have been positive. Some repeated comments praise the reduced weight of the prosthesis which has led to increased wear time per day, increased proprioception attributed to vibrations of ground contact being transmitted directly to the socket without vibration loss amidst modular componentry, and feelings of greater stability due to the medially split keel.

It was hypothesized that users of the MC prosthesis would feel greater balance confidence in the MC as opposed to their conventional prosthesis (CP).

METHOD

Attempts were made to contact all users of the MC to fill out the Activity-specific Balance Confidence Scale (ABC) survey either via electronic or hard copy survey. 22 of 52 potential subjects participated.

Subjects: 20 males and 2 females participated in the study. The average age was 42.73 years. 17 of the 22 subjects had a unilateral TTA, 3 had bilateral TTA, 1 had TT/TF amputations, and 1 had partial foot/TT amputations. All were of K3 ambulatory status.

Outcome Measure: The ABC was developed by Powell et al. to assess subjects' balance confidence when performing a variety of tasks (Powell, 1995). Two scoring systems are available: the original 0-100% interval scale and a five point Likert scale ranging from 0-4 points (Sakakibara, 2011). Normative data has been collected for subjects with amputations using the Likert scale version (Hafner, 2013).

Four ad hoc questions were added due to a known ceiling effect of the ABC with high-activity users.

Procedures: All subjects filled out the 5-point Likert scale version of the ABC twice, first answering the prompts regarding their confidence while wearing their CP and the second time regarding their confidence while wearing their MC prosthesis.

Data Analysis: Averages, standard deviations, and differences were calculated using Microsoft Excel and the Catalyst WebQ survey tool.

RESULTS

Subjects scored an average of 2.75 points with their CP and 3.69 points with their MC. The five most difficult tasks had an average increased balance confidence of 1.094 points. Ad hoc questions had an increased balance confidence of approximately 1.36 points. 59.1% more subjects reported feeling "Somewhat" or "Very Energetic" at the end of the day in their MC prosthesis compared to their CP.

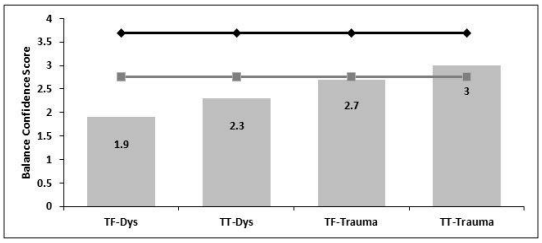

Figure 1. Averages for CP condition (gray line) and MC condition (black line) compared to normative data (light gray bars). Norms presented by etiology and level of amputation.

DISCUSSION

Total score balance confidence improved by an average of 0.94 points with more difficult tasks averaging upwards of a 1.094 point improvement. Improved balance confidence may correlate to the M/L stability provided by the prosthesis, the improved proprioception felt by users, and/or the increased energy experienced by users at the end of the day.

Prosthesis users and clinicians are often concerned with improving balance; the Modified Cheetah may be a viable option for patients that require increased stability and a lightweight device.

CONCLUSION

The Modified Cheetah has the capability of increasing the balance confidence of high K-level prosthesis users as compared to wearing a conventional prosthesis.

CLINICAL APPLICATIONS

With such vast improvements in balance confidence for a population that is constantly concerned with balance, the Modified Cheetah is another prosthetic option for clinicians to turn to for their patients.

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Test to Failure of Prosthetic Tube Clamp and Pylons Due to Incomplete Seating

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INTRODUCTION

Endoskeletal componentry has changed the way prosthetists construct prosthetic devices for their patients. Modular components save prosthetists time and money in fabrication and allow them to easily adjust alignment and exchange parts. It is imperative that components be used properly and specifications are followed in order to maintain the safety of the patient and prevent injury. Sometimes, however, the prosthetist is prevented from strictly following manufacture recommendations. One way prosthetists can deviate from the recommended specifications is to not fully seat the pylon in the tube clamp. The aim of this project is to investigate the relationship between improper pylon seating within the tube clamp and ultimate strength of the prosthetic system. In clinical practice, a pylon may be cheated out of the tube clamp to lengthen the prosthesis if a flightly longer pylon is unavailable. This might create an unsafe system for the patient, and put them at a higher risk, it is unclear how much a prosthetic system's strength would be affected by this practice.

METHODS

A standard aluminum pylon will be inserted into a titanium tube clamp adapter mounted on a four hole pyramid and tested in five different "seated" positions: fully seated, and unseated at increments of 1/8", 1/4", 3/8", and 1/2". The orientation of the tube clamp face will be changed in the transverse plane after each set of trials and seating positions Thus, positions would include anterior, posterior, medial and lateral facing directions. Each combination will be trialed three times, for a total of sixty trials.

Testing to failure will conform with ISO 22675:2006 prosthetic testing procedures, specifically 16.3 which involves testing to failure.

The tests will be conducted using a proximal pyramid, mounted vertically, in a neutral position to a female tube clamp, connected to the pylon. Distally, the pylon will be inserted into a female tube clamp that will be the location of manipulation of seating and face orientation. The distal female pyramid will be mounted to a four hole pyramid. All bolts will be torqued to manufacture specifications, and Loctite (Westlake, OH) will be applied to the threads between test conditions. All new componentry will be used, to eliminate any error due to damaged components.

RESULTS

All trial results will be presented in a table that shows all measurements as well as summary data. ANOVA will be used to identify significant differences in endoskeletal system strength. In any instance where another part of the system failed prior to the tube clamp or pylon, this will be noted.

DISCUSSION

This study provides useful information that will benefit prosthetists and patients, and will inform prosthetic practice relative to component assembly. The authors chose to use test to failure rather than cyclic testing due to ease of use and machine availability. Although this may be seem to be a limitation, test to failure still provides valuable information regarding when and why a prosthesis might fail.

CONCLUSION

This project will generate valuable data that will help prosthetists make more informed decisions in clinical practice. There will be concrete evidence on how much the practice of "cheating" out pylons of endoskeletal systems potentially impacts system integrity.

CLINICAL APPLICATIONS

This project shows direct clinical significance. Although the majority of prosthetists would assume that improper componentry usage would be detrimental to the strength of the prosthesis, and possibly put their patient in danger, there is not clear evidence to support how great the risk may be. Therefore, this project is applicable and worthwhile.

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ANATOMICAL MODELS OF BONE DEFORMITIES FOR MEDICAL EDUCATION

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INTRODUCTION

Human anatomy lays the foundation for all medical professions. Even with today's technologies such as virtual dissection tables (Anatomage, San Jose, CA) models of skeletons display only normal bone structure, although often care providers are confronted with abnormal structure (Noelle, 2006). The current standard for medical education is often 2D images which do not address kinesthetic learning. As technology improves, the ways in which health science teaching is approached to engage students is changing (Tanner, 2004). Beginning in elementary school, students are first presented with kinesthetic learning followed by visual learning. During high school aural and reading and writing are introduced, which continue and increase much more through the college years in the form of lecture classes (CAST.org).

One goal of this project is to generate 3D models of deformed skeletal structures that will provide a wider variety of instructional opportunities, using physical models to supplement visual, aural, and reading and writing methods. An additional benefit of our method is that the cost of materials for each device will be lower since each bone model will consist of interchangeable pieces of various deformities. This project specifically addresses anatomical deformities of the femoral neck.

METHOD

A human femur is acquired; the femur is scanned (Figure 1.) using a Sense 3D scanner (3D Systems Inc., Rock Hill, SC). Using Rhino 3D software (McNeel, Seattle, WA) the model of the femur is cut at the proximal end of the diaphysis just distal to the lesser trochanter. The neck of the femur is manipulated to create a model of four different deformities of the femur: coxa valga, coxa vara, (Figure 2.) anteversion, and retroversion. An interlocking mechanism is integrated into the cut ends to allow interchangeability of parts. A DaVinci 3D printer (XYZ Printing, San Diego, CA) is used to print the model. The printed models are rectified then used to create separate molds from which the normal shaft/distal end, and five separate femoral heads (four with deformities and the fifth that is anatomically normal) are cast in structurally stable urethane.

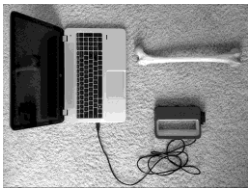

Figure 1. Original human femur model ready for 3D scanning.

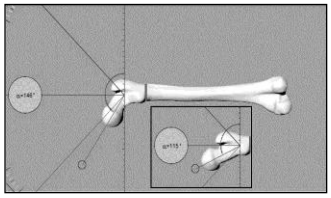

Figure 2. 3D CAD model of femur and two deformities coxa vara (left) and coxa valga (inset).

RESULTS

By creating 3-D models of deformities we can extend the impact of medical education by allowing students to learn what these deformities look and feel like. As an example, these models can aid in visualizing how anteversion alters biomechanics.

DISCUSSION

There are currently a plethora of anatomically correct models that are used in teaching anatomy; however, professionals often need to provide care to individuals with abnormal anatomy. The creation of this product will facilitate teaching, learning, and understanding the biomechanical ramifications of skeletal abnormalities.

CLINICAL APPLICATIONS

These models can be effective tools for instructors teaching students in health sciences, as well as for orthotics or prosthetics clinicians when educating patients.

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SIMPLE, LOW-COST UPPER EXTREMITY TERMINAL DEVICE FORCE FEEDBACK SYSTEM

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INTRODUCTION

Regardless of how intricately it is designed, an upper extremity prosthesis (UEP) can never fully replace the function, sensation and expressiveness of a human hand (Dapka, 1997). This is supported by commonly cited reasons for abandonment of use of UEPs, which include user perception of comfort and function (Biddiss, 2007). The ability to "feel" objects (force feedback) provides better function through enhanced control. New technologies attempt to provide this (Catalano, 2014) at high cost or requiring invasive procedures. Lower cost devices have been attempted (Pylatiuk, 2006).

One of the keys to learning how to effectively use a newly fit prosthesis is to understand the different localizations of sensations (the tactile-map). This is even more important when force feedback is sought. Another key to using a UEP effectively is the contact cue (temporal aspect), since near-instantaneous feedback is how our nervous system works. Perception of magnitude of sensation (force) is also important.

The goal of this project was to design a low cost system that can be retrofitted and provide physical pressure feedback at a remote location on the user's arm, while avoiding the complexities inherent in existing systems.

METHOD

When force is applied to the tips of the digits, the fluid in the bladders at the tip of each finger and on the thumb is displaced into the cuff around the upper bicep (Figure 1).

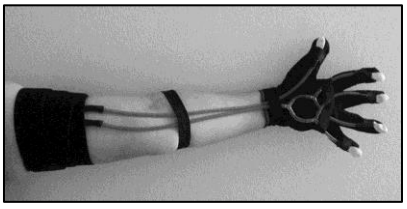

Figure 1. Device (alpha v0.5) demonstrating separate feed lines for thumb and grouped remaining digits, worn by one of the authors.

The amount of fluid displaced is directly related to the amount of pressure that is transmitted to the arm cuff. This is to mimic sensory input of a non-artificial limb.

RESULTS

Because this device is in the alpha prototype stage of development, no results regarding reliability are available. *NOTE: Results will be available at the time the poster is presented, as beta versions are being developed.*

Ongoing work will lead to the development of multiple iterations of prototypes, each of which will be tested for reliability under both acute and long-term use.

DISCUSSION

Being able to wear and properly use this device due to its low cost and simplicity provides the potential to benefit a broad spectrum of UEP users. Future areas of exploration include altering the design to optimize localization of sensation.

CLINICAL APPLICATIONS

In developing this device, both the patient and the practitioner themselves will benefit from its application and use. It will seek to create a relationship between the patient and the practitioner that is centered on a mutual understanding of the patient's needs and the capabilities of the prosthesis.

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Efficiency Trends of Upper Extremity Prosthetic Cable and Housing

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INTRODUCTION

Transradial patients are the most common level of upper extremity amputation seen by prosthetists (Black 2005). However, at this level, prostheses have a 10.5% rejection rate with reasons for rejection including pain, lack of functional benefit, poor cosmesis and weight of prosthesis. The most common upper extremity prosthesis currently used is a body powered system with a hook terminal device. This is due to durability, clear sight of grasped objects, and ease to clean (Millstein 1986, Lake 2006). Black notes that "unilateral upper limb amputees are roughly three times as likely to suffer repetitive motion or overexertion type injuries as the general workforce" (Black 2005). Decreasing the force required to operate a body powered upper extremity prosthesis could lead to a reduction in the rate of overuse injury to the contralateral arm. The purpose of this study is to compare the efficiency of different cable housing configurations and the forces needed to operate the terminal device for each of these.

METHOD

The same 5XA terminal device (TD), Hosmer tension bands, load machine and test personnel were used throughout the study. The force of activation was measured with a calibrated load machine. A fixture was used to evaluate the force required to operate the TD without housing, this was later used as a base line for comparison with the different housing configurations in the second part of the study. Base line data was collected at single band intervals from 1 – 10 bands, each measurement repeated for 12 cycles. A second testing fixture was constructed using 50th percentile anthropomorphic data (average of male and female) for arm and forearm lengths. The two cable housing attachment points were positioned at midpoints between elbow-shoulder and elbow-MCP joints with an elbow flexion angle of 100º. Base plates and retainers were used as connection points between cable housing and fixture. The cable housing lengths between connection points were 0.5cm greater than the linear measurements from mid-humerus to mid-radius to create a curve in the cable housing. All four housing configurations used Hosmer products and were as follows: standard cable and housing, standard housing and cable with paraffin wax, standard cable with HD housing and Teflon insert, and standard cable with paraffin in HD housing with Teflon insert.

RESULTS

Forces were recorded at the beginning of TD opening and maximal TD opening (before the TD reached the mechanical stop). These two forces were averaged for each cycle. Mean pull forces for 5, 7, and 9 bands in each of the cable housing configurations are shown in Table 1. A α=0.05 was used for statistical analysis. No significant difference was found between Teflon and base line data. Paraffin with Teflon was found to require significantly greater force to operate the TD than baseline alone, however there was no significant difference between paraffin with Teflon and Teflon alone. Significantly more force was required for operation of paraffin than paraffin with Teflon and for housing alone compared to paraffin.

Table 1: Mean force to operate a 5XA terminal device.

Number of bands	5	7	9
	Force in pounds		
No Housing	19.6	27.4	34.3
Housing only	25.5	34.7	42.8
Paraffin	24.6	33.9	42.0
Teflon	20.0	27.4	33.6
Paraffin + Teflon	20.7	28.1	34.2

The relationship between the number of tension bands and the force required to operate a terminal device is approximately 4 pounds per tension band in an ideal situation. Approximately 25% more force is required to operate the TD when a Teflon insert is not present.

DISCUSSION

This data shows that the use of Teflon inserts reduce the force required to operate the terminal device to a scenario similar to zero bend radius and no cable housing. A small amount of band fatigue was seen in the data after only 12 cycles and may explain two of the Teflon housing scenario results measuring less than the control scenario. Statistical analysis was not performed to determine the significance of band fatigue in this study.

CONCLUSION

The use of a Teflon insert reduced the pull force required to operate the terminal device. This reduction in force could increase the use and wear time of the prosthesis and reduce the incidence of overuse injury to the contralateral limb.

CLINICAL APPLICATIONS

This data shows that a Teflon insert provides a significant benefit to a patient and could be used as justification of medical necessity to reduce or delay the chance of an overuse injury to the contralateral limb.

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THE USE OF A TARGETED SHEAR REDUCTION PATCH TO INCREASE PROSTHETIC SOCKET COMFORT.

Charles Kuffel MSM, CPO, FAAOP

INTRODUCTION

Shear within a prosthetic socket is oftentimes problematic for prosthetic users of all activity levels. If shear is not addressed, it can cause skin integrity disruption or breakdown, limiting overall function. The use of advanced prosthetic componentry allows amputees to function at higher levels, but often fails to address the skin trauma associated with aggressive or prolonged prosthetic use. As a result, increased function and activity can often lead to skin integrity breakdown.

Prosthetists have used techniques such as lubricated gels, socks, or sheaths beneath interface liners to address areas of concern. Some of these areas of most concern include the patella during knee flexion, the fibular head during ambulation and the distal anterior tibia. Most interface liners are fabricated in a linear fashion but undergo multiple plane disfigurations during dynamic prosthetic use. This pushing and pulling between the skin, liner, and socket can create areas of shear strain, leading to skin disruption. Ultimately, any disruption or breakdown of the skin can result in reduced prosthetic use and function. Although lubricated gels, socks, and sheaths can be helpful when used beneath the liner, they do not always provide adequate relief. Even though these methods can help to reduce the contact area of the suspension liner and the skin, they can also cause distal migration of the liner and possible loss of suspension.

METHOD

Tamarack Habilitation Technologies, Inc. has developed a dual layer low friction textile technology called GlideWear that is successfully being used by individuals in wheelchairs to reduce prevent tissue breakdown beneath the ischial tuberosities. This technology has also been developed for use by prosthetic wearers to reduce shear on affected areas of the residual limb. The patch is placed between the skin and prosthetic liner to spot reduce shear by creating a gliding motion between the two layers of fabric that otherwise cause the skin to absorb the motion and disrupt skin integrity. This Patch has been used on all areas of potential breakdown of the residual limb. Patients have been sampled from different geographic areas of the United States to validate non geographic results. The results have been documented using photographic documentation with survey materials provided to both the patient and prosthetist.

RESULTS

This study has helped to substantiate those areas of shear within a prosthetic socket which limit function and that reducing shear through the use of a textile patch helps amputees to resume their desired activity. Prosthetic users are functioning at higher activity levels than ever before. However, the limiting factor of skin trauma still remains. No matter how well prosthetic sockets and components function, skin integrity breakdown can develop during prolonged or aggressive prosthetic use. Simple solutions like the use of a targeted low friction interface can allow amputees to gain the full benefit of their advanced prosthetic componentry by allowing them to spend additional time in their prostheses without the incidence of skin breakdown.

DISCUSSION

The results of this study will demonstrate that providing patients with a simple tool to spot reduce areas that are susceptible to skin breakdown will allow them to function at the highest desired level with reduced incidence of skin integrity disruption or breakdown.

CONCLUSION

New innovations in prosthetic componentry have allowed amputees to achieve higher functional levels than ever before. Increased activity oftentimes creates unwanted shear within a socket interface limiting further functional activity and necessitating time out of the prosthetic limb. By spot addressing the damaging shear forces within a socket, prosthetists and prosthetic users can utilize the advanced prosthetic componentry to the fullest potential for longer periods of time.

CLINICAL APPLICATIONS

The use of a targeted shear reduction patch placed between a prosthetic liner and skin tissue will allow amputees to function for longer periods of time with reduced risk of skin integrity disruption secondary to shear. This simple solution allows the amputee to spot manage many areas of concern without the need for episodic follow up with the clinical prosthetist for socket adjustments.

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FPTH14

"The reliability of a video analysis system (*Siliconcoach*™) and the universal goniometer in the measurement of lower limbs joints"

"Mohsin, F. 1, McGarry, A. 2, Bower, R. 3"
"Strathclyde University1, Strathclyde University2, Strathclyde University3"

INTRODUCTION

Throughout the rehabilitation process, adequate recording of joint range of motion (ROM) is essential to facilitate and evaluate the most appropriate treatment. The universal goniometer (UG) is the most common and inexpensive tool used in clinical settings to record ROM. However, a review of the literature examining the intratester reliability of the UG demonstrated considerable variation in results. The review highlighted the gap in current research about the intratester reliability of the UG and the necessity of introducing a more reliable measuring tool (Boone et al., 1978, Stuberg et al., 1988, Herrero et al., 2011).

This research investigated the intratester reliability of the *Siliconcoach*™ video analysis system compared to the UG in measuring passive ROM of the lower limb joints amongst healthy candidates.

METHOD

Three testers and eight healthy participants were included in this study. Sagittal plane motion of the hip joint, knee joint and ankle joint of the dominant leg was measured with both tools. Testers were provided with instructions manual for measurements procedures. Additionally a training session for the use of the *Siliconcoach*™ was arranged. Each tester repeated each measurement three times using each tool to calculate intratester reliability. Intraclass correlation coefficient (ICC) and Bland-Altman plot (difference plot) were used to calculate intratester reliability. ICC values above 0.60 were considered to be satisfactory for research purposes (Evers, 2001).

RESULTS

In this work, ICC values for *Siliconcoach*™ for all the joints measured were found to range from (0.24 to 0.98). ICC values for *Siliconcoach*™ for ankle dorsiflexion for all the testers were found to be lower in comparison to the other motions measured and below the satisfactory limits (<0.6). Additionally, ICC value for one tester for hip extension was found to be lower than the satisfactory limits (0.53). The highest ICC values for *Siliconcoach*™ for all the testers were found for hip flexion measurements. On the other hand, ICC values for UG across all the joints measured were found to vary widely from (0.39 to 0.93). The lowest ICC value for UG was found for ankle dorsiflexion for one tester while the highest was found for ankle plantarflexion for one tester.

DISCUSSION

In general, ICC values for *Siliconcoach*™ were found to be higher, and therefore more reliable, than UG. All ICC values obtained using *Siliconcoach*™ excluding one testers value for hip extension measurements and ankle dorsiflexion measurements for all the testers were found to be above the satisfactory limit (>0.60) with small variations in the values, which demonstrates the reliability of using this tool for specific joint motions measurements. In addition, it was shown in this work that all ICC values for UG across all the joints measured ranged considerably, and in some of these measurements the values were below the satisfactory limits (<0.60). This demonstrates the unreliability of using this tool in comparison to *Siliconcoach*™ for specific joints motion.

CONCLUSION

In conclusion, *Siliconcoach*™ was found to be more reliable than UG in measuring passive Sagittal motion ROM of specific lower limb joints motion which included, hip flexion, knee flexion, knee extension and ankle plantarflexion.

CLINICAL APPLICATIONS

The present work opens up new possibilities for using advanced technology in joint ROM measurements to achieve more reliable and repeatable measurements. *Siliconcoach*™ is an applicable clinical tool which is easy to use in a clinical situation.

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NEW RESEARCH IMPROVES SOCKET FIT THROUGH IMPROVING LIMB HEALTH

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Martin Bionics Innovations, LLC

INTRODUCTION

Clinical prosthetists focus much of their efforts on tailoring the prosthetic socket fit and alignment to improve function and comfort outcomes of their patients. However, there remains another critically overlooked element for improved socket fit – improving the residual limb skin health itself.

The majority of amputations occur due to peripheral vascular disease or diabetes, therefore resulting in residual limb and skin health that is suboptimal from the start. This, in combination with the hostile environment of conventional socket interface designs leads to a variety of potential skin issues.

Skin disorders that result from wearing an artificial limb include pressure sores, heat rash, abrasions, chaffing, dryness, folliculitis, dermatitis, ulcers, eczema, and dry skin. Most amputees experience skin related issues from time to time, and some quite frequently.

Skin issues, however minute they may appear, can greatly affect the quality of life of an amputee. Even a small skin issue can be the beginning of a much more significant skin disorder that may prevent the amputee from effectively using their prosthetic device. If severe enough, the amputee may have to remain off of the prosthesis, and use crutches or wheelchair, which may be emotionally, socially, or economically damaging.

Newly discovered clinically active botanical extracts can be used to improve skin and limb health by promoting circulation and skin regeneration, thereby preventing skin diseases and repairing damaged residual limb skin.

METHOD

Several studies were performed to investigate the effects of the clinically active botanical extract formulation on healing and preventing various skin conditions, which can be experienced by amputees. These studies included investigating its effects on diabetic ulcers, pressure sores, burn relief, and various skin diseases.

For instance, a 10 week open-label clinical study was performed on patients with chronic diabetic ulcers.

Patient eligibility required patients that confirmed diagnosis of diabetes mellitus type 1 or 2 for at least 3 years and with at least one ulcer persisting for greater than 1 mth and measuring greater than 1 cm2.

Patients received twice daily applications, which were applied directly onto the ulcer. These patients were then evaluated at 2 week intervals throughout the study.

RESULTS

The primary outcome for this study was the time to complete wound closure. The median time to complete diabetic ulcer closure was 5.5 weeks for Grade I, 6 weeks for Grade II, 9 weeks for Grade III, and 10 weeks for Grade IV.

In another set of 10 and 12 week clinical studies, the formulation provided complete remission or dramatic resolution of symptoms in 86% of patients who suffered from severe skin issues.

An additional 12 month clinical study on pressure sores found a reduction in the incidence of decubitus sores by 90%.

As circulation and skin regeneration are enhanced, skin and residual limb health are improved, thus providing greater socket comfort and functional outcomes.

DISCUSSION

The hostile socket interface environment can lead to a number of potential skin issues for an amputee. Residual limb health is critically important to maintain quality of life.

CONCLUSION

The use of these botanical extracts has been found to have significant benefits of preventing and healing skin conditions typically found in prosthetics users.

CLINICAL APPLICATIONS

What could have been the beginning of a skin issue due to poor socket fit, rubbing, or heat and moisture induced issues can now possibly be prevented through using a daily skin protectant which increases circulation and skin regeneration.

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"Muscles Proving to be Stronger Utilizing New Methods, Techniques, and Technologies in Lower Limb Orthoses"

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INTRODUCTION

Independently collected data proving people utilizing Lower Limb Orthoses with new methods, are getting stronger. Orthotic clients were asked to obtain before and after Manual Muscle Testing (MMT). One case study will also include surface mount EMG\s to prove muscle strength improvement.

METHOD

Subjects: One male retired Physiatrist and one female retired Physical Therapist; 72 year old, 6'1," 165 lbs. male and a 67 year old female, 5'6," 152 lbs. Female. Both clients were Polio survivors with history of Post-Polio Syndrome. Both subjects utilized Triplanar Management, dynamic response monolithic carbon composite technologies with corresponding orthotic training. MMT & EMG's were done by the client's PTs.

RESULTS

Significant improvements were made in muscle strength in both subjects. No other treatment plan has shown such promise for people with lower limb weakness. This is especially true for people with Post-Polio Syndrome, who have a history of continual decline.

The results were obtained by identifying overuse syndromes, structural deviations in each plane, designing for the weight-bearing stance phase and managing alignment and proper support required to enable a more natural gait pattern to be introduced.

Muscles get stronger with triplanar realignment to allow for more efficient mechanics, reduction of overuse with proper support in three dimensions, coupled with a more efficient and natural gait pattern. This can only take place with solving the complex issues of the individual's stance phase under full load bearing.

EMG Activity Muscle Sessions with values in microvolts

			% Change
Biceps femoris	105	210	50%
Vastus medialis	48	140	66%
Rectus femoris	26	150	83%
Anterior tibialis	180	198	9%
Peroneus longus	149	204	27%
Gastrocnemius	161	221	27%
Rectus abdominus	22	104	79%
Internal obliques	58	110	47%
External obliques	54	75	28%
Overall % Change of all muscles			46%

Table two – Muscle Strength Male August 4, 2008

Muscle	Initial Strength	Current Strength
Rectus Abdominus	0/5	1.5/5
Internal Oblique Abdominal	0/5	1.5/5
External Oblique Abdominal	0/5	5/5
Biceps Femoris	1/5	2.5/5
Vastus Medialis	0/5	2.5/5
Rectus Femoris	0/5	2/5
Anterior Tibialis	2.5/5	2.5/5
Peroneus Longus	0/5	2/5
Gastrocnemius	1/5	2/5

DISCUSSION

It is often the belief by many healthcare professionals and from people in need of bracing, that braces will make them weaker. There are no known studies to validate these beliefs. Utilizing new methods, techniques and technologies we can prove the benefit of lower limb bracing. The same methods, techniques, and technologies have shown many benefits for people in need of our services, such as, improved bone density, prevention of surgeries, increased activities, and reduction of pain and falls.

CONCLUSION

New complex methods, techniques and technologies in lower limb orthotics are proving to enable muscles to strengthen for many people in need of bracing. An expansion of this study is proving that this is not an aberration.

CLINICAL APPLICATIONS

Millions of people in need of lower limb orthotics can benefit with proven benefits from these methods. With additional studies and additional clinicians utilizing these more advanced methods, the orthotic profession will gain more respect from the medical and insurance professions.

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“Muscles Proving to be Stronger Utilizing New Methods, Techniques, and Technologies in Lower Limb Orthoses”

Loke, M.D.R., DynamicBracingSolutions, Inc.

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FPTH14

Post Viral Rhabdomyolysis
Literature Review and Stance Control Case Study

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Becker Orthopedic[1], Ann and Robert H. Lurie Children's Hospital[2]

Introduction

Rhabdomyolysis is frank dissolution of skeletal muscle. The striated cell necrosis leads to leakage of muscle constituents into the circulation. Myoglobin is the primary oxygen constituent carrying pigment of muscle tissues. The released myoglobin is filtered by the kidneys and can block tubules leading to acute renal failure. Renal failure occurs in a reported 10 – 50% of rhabdomyolysis cases. Presenting symptoms in viral cases include myalgias, weakness, muscle tenderness, and brown urine.

Influenza is the predominant reported viral infection. The exact pathophysiology of the virus induced myoglobinuria is unknown; two mechanisms have been offered, direct viral invasion and toxin generation. Other avenues to rhabdomyolysis include traumatic crush injuries, the use of limb restraints, strenuous exertional activities (e.g. marathon) and intoxicated individuals subjected to prolonged muscle compression from being motionless. Treatment is rapid hydration with up to ten liters a day of IV fluid. Overall prognosis if renal failure is prevented is good.

Case Description

A 15 year-old female with a diagnosis of Post Viral Rhabdomyolysis was seen at two institutions with an unknown etiology. Due to presenting symptoms the original diagnosis was thought to be Guillain-Barre' but was ruled out as the presenting symptoms are similar. Two weeks of inpatient care were followed by 3 months of outpatient physical therapy before being followed at Lurie Children's Hospital. PLS ankle foot orthoses were initially used for ambulation with "knee cages" without success. Patient c/o muscle pain in lower back and thighs at the level that sleep was impacted. Patient demonstrated exercise intolerance, and unsteady abnormal gait. An early positive fall history was provided during her history.

Physical Rehab

Observational gait revealed a high degree of stance phase anterior/posterior knee hysteresis; "wobbly knees" when walking with a wheeled walker. Additionally there was a noticeable decrease in step length and velocity.

Immediate fit stance control orthoses (IFSCO) were utilized to assess and stabilize the patient's gait pattern. Swing and stance phase gait training techniques were utilized to appropriately activate the IFSCO. These techniques helped the patient to recognize the step length release of the mechanical stance control orthotic knee joints along with swing phase technique to register appropriate hip flexion velocity for engagement of the knee locks at terminal swing.

MUSCLE STRENGTH

	Left	Right
Iliopsoas	2+	2+
Gluteus Max	2+	2+
Gluteus Med	2+ with TFL	2+ with TFL
Adductors	2	2+
Quadriceps	3+	3+
Hamstrings	X *painful	X *painful
Ant Tibialis	4-	4-
Post Tibialis	4-	4-
Peroneals	4-	4-
Gastroc	4- hand test	4- hand test

Improvements in gait stability were achieved and custom stance control orthoses were provided. Gait training continued in the custom devices with a marked reduction in knee hysteresis and corresponding increase in gait velocity. Subjective feedback from the patient included improves stability during standing and ambulation and improved endurance.

Conclusion

Massive necrosis of stiated muscle cell with the leakage of cell constituents into the blood stream is characterized by muscle weakness and gross pigmenturia for both traumatic and nontraumatic Rhabdomyolysis. Nontraumatic toxic elements to muscles include alcohol, illicit drugs, viral infections and strenuous exercise. In this particular case, renal failure was not evident, but the muscle necrosis was present along with associated pain.

The physical rehab utilization of the IFSCO demonstrated an immediate improvement in gait stability while the provision of custom SCO offered a public means for the patient to acquire a stable gait for locomotion.

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Multiple sensor embedded prosthetic sockets with wireless data communication capabilities for improved quality-of-life for transtibial prosthesis wearers

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Abstract:

Quantitative measurement of prosthetic socket/residual limb interface environment, specifically pressure, temperature and moisture (P/T/M) does not currently exist. As a result tolerable limit for comfort is established only through subjective feedback from amputees coupled with visual observation, manual palpation, probing etc. This presentation reports on the development of a multiple sensor embedded prosthetic socket system with wireless data collection capabilities to define a comfortable inner-socket environment profile (ISEPs) for people with lower limb amputations. With development of such a socket system, objective ISEPs will be created and associated with gait activities such as level surface ambulation, stairs, inclines.

When ISEPs are correlated to subjective amputee feedback (i.e. comfort), the end result will be defined comfort tolerances for prosthetic socket pressure, temperature and moisture over varied activities. The prosthesis system is novel and highly innovative because it allows the medical team to collect continuous of real time P/T/M that cannot be achieved by instrumenting an amputee in a Gait Lab or observing them in their natural surroundings. No socket system currently exists that can communicate directly with the patient or clinician by providing information related to prosthesis' inner socket environment conditions.

Effects of RAC Audits on K Level and Foot Selection in the Transtibial Prosthetic User Population

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Abstract
Recovery audits (RA), have been reported to effectively cause a decrease in the number of high-activity Medicare Functional Classification Level (MFCL) prescriptions as well as high-activity foot L-Codes. We hypothesized a decrease in high-activity MFCL prescriptions and prosthetic foot L-Code selection in the transtibial prosthetic user population since the RA implementation.

Methods: A survey was sent to O&P listserv members to approximate the beginning of the RA implementation period, which was found to be in first 6 months of 2011. OPIE software served as the data source for retrospective data from 10 facilities across the United States. From the collected dataset, there were a total of 3728 prescriptions available. 2015 of these prescriptions fell into our exclusion criteria and were not included in this study. There were a total of 1713 prescription with MFCL via foot LCodes and 868 practitioner-assigned MFCL available for analysis.

Results: Practitioner-assigned high-activity MFCLs had a significant decrease of 33% ($p=<0.001$) and prosthetic foot LCode selections had significant decrease of 39% ($p=<0.001$) since the RA implementation. Significant changes in high-activity foot selection were identified among Medicare (<0.001), private (<0.001), and worker's compensation (0.04) insurance patients. These results confirm our hypothesis of a decrease in high-activity MFCL and prosthetic foot LCode selection.

Discussion:
This study sought to examine the effects of recovery audits on transtibial prosthetic prescriptions on practitioner-assigned MFCL and MFCL via foot L-Codes from the pre- to post-audit implementation period. We hypothesized that there would be a decrease with both of these aspects, to which we accepted both of these hypotheses. We found that there was a 33% and 39% reduction in the amount of high-activity practitioner-assigned MFCL and MFCL via foot LCodes, respectively; these p-values were both found to be <0.001.

THE EFFECT OF MULTIAXIAL FOOT STIFFNESS WITH PROSTHETIC EMULATORS OVER UNEVEN TERRAIN

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INTRODUCTION

Individuals that have undergone trans-tibial amputations encounter serious dilemmas when navigating over uneven terrain. The combination of an altered motor system in conjunction with the non-rigid residuum/socket interface results in two pathways leading to impaired stability. This work focuses on using a prosthetic emulator to test prosthetic feet in isolation of the residuum/socket interface.

Increases in the displacement of whole body center of mass (CoM) indicate increased energy expenditure (Kuo, 2010). A decrease in the CoM height is indicative of compensation for gait instability (Curtz, 2010). These outcomes provide a way to evaluate the performance of multi-axial prosthetic foot stiffness over uneven terrain.

The purpose of this study was to determine the effect of multi-axial foot stiffness on COM height and displacement and utilize this information in strengthening evidence-based clinical practice.

METHOD

Subjects: One (of seven recruited) male (92.5 kg, 172.72 cm, 33 yrs) non-amputee utilizing bilateral prosthetic emulator ankle foot orthoses(AFO's) completed this pilot study approved by the Alabama State University Internal Review Board.

Apparatus: Ambulation over the uneven terrain occurred on an uneven walkway with blocks specifically placed in a sequential pattern. The center of each block was spaced 8" apart from each other with 4" around the perimeter. A mat was placed over the uneven walkway reducing visual feedback and a harness system was used for safe ambulation over the uneven walkway. An eight camera motion capture system (Vicon Motion Systems, Oxford, UK) recorded limb kinematics at 100 Hz.

Procedures: A single subject walked 10 times at 100 steps/min on even and uneven terrain with varying multi-axial ankle stiffness (Endolite Multi-flex foot set to soft, typical, and firm via ankle snubber selection).

Data Analysis: Vicon Nexus 1.8.4 calculated CoM movement. Mean displacement of the CoM in the sagittal plane was defined as the difference between low and high peaks in CoM movement. Mean displacement and mean CoM height was used to compare conditions.

RESULTS

The uneven walkway decreased gait stability as evidenced through lower CoM height regardless of ankle stiffness. The height decrease was most pronounced for the soft ankle stiffness with relative parity between the typical and firm ankles (Figure 1). There was decreased CoM displacement observed on uneven terrain for soft ankles (Figure 2).

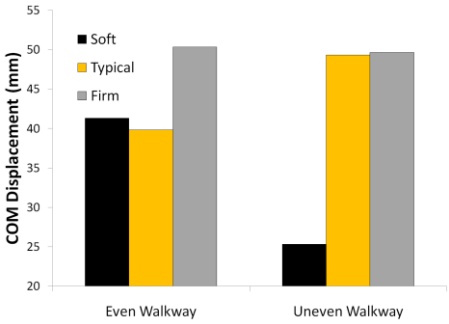

Figure 1: Mean CoM displacement

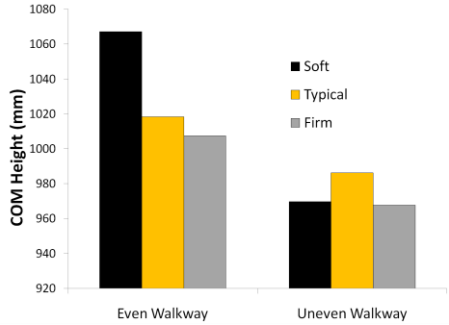

Figure 2: Mean CoM height

DISCUSSION

CoM height suggests the uneven surface resulted in reduction in stability for the subject. CoM displacement data is inconclusive regarding energy expenditure with this first of seven subjects.

CONCLUSION

CoM height data suggests while using prosthetic emulators, subjects' stability differences broadly resemble those of people with amputation. These pilot results indicate prosthetic emulator AFO's may be useful tools for research. However, more subjects are needed before conclusions may be drawn about the utility of variable stiffness multi-axial components.

CLINICAL APPLICATIONS

More research with prosthetic emulators will demonstrate which, if any, of the variable stiffness ankle components are most suitable to ensure the stability and safety of prosthetic users.

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PROSTHETIC FEET WITH MULTI-AXIAL FEATURES BEING USED ON UNEVEN TERRAIN: A PATIENT-CENTERED INVESTIGATION.

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INTRODUCTION

Prosthetic users experience various challenges when ambulating over uneven terrain. Prosthetic foot manufactures have attempted to minimize these challenges by designing multi-axial prosthetic feet that can conform and adapt to uneven terrain. This design has been tested in previous research (Curtz, 2010) but the effect of ankle stiffness on was not addressed. This lack of evidence now poses new challenges for practitioners and patients as the landscape of American healthcare changes. Third party payers now require outcome measures and justification to provide reimbursement for prosthetic devices

Increases in the displacement of whole body center of mass (CoM) indicates increases in energy expenditure (EE) (Kuo, 2010) while decreases in CoM position indicates compensation for gait instability (Curtz, 2010). These methods provide a way to evaluate prosthetic foot performance over uneven terrains.

The purpose of this study was to determine the effect of multi-axial foot stiffness on COM height and displacement and utilize this information in strengthening evidence-based clinical practice.

METHOD

Subjects: One bi-lateral trans-tibial amputee (92 kg, 177 cm, 46 yrs) has completed this pilot study approved by the Alabama State University Internal Review Board.

Apparatus: Ambulation over the uneven terrain occurred on an uneven walkway with blocks specifically placed in a sequential pattern. The center of each block was spaced 8" apart from each other with 4" around the perimeter. A mat was placed over the uneven walkway reducing visual feedback and a harness system was used to safely ambulate over the uneven walkway. An eight camera motion capture system (Vicon Motion Systems, Oxford, UK) recorded limb kinematics at 100 Hz.

Procedures: A single subject walked 12 times at a fixed cadence on even and uneven terrain. varying multi-axial stiffness (Endolite Multi-flex foot set to soft, typical, and firm via ankle snubber selection).

Data Analysis: Vicon Nexus 1.8.4 calculated CoM movement. Displacement of the CoM in the sagittal plane was defined as the difference in the lowest and highest peaks of these waves Mean displacement were used to compare conditions.

RESULTS

The uneven walkway decreased gait stability as evidenced through lower CoM height yet ankle stiffness had no effect (Figure 1). There was greater CoM displacement observed with decreasing ankle stiffness (Figure 2).

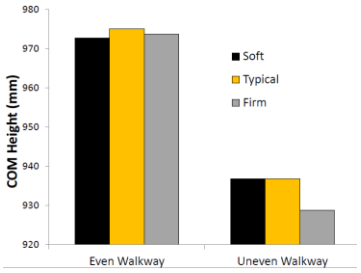

Figure 1: Mean CoM height for each multi-axial setting across each walkway

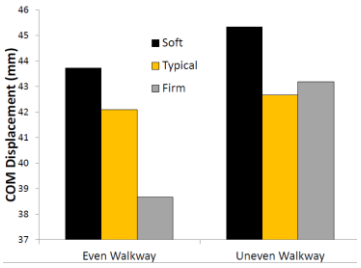

Figure 2: Mean CoM displacement for each multi-axial setting across each walkway

DISCUSSION

The subject was able to adapt to the component stiffness to stabilize CoM height but the surface change showed a loss in stability. CoM displacement data suggests energy expenditure increases with decreases in ankle stiffness decreases.

CONCLUSION

These pilot results indicate prosthetic feet with multi-axial properties may not be advantageous for prosthetic users but more subjects are needed to before conclusions may be drawn.

CLINICAL APPLICATIONS

The study results are expected to strengthen the evidence for prosthetic/rehabilitation interventions.

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Gates, D.H. Gait & Posture 35, 63-42. 2012.
Kuo, A.D. Physical Therapy 90. 157-174. 2010.

Custom Harness Design for Elite Wheelchair Basketball to Increase Performance in Class 1 Paralympic Players

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INTRODUCTION

The International Wheelchair Basketball Federation (IWBF) describes wheelchair basketball as the most popular sport played by people with physical disabilities. To ensure fair play, the IWBF has a classification system that assigns every player a point value ranging from 1.0-4.5 based on the players' functional ability. (IWBF 2010) Players with the least functional ability are classed 1.0 and are completely reliant on their wheelchair design and strapping for stability. (Goosey-Trolfrey, 2010)

Trunk stability is needed to appropriately apply forces to the wheelchair rim during acceleration and deceleration. Class 1.0 athletes are unable to stabilize their core preventing them from using their abdominal and postural back muscles during the propulsion cycle. (Vanlandewijck et al, 2001) To compensate for the lack of function, most class 1.0 players are using a neoprene waist strap to support their torso during competition; however, no research has been done to determine if the neoprene is offering enough support.

The objective of this study is to design and test a new harness system to support without restricting the player's torso; while being comfortable enough for long term use. By supporting the player's torso, improvements should be seen in the player's acceleration time.

METHOD

Subjects: One of two Paralympic level wheelchair basketball players have completed the study approved by the Alabama State University Internal Review Board. The first athlete will serve as the control group, and the second athlete, a class 1.0 player will be in the experimental group.

Apparatus: The experimental group will utilize an abdominal harness made of soft material to not put excessive pressure on the abdomen or costal cartilage. The harness will be attached to the wheelchair backrest with elastic straps of varying stiffness. A survey will be given to the participant to determine the comfort of the harness system to determine the likelihood of future compliance.

Procedures: Each participant will perform a rapid start/stop maneuver 20 times. The experimental group will use their current neoprene strap for 10 trials and the new harness system for 10 trials. Reflective markers will be placed on the wheelchair axle hub, greater trochanters, ulnar styloid processes, and C7. An eight camera motion capture system (Vicon Motion Systems, Oxford, UK) will record limb kinematics at 100 Hz.

Data Analysis: SPSS software will be used to determine the statistical significance of our data using repeated measures ANOVA (Significance of $p < .05$).

RESULTS

The control group's velocity was measured to and showed the areas for possible improvement to increase total velocity. The control was able to accelerate to a speed of 4.6 m/s and come to a complete stop in .27 seconds. The next push from the control showed a velocity of 5.52 m/s in .22 seconds. For the experimental group, a statistical analysis will be used to determine if the time needed to decelerate will decrease, the peak acceleration will increase, or the time to reaccelerate decreases.

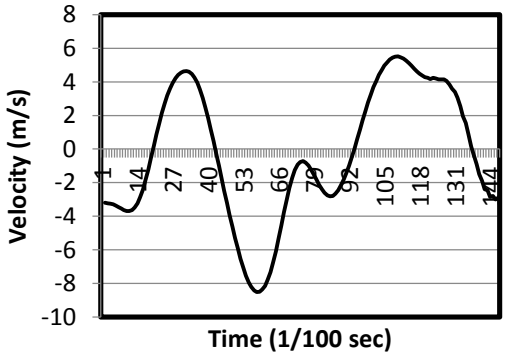

Figure 1 - Wheelchair velocity over a stop-start maneuver.

DISCUSSION

The control group set a baseline performance that can be compared to the class 1.0 athlete. Data collected from experimental group will be compared to the base performance to determine if the custom harness improved the player's deceleration/ acceleration time.

CLINICAL APPLICATIONS

Knowledge gained from our research can be used to develop a standard system of torso support for class 1.0 wheelchair basketball players including collegiate, recreational, and training of young athletes.

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PROSTHETIC KNEE JOINT CENTER OF ROTATION ERROR IN GAIT ANALYSIS

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INTRODUCTION

Data generated from gait analysis is an important tool in a number of research and clinical endeavours, particularly as it pertains to prosthetics. Like human knees, polycentric prosthetic knees have a center of rotation that moves throughout flexion and extension[1]. There is therefore a resulting risk in placing too much faith in data derived from these estimated joint centers. Small differences between estimated and actual knee joint centers (KJC) may propagate through the calculations and derivations of forces, as well as joint powers and moments. In addition, variations in prosthetic design influence knee joint center placement, and likely result in different degrees of variation between estimated and actual KJC. For example, a single-axis knee has been shown to transition to a flexion moment more quickly than a polycentric knee during swing phase[2]. The purpose of this study was to quantify the difference between a single chosen estimated knee center marker and the instantaneous center of rotation throughout flexion and extension for a variety of models of prosthetic knee.

METHOD

Seven prosthetic knees from a number of manufacturers and with multiple mechanisms were tested. The estimated center of the knee was a single marker placed at a location on the knee component that would be used during a typical gait analysis. The actual instantaneous KJC is defined as the point of intersection of lines defined by 2 markers each on pylons distal to (shank) and proximal to (thigh) the knee component. The two markers on the thigh and the two markers on the shank were placed so as to be collinear at full extension. Markers were tracked using seven infrared Vicon cameras as the knees were moved manually through their full range of motion. Angle position, instantaneous KJC and the resultant 3-D difference in estimated and calculated KJC were determined using MATLAB™.

RESULTS

Errors were present with every knee model (Figure 1). The single marker was closest to the actual KJC between 60 and 120 degrees of flexion, and several asymptotic errors were present at end-ranges of motion. Even the single axis knee showed multiple-centimeter errors (Table 1) since the prosthetic knee joint was offset from the intersection of the segments.

DISCUSSION

The errors found in this study were alarming, given the importance in the knee joint angle calculated from standard gait analysis. The angles at which the errors were minimized are amounts of flexion beyond those encountered in walking, increasing the concern.

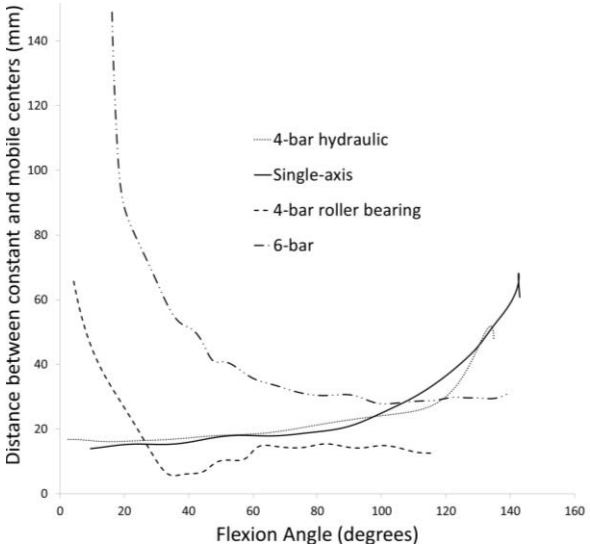

Figure 1. Difference between calculated and estimated knee joint center across the range of motion for four types of prosthetic knee.

	Peak Difference (cm)	Angle of peak difference (deg)
Single Axis	6.8	143
4-bar roller	65.7	4
4-bar hydraulic	5.1	134
6-bar	14.8	16

Table 1. Maximum difference between estimated and calculated knee joint center for four representative knees, and the angle at which it occured.

CONCLUSION

These results indicate that extreme caution should be taken when applying a shared-marker model in gait analysis involving a prosthetic knee. Future research should address improved means to measure the KJC in gait.

CLINICAL APPLICATIONS

Interpretation of data for gait involving a prosthetic knee should consider the potential for error in knee joint placement.

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Effects of Feedback-Based Training on Grip Force Control in Body-Powered Transradial Prostheses

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INTRODUCTION

Body-powered prostheses are still the standard in upper limb prosthetic care (Salem, 2013), however, limited research exists to improve or validate current body-powered upper limb prosthetic training methods. Rehabilitation programs for upper extremity amputees often stress training to perform ADLs single handed, in order to minimize use of the amputated side (Smurr, 2008), which may contribute to the high rejection rates of upper limb prostheses (Smit, 2014).

Visual feedback-based training has been found to improve grip force control in non-amputees with head injury (Kurillo, 2005). We hypothesized that participants exposed to force target feedback-based training would exhibit better grip force control using a body-powered prostheses than those exposed to training without feedback.

METHOD

Two male and two female subjects, aged 23-26 years, with normal ROM/MMT, participated in this study. Subjects were fit with a mock transradial prosthesis with a voluntary closing (VC) terminal device, and divided into two groups: one receiving feedback-based (FB) training and the other given traditional occupational therapy modeled non-feedback (NFB) training. Five training sessions were provided for each group.

Three types of tests were administered to both groups: number of blocks transferred in one minute in a box and blocks test (BBT), time taken to complete a nine-hole peg test (NHPT), and ability to track a set of five grip force targets on a computer screen. A root means square error (RMSE) value represented the difference between the target and force provided by the subject. A baseline test, mid-test, exit-test and retention fallout test were administered.

Statistical analysis analyzed percent change between baseline, exit, and fallout testing for each test parameter. A two-way ANOVA was performed on the data between the two groups using an alpha level of $p<0.05$ for significance.

RESULTS

The greatest changes in RMSE occurred for sine wave force tracking. Sine offset force tracking produced the smallest change in RMSE. The FB group was observed to have a greater percent change in 4 out of 5 force tasks (table 1). Significant difference in change in RMSE was noted only for the sine force tracking task (table 1). Percent changes in score for BBT and NHPT were noted to be greater for FB group, compared to NFB group, although these findings were not significant (figure 1).

Subjects from both groups reported maintaining grip force and matching targets as more difficult than BBT and NHPT. Feedback on prosthetic design reflected poor satisfaction with weight, comfort, and function.

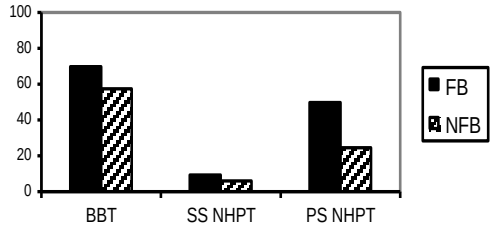

Figure 1. Percent change in outcomes measure score for FB and NFB groups. Note: SS indicates sound side, PS indicates prosthetic side

	FB	NFB	P value
Sine	61.285	47.70	0.0404
Sine offset	34.61	6.39	0.4434
Square	43.30	28.54	0.5306
Square offset	19.54	14.54	0.8059
Step	20.34	29.11	0.9026

Table 1. Average change in RMSE by percent, and p value for FB and NFB groups

DISCUSSION

A significant difference was observed in only 1 testing parameter, suggesting that there does not appear to be a significant difference between FB and NFB groups. However, overall a greater trend toward improvement in the FB group was observed. This follows results obtained in the assessment of feedback training for grip force control in subjects with brain damage (Kriz, 1995). It is believed that with a greater number of subjects, and incorporation of a control group, significant results may be obtained.

CONCLUSION

There does not appear to be a significant difference between grip force control in FB and NFB subjects. Further study is required to determine whether feedback training is a viable upper limb prosthetic training method.

CLINICAL APPLICATIONS

Determining the validity of feedback training in improving grip force control in amputees will provide potential for better prosthetic control and easier completion of ADLs.

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QUANTIFYING PLANTAR PRESSURES OF FOS, UCBLS, AND SMAFOS IN PATIENTS WITH PROBLEMATIC PRONATON

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INTRODUCTION

Pronation of the foot is normal during early stance phase, but this flattening of the medial longitudinal arch during all phases of gait can lead to deformity and pain. Three commonly used orthoses in the treatment of problematic pronation, or pes planus, include the rigid foot orthosis (FO), the University of California Berkeley Laboratory orthoses (UCBL), and the articulated supramalleolar ankle-foot orthosis (SMAFO). The purpose of this study was to quantify and compare the corrective pressures and comfort level between those three different devices used in the treatment of pes planus. It is hypothesized that the articulated SMAFO has a greater distribution of corrective pressures than the FO and the UCBL leading to less pressure in the medial longitudinal arch and a higher acceptance rate.

METHOD

Subjects: Three adult males with a Foot Posture Index (FPI-6) score greater than 5, indicating abnormal pronation

Apparatus: Teckscan's F-Socket and F-scan systems, questionnaire about perceived comfort and support

Procedures: Subjects were evaluated using the FPI-6 and casted. Three custom orthoses were made using the same model: articulated SMAFO, UCBL, and FO. The F-Socket sensor and F-Scan sensor were placed on the medial and plantar surfaces of the foot, respectively. Each subject ambulated three times on a 25-foot walkway in each orthosis and a shoe-only condition. The comfort surveys were completed between conditions and after all testing was complete.

Data Analysis: The F-Socket sensor was divided into four regions: first metatarsal head, medial border of arch, navicular, and medial malleolus. The F-Scan sensor was divided into six regions: the lateral and medial forefoot, midfoot, and hindfoot. The maximum peak pressure was identified at each trial, and the trials were averaged for each condition. An ANOVA test was then completed.

RESULTS

No significance was found for any region of the plantar or medial surfaces of the foot. Therefore, each subject was considered individually. Figure 1 is a sample of one subject's data. Table 1 shows the rankings for comfort and support from each subject after testing was complete.

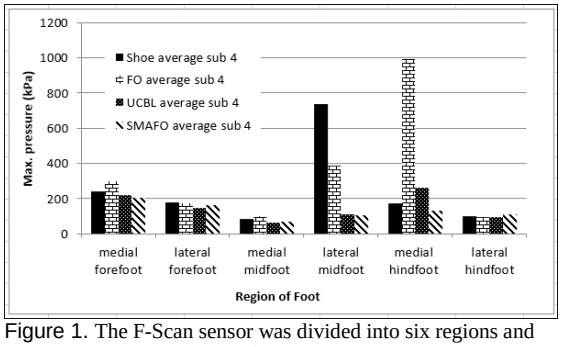

Figure 1. The F-Scan sensor was divided into six regions and the maximum peak pressure for each region in each trial was identified and averaged for Subject 4.

	Most Comfortable	Least Comfortable	Most Supportive	Least Supportive
Sub 3	FO	SMAFO	UCBL	Shoe
Sub 4	Shoe	SMAFO	SMAFO	Shoe
Sub 6	Shoe	SMAFO	UCBL	FO

Table 1. Subjects ranked each orthosis in comfort and support.

DISCUSSION

The maximum peak pressures in the FO were higher than the UCBL or SMAFO in five of the six regions, and the UCBL showed higher pressure than the SMAFO in three of the six regions, which begins to support the hypothesis. The other two subjects did not follow this same trend, though. All three subjects noted that the orthoses with higher trimlines felt most supportive, but this did not correlate to more comfort.

CONCLUSION

The SMAFO did not significantly lower the pressures on the medial longitudinal arch. The subjects found the orthoses with higher trimlines were most supportive but least comfortable. Although methods were improved from the pilot study, further research is needed with a larger sample size.

CLINICAL APPLICATIONS

This study does not indicate any change in clinical practice due to the lack of statistical significance or common trends in subject pressure data.

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EFFECTS OF MACHINE-ASSISTED STRETCHING COMPARED TO AT-HOME STRETCHING ON PLANTAR PRESSURES IN A POPULATION WITH TIGHT ACHILLES TENDON

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INTRODUCTION

In 2010 there were about 200 amputations performed per day on patients with diabetes in the United States (National Diabetes Statistics Report, 2014). Previous research identifies one pathway leading to diabetic amputation: a decrease in dorsiflexion range of motion (DROM) will likely result in an increase in forefoot peak plantar pressures (FPPP), which in turn will increase the risk of ulceration and eventually amputation (Mueller et. al., 2003).

The current study attempted to seek a cost-effective (i.e. non-surgical) therapeutic intervention to increase DROM and potentially decrease FPPP and risk leading to ulceration in the diabetic population. We compared the effects of two ankle ROM interventions: a supervised motorized stretching and at-home stretching programs. We hypothesized that a 4 week routine using CCMASM will have better outcomes than unsupervised at-home routine in increasing DROM and secondarily decreasing FPPP. Diabetics were not used in this preliminary study, instead two healthy participants with tight Achilles tendons bilaterally were recruited to perform one stretching routine per leg and serve as their own control.

METHOD

Subjects:

Participant	Sex	Age (yr)	Body weight (lb)
1	M	23	170
2	F	24	115

Apparatus: F-Scan in shoe pressure mapping system and CCMASM. The CCMASM was also used as the stretching apparatus with graded torques through the study adjusted based on participants' tolerance.

Procedures: Sides were randomized. **Machine Assisted:** Three 25 minute stretching sessions (including rest time) per week for 4 weeks on ankle on selected side. **At-Home:** Same as Machine-Assisted in length and duration but on contralateral ankle and included separate gastrocnemius and soleus targeted stretches.

Data Analysis: Paired T-Test, F-Scan, and Data from the CCMASM at baseline and post-intervention.

RESULTS

At-home stretching resulted in a decrease in DROM for Participant 1 and an increase in DROM for Participant 2. There was an increase in FPPP for Participant 1 and a decrease in FPPP for Participant 2.

Machine-Assisted stretching resulted in an increase in DROM for Participant 1 and a decrease in DROM for Participant 2. There was an increase in FPPP for Participant 1 and a decrease in FPPP for Participant 2.

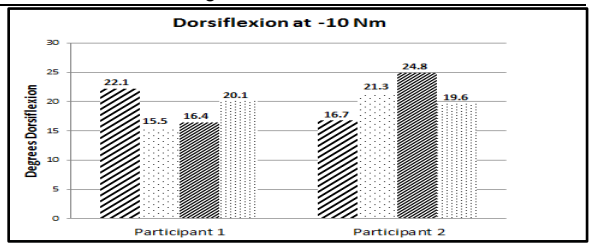

Figure 1: Striped bars = the At-Home DROM pre and post intervention while the dots = Machine Assisted DROM pre and post intervention. The less dense pattern = pre-intervention while more dense = post intervention.

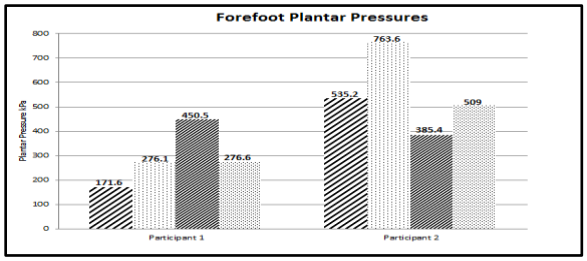

Figure 2: Striped bars = the At-Home FPPP pre and post intervention while the dots = Machine Assisted FPPP pre and post intervention. The less dense pattern = pre-intervention while more dense = post intervention.

DISCUSSION

At-home stretching: Participant 1 had a 25.9% decrease in DROM with 61.9% increase in FPPP. Participant 2 had a 32.6% increase in DROM and a 38.8% decrease in FPPP.

Participant 1 had results that supported the hypothesis because even with a 0.18% increase in FPPP it was smaller than his at-home routine. Participant 2 had inconsistent results.

Machine-Assisted: Participant 1 had a 23.2% increase in DROM with a 0.18% increase in FPPP. Participant 2 had a 7.9% decrease in DROM with a 50% decrease in FPPP.

CONCLUSION

Definitive conclusions could not be made, one participant supported the hypothesis while the other did not. A larger sample size is needed in future study.

CLINICAL APPLICATIONS

Finding effective non-surgical means of preventing ulcerations could prevent amputations and lower the healthcare expenses associated with them.

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Quantifying Gait Differences and Muscle Activation Between Conventional Footplates and Neurological Footplates in an Adult Subject with Spastic Paralysis

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INTRODUCTION

Spasticity is commonly seen following upper motor neuron injuries such as stroke or MS. A hyperexcitability of the stretch reflex leads to involuntary muscle control, which can lead to gait deviations. The neurological footplate was designed to increase pressure on the metatarsal shafts and peroneal notch, place the toes in extension, support the arch, and maintain the ankle in subtalar neutral in order to decrease the tone on the soleus muscle and improve gait characteristics (Dieli, 1997, Ibuki 2010).

The purpose of this study was to investigate gait characteristics and soleus muscle activation in a single adult subject with spastic paralysis when comparing footplate designs and articulation of the ankle foot orthoses (AFOs). Both standard and neurological footplates were compared. We hypothesize that there will be no significant difference in muscle activation or gait characteristics when comparing footplate design or ankle joint inclusion.

METHOD

Subject: 74-year-old male with left hemiparesis one year post-stroke, uses a left double adjustable AFO and right cane, and presents with spasticity of 1+ on Modified Ashworth Scale.

Apparatus: GAITRite for spatial and temporal gait characteristics, DelSys EMG for soleus activity

Procedures: The first visit involved an evaluation and casting by a Certified Orthotist. A standard AFO and neurological AFO were fabricated using 5/32 polypropylene with a plantarflexion stop and tamarack joints. The AFOs were articulated after the solid AFO conditions were tested. Data was collected on the second visit using 6 testing conditions: 1) shoes only (baseline), 2) Solid Standard 3) Solid Neurological 4) Articulated Standard 5) Articulated Neurological and 6) shoes only. Conditions were compared to the right limb as a control.

Data Analysis: EMG data processed using LabVIEW and MATLAB, gait data processed in Excel. No statistical analysis performed due to study design.

RESULTS

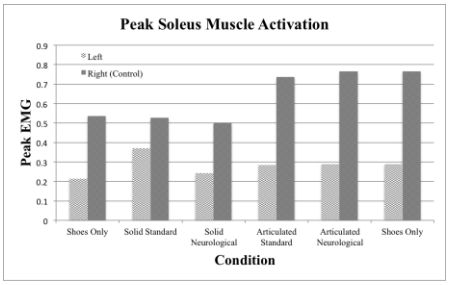

Figure 1. Peak soleus muscle activity for all conditions

Peak soleus activity was higher on the right leg and increased after articulation at the ankle. Notable results for temporal gait parameters include velocity (0.55-0.65 m/s) and time spent in single limb support (right 0.67-0.76 and left 0.47-0.52 s).

Table 1. Spatial gait parameters for all conditions.

Condition	Step Length (cm)			Base of Support (cm)	Toe Out (degrees)	
	Left	Right	Differential		Left	Right
Shoes Only	57.4	50.6	6.86	15.3	5.5	5.5
Solid Standard	54.1	46.7	7.41	14.6	10.6	5.8
Solid Neurological	54.8	49.8	4.98	12.3	8.7	5.2
Articulated Standard	57	49.2	7.83	14.2	3.7	4.7
Articulated Neurological	58.1	52.2	5.89	14.5	3.2	5.6
Shoes Only	58.4	44.9	13.51	15.1	3.1	5.1

DISCUSSION

For this subject, right peak EMG values increased after articulation, which demonstrates compensation due to decreased stability on the involved side. The paretic limb recorded the lowest EMG values under every condition and the neurological footplate had no effect on EMG results.

The subject walked at his fastest velocity with the articulated neurological trial but showed no clinical significance because his age matched normals are 1.24 m/s (Perry, 2010). The subject's mobility is best described as a limited community ambulator since he falls into the range of 0.4-0.8 m/s (Bowden, 2008).

The step length differential was smallest with neurological designs indicating a more symmetric step pattern. The time spent in single limb support was longer on the right than the left and was found to be clinically significant. The increased duration of right single and double limb support both demonstrate the subject's need for stability and confidence.

CONCLUSION

The neurological footplate was minimally effective for this patient with low spasticity. AFO articulation provided faster walking velocity without negatively impacting soleus spasticity but had little clinical significance. Respective EMG data demonstrated the subject's need for stability and confidence. Further accommodation periods or subjects with higher spasticity may benefit more from tone reducing modifications with respect to soleus muscle activation.

CLINICAL APPLICATIONS

Based on this study a solid neurological AFO may be applicable when a patient with spastic paralysis requires increased stability during gait.

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THE EFFECT OF PROSTHETIC FOOT ARTICULATION ON STATIC BALANCE IN TRANSTIBIAL AMPUTEES

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INTRODUCTION

Static stability (balance) is the ability to keep the body's center of gravity over the base of support in quiet standing. Following a lower-limb amputation, the loss of sensory input and musculoskeletal output impairs balance. A prosthesis can partially replace the input/output mechanisms, however little literature exists to guide component selection. This study aims to investigate the effects of ankle articulation on balance. Good stability is quantified by small COP variance, large Entropy, and WB% near 50%. The two hypotheses were that: 1) Less articulation will result in improved balance due to better transmission of ground reaction forces and 2) Occluding vision will impair balance for all foot conditions since vision is a major feedback mechanism for stability.

Trial Conditions Abbreviations		Measurement Abbreviations	
Sb	Soft bumper	Sound	Sound side only
Gm	Gait matched bumper	Amp	Prosthetic side only
Hb	Hard bumper	RLR	Residual Limb Ratio
Own	Own prosthetic foot	COP	Center of Pressure
Eo	Eyes open	Entropy	Sample Entropy
Ec	Eyes closed	WB%	Percent weight borne on prosthetic side

METHOD

Subjects: Eleven unilateral transtibial amputees with no known balance issues were recruited for this study (Age=57±9years).

Apparatus: The CPI Trustep with three bumper configurations modulated foot articulation. The COP and its velocities were captured using AMTI Dual-top AccuSway force plates.

Procedures: Each subject underwent a total of eight trials: four foot conditions (Hb, Gm, Sb, Own), each with two visual conditions (EO, EC).

Data Analysis: The main effects of vision, foot type and their interaction were tested using a doubly multivariate, repeated measures MANCOVA. The length of the residual limb normalized to height (RLR) and age were included as covariates.

RESULTS

None of the Wilk's lambda F tests were significant at the α=0.05 level, precluding further univariate or pairwise analysis. Regression analysis of RLR and age showed weak correlation (R^2<0.2). Figure 1 illustrates the effects of the foot and visual variable on overall balance.

DISCUSSION

The results fail to support either of the hypotheses; varying prosthetic foot articulation and occluding vision had no significant effect on static stability. The two covariates, subjects' age and RLR, also did not have a significant effect on balance. This may be due to low statistical power (0.17 to 0.77) secondary to a small sample size or large inter-subject variance. Similar to Nederhand et al, we recommend considering the differences in COP and Entropy between the prosthetic and sound sided as measurements of good balance. Further, investigating dynamic stability may increase the effect size.

CONCLUSION

Given the findings of the current study, no conclusions guiding foot selection for optimizing balance can be made.

CLINICAL APPLICATIONS

At this time, prosthetic feet should continue to be prescribed based on individual preferences, activities, gait characteristics and expert opinion.

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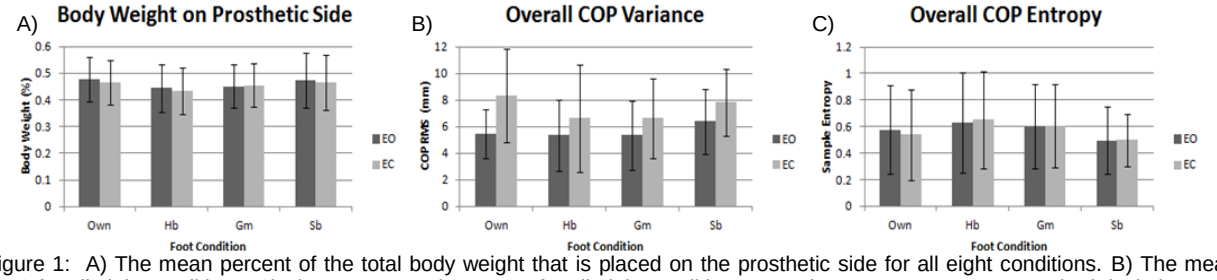

Figure 1: A) The mean percent of the total body weight that is placed on the prosthetic side for all eight conditions. B) The mean COP RMS for all eight conditions. C) The mean sample entropy for all eight conditions. Error bars represent ± one standard deviation.

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"Effects of articulated vs. non-articulated prosthetic feet on knee-extensor muscle activity and socket interface pressure during loading response in transtibial amputees"

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INTRODUCTION

Skin problems are common in transitibal amputees and are exacerbated as 70% of amputees suffer from vascular diseases and associated comorbidities (Ustal et al., 2006). The anterior distal tibia is a common area of skin breakdown due to increased pressure at loading response.

A literature review was conducted on ulcer formation, socket pressure, and muscle activity in transtibial amputees. Sangeorzan et al. (1989) showed that less pressure is required at the distal tibia to cause ischemia and skin problems. Sanders et al. (1997) found socket interface pressure reached 415 kPa. Ramp decent resulted in an increased pressure at the anterior distal tibia compared to flat walking. However, only one foot type was tested (Wolf et al., 2009). Portnoy et al. (2012) found that a hydraulic ankle significantly decreased peak socket pressure at the anterior distal tibia.

From the literature review, it was concluded that there was a lack of research on the effects of an articulated ankle on socket pressure. It was expected that using the articulated foot would result in lower peak socket pressure and lower muscle activation than the non-articulated foot at loading response and that the differences would be greater when walking at a faster velocity and on a decline.

METHOD

Subjects: Nine male UTSW patients; unilateral transtibial amputees; K3 functional level; at least one year of prosthetic use

Equipment: Nordic X7i incline trainer treadmill; EMG Event Switch MA-153; Delsys 8-channel EMG Pickups; TekScan FlexiForce sensors

Procedures: With each foot (TruStep and Axtion) participants walked at a velocity of 1.2mph at a level incline, a velocity of 2.0mph over a level incline, a velocity of 1.2mph at 3% decline and a velocity of 2.0mph at a 3% decline. EMG of the rectus femoris and vastus medialis, and pressure over the anterior distal tibia were recorded.

Data Analysis: Three-way repeated measures MANOVA using SPSS

RESULTS

Averaged results for socket pressure at the anterior distal tibia measured by the FlexiForce sensor are shown in Figure 1. TruStep was found to have higher socket pressure during the 2.0mph conditions and lower socket pressure at the 1.2mph conditions. TruStep was found to have lower EMG activity in the 1.2mph conditions, while Axtion was found to have lower EMG activity in the 2.0mph conditions. Statistical analysis of the results showed that foot type, treadmill velocity, and treadmill slope did not significantly impact socket pressure and knee extensor muscle activity. P-valves for foot type, velocity, and slope were 0.393, 0.385, and 0.101, respectively.

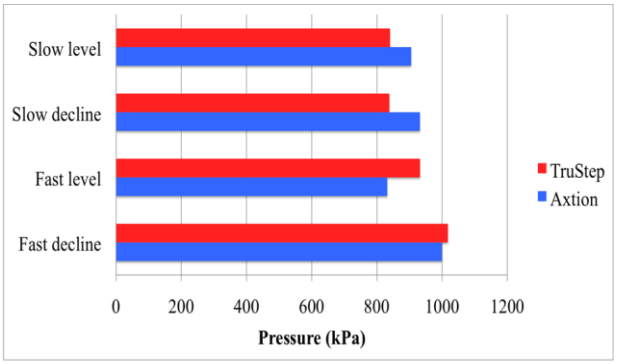

Figure 1. Average anterior distal tibia pressures for the four tested conditions

DISCUSSION

While the articulated foot had less impact on socket pressure than expected, large inter-subject inconsistencies were noted. Foot choice, socket interface control, and sensor setup are critical. Future research should control socket interface, use multiple sensors, and compare Trustep feet with stiff and soft bumpers.

CONCLUSION

The results showed that changing the foot, walking velocity, and level of incline yielded no measurable difference in muscle activity or socket pressure.

CLINICAL APPLICATIONS

This study helps clinicians better understand the effects of prosthetic feet on socket interface pressures and muscle activity to aid in foot selection.

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Effects of Off-the-Shelf AFOs vs. Custom Posterior Leaf Spring AFO on Gait in Patients with Foot Drop

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INTRODUCTION

The purpose of this research project was to compare three prefabricated, carbon fiber ankle foot orthoses (CAFOs) to a custom-fabricated posterior leaf spring (PLS) AFO on adult subjects with unilateral foot drop. While PLS AFOs and CAFOs have both been validated in the literature for their positive effects on hemiparetic gait (de Wit,2004)(Caker,2010) (Bregman,2012), there is no research to date directly comparing the two.
Using a GAITRite system, subjects' temporal gait parameters were collected while ambulating with each of four tested orthoses and while wearing no orthosis (shoes only). A mEFAP test and a subject questionnaire were also conducted.

METHOD

Subjects (N=4): Four adult subjects having unilateral foot drop (dorsiflexor strength <2/5) for at least 6 weeks completed this study. Modified Ashworth Scale 2 or less required. Subjects were also required to ambulate with or without assistive devices for at least 25 meters.
Procedures: Initial visit consisted of informed consent screening questions and MMT/ROM measurements and casting by ABC certified orthotist.
The final visit involved orthoses being fit according to manufacturer's guidelines followed by a 5 minute acclimation period prior to testing. The orthoses were tested in random order. The mEFAP followed by, 3 trials on a GAITRite at a self selected speed, and a questionnaire were completed for each condition. A 15 minute rest period was given following each condition tested.
Statistics: $\alpha \leq 0.05$ for all statistics
One-way repeated measures ANOVA - velocity, stride length, and step length differential
One-way ANOVA – mEFAP.

RESULTS

No statistical significance was found between AFO designs. Velocity yielded a p value of 0.170. Stride length p value was 0.116. Step length differential had a p value of 0.610. The mEFAP yielded a p value of 0.818.

DISCUSSION

The AFO that provided the fastest velocity also provided the longest stride length for each particular subject. The PLS AFO tended to provided a more symmetrical gait compared to the off the shelf AFOs.

	SUBJECT 1	SUBJECT 3	SUBJECT 5	SUBJECT 7
Velocity	Noodle	Toe Off	Noodle	PLS
Stride Length	Noodle	Toe Off	Noodle	PLS
Step Length Differential	PLS	PLS	PLS	Dynamic Walk
mEFAP	Noodle	Toe Off	Dynamic Walk	Noodle

Table 1. Shows the AFO that the subject performed best in for the given parameter

Each subject had had varied gait parameters that they performed higher in with the AFO that they rated higher. There was no one AFO that consistently improved gait parameters. Subjects rated the Noodle a 4 or 5 for likelihood to use.

CONCLUSION

Due to small sample size and differing presentations combining all four subjects' data yields non-statistically significant differences among devices, though the results allow for some generalizations.
Patient's preference for a device is related to their performance while wearing it
While there is no one AFO that is best suited for every patient with foot drop, each patient may have an AFO design that is most appropriate for them
Trial use of various orthoses may improve outcomes

CLINICAL APPLICATIONS

This information can be applied clinically when deciding between custom or off-the-shelf. Knowing that an off-the-shelf may be preferred over the custom design in some patients may influence clinical practice and lead practitioners to trial an off-the-shelf before custom making a device for a unilateral drop foot patient.

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The Effect of Solid Ankle AFO Foot Plate Length on Third Rocker Function

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INTRODUCTION

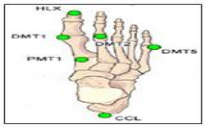
Third rocker function is theorized to be limited by longer foot plate lengths (distal to metatarso-phalangeal joint). A standardized clinical approach is desired for making clinical foot plate length decisions for populations whose pathologies do not dictate a specific foot plate length. A non-AFO condition will serve as the control trial for each patient against full, sulcus and proximal to the metatarsal heads footplate length conditions. This study will focus on hallux angle and temporospatial parameters including step and stride length, cadence, and velocity.

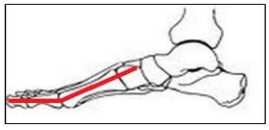
METHOD

Subjects: Subjects were recruited via flyers from the UT Southwestern School of Health Professions and must be at least 18 years of age. Subjects were excluded if they have less than 5/5 MMT or 80% normal ROM values for the lower extremity.

Apparatus: This study was completed through the use of an 8 camera OptiTrack Motive motion capture camera system to capture hallux joint angle motion, and a GAITRite mat and software to obtain temporospatial parameters.

Procedures: Subjects were evaluated and casted by the same CPO to gain a consistent, accurate impression for unilateral AFO fabrication. AFO's were pulled with 3/16" polypropylene and trimmed to solid ankle AFO trimlines. AFOs were fit by the same CPO and put in an appropriate shoe size with marker placement at the first and fifth metatarsal heads, distal lateral hallux, posterior calcaneus, and base of the first metatarsal to capture the hallux angle, following a modified Heidelberg method[3] (fig. 1). A five minute acclimation time was given prior to testing each foot plate length. Trials were done in the following order: no AFO, full, sulcus and then proximal to metatarsal heads plate lengths. The motion capture and GAITRite trials were completed simultaneously. Three trials were done for each condition.





Data Analysis: This study used OptiTrack Motive motion capture and MATLAB to obtain hallux angle data, Microsoft Excel was used for statistical analysis for all tests. One way ANOVA was used to determine significance at $p<.05$ and if found significant, pairwise comparisons would be done using paired t-tests.

RESULTS

Four subjects were initially tested with inadequate camera configuration and were not tested again. Two subjects were unable to complete testing due to small foot size, leading to cameras identifying one marker cluster opposed to individual markers. 4 subjects' data were captured and analyzed. GAITRite (table 2). Trumper determined that temporospatial parameters alone are not indicators of third rocker fuction.[4] He also determined that stride length, step length, cadence and velocity were primary indicators of gait which were not found to e significant in this study.

	Full	Sulcus	Mets
None	0.044	0.047	0.097
Full	--	0.583	0.866
Sulcus	--	--	0.859

	Footplates
Stride length (cm)	0.80
Step length (cm)	0.97
Cadence (steps/min)	0.65
Velocity (cm/min)	0.71

GAITRite (table 3): One way ANOVA was conducted for the hallux angle and determined to be significant at $p=0.015$. Paired t-tests were performed and found to be signifcant for full plate versus no AFO and Sulcus versus no AFO. Figure 3 shows the hallux angle average over each of the 4 conditions.

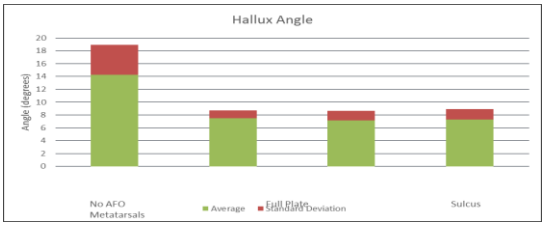


Figure 3. Average of 4 subjects at each foot plate condition.

DISCUSSION

Hullin and Robb[4] determined that temporospatial parameters could not be used as the sole determinants of third rocker function. Owen discussed that people with no weakness or gait deviations were able to compensate AFO effects as in the GAITRite results which were not significant.[2] Motion capture results were significant specifically in the full versus no AFO and sulcus versus no AFO conditions. There was slight motion due to the use of tall, active males who overcame some of the effects of the full and sulcus plates. The metatarsal late was least significant; meaning it most closely mimicked normal walking and least hallux angle impact.

CONCLUSION

This study determined that shorter foot plate lengths impact hallux angle less than longer foot plate lengths. Limitations include the use of only healthy, normal male subjects. Inherent motion exists between skin, AFO, shoes and markers. The motion capture system has insufficient resolution, leading to inaccuracy and inability to differentiate between closely placed forefoot markers.

CLINICAL APPLICATIONS

This study does not offer conclusions that warrant the alteration of footplate lengths in clinical practice. The results do provide significant quantitative proof of the benefits in various footplate lengths and justify the need for continued research.

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ANKLE FOOT ORTHOSES FOR CHILDREN WITH MYELOMENINGOCELE: FUNCTIONAL EFFECTS UNDER A DUAL TASK PARADIGM

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INTRODUCTION

Ankle foot orthoses (AFOs) are a common intervention used to improve the gait of children with myelomeningocele (MMC). They are designed to improve balance, stability and efficiency (Duffy, 2000; Mazure, 2004). Recent evidence suggests that in everyday life, walking involves a cognitive component (Davis, 2011; Karakostas, 2013). The cognitive component involves allocating attentional resources to concurrently address environmental needs such as conversing or negotiating obstacles while walking. Our recent clinical observations suggest that ambulatory aids, such as AFOs, in addition to improving walking performance, may also facilitate concurrent performance of a secondary cognitive-related task. There is the need, therefore, to investigate the potential concurrent functional effects of ambulatory aids, such as AFOs, in children with pathological conditions. Consequently, the purpose of this study was to assess the potential additional effects of AFOs on the functional performance of children with MMC under a dual task paradigm, where the single task involves walking only whereas the dual task (walking while counting) involves recruitment of cognitive resources.

METHOD

Subjects: Eighteen ambulatory children with MMC at sacral and lumbar levels (ages between 7 and 13, GMFCS I-III) were tested at our institution.

Apparatus: Gait parameters were measured using a GAITRite instrumented walkway (CIR Systems Inc. Clifton, NJ 07012). Counting performance audio and gait were recorded on a video-tape recorder.

Procedures: A certified orthotist molded subjects for solid AFOs, measured them for shoes and assessed their counting ability before testing. The experimental procedure involved two visits to our institution, two weeks apart. During the first visit subjects walked at their self-selected speed on a GAITRite instrumented walkway with shoes but without their AFOs, under two conditions, a dual task involving walking and counting (WC) and a single task involving walking only (W). During the second visit they performed, again, WC and W at their self-selected speed with AFOs. Task order was randomized.

Data Analysis: Repeated measures ANOVA was performed on the variables of walking velocity, cadence, stride length, rate of correct responses and rate of responses per unit time ($a<0.05$).

RESULTS

The gait parameters and counting task variables that were statistically significant between conditions can be seen in Table 1. Velocity and stride length significantly increased with the use of the AFO in the W as well as WC conditions. Counting performance also significantly improved with the use of the AFO in the WC condition.

Condition and Parameter	Mean	SD	p
W_NoAFO_Vel (cm/s) W_AFO_Vel	65.96 77.38	29.58 27.67	0.005
W_NoAFO_StrL (cm) W_AFO_StrL	79.60 94.26	17.44 38.34	0.004
WC_NoAFO_Vel (cm/s) WC_AFO_Vel	43.89 55.88	24.63 24.47	0.002
WC_NoAFO_Rate (resp/s) WC_AFO_Rate	0.44 0.54	0.28 0.30	0.02
WC_NoAFO_Rate_Corr(resp/s) WC_AFO_Rate_Corr	0.33 0.45	0.28 0.30	0.001

Table 1. Spatiotemporal data and Verbal responses. Velocity (Vel), Stride length (StrL), Rate of responses (Rate), Rate of Correct Responses (Rate_Corr) with (AFO) and without (No_AFO) AFO during single walking (W) and dual, walking and counting (WC) tasks.

DISCUSSION

Our data support previous findings that AFOs significantly improve gait parameters in children with MMC during ambulation (W). We have also shown that the use of AFOs allowed for significant improvements in gait as well as in the simultaneous counting task in the WC condition. This is most likely attributed to the AFOs decreasing attentional demands for effective ambulation and unloading cognitive resources that would otherwise be engaged in the walking task. These, in turn, can be used to facilitate performance of the cognitive task. Future work will further explore the interaction between the spatiotemporal and counting task variables.

CONCLUSION

AFOs can facilitate performance of concurrent motor and cognitive tasks in children with MMC.

CLINICAL APPLICATIONS

This information can ultimately be used to create an outcome measure combining motor and cognitive performance to drive better clinical decision making in the orthotic management of children with MMC.

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Quantification of Residual Limb Skin Health and Circulation in Response to Elevated Vacuum Suspension

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INTRODUCTION

Elevated vacuum suspension sockets continue to grow in popularity for improved fit and suspension. Case reports and clinical trials support qualitative claims for vacuum-dependent improvements to skin health[1] and wound healing[2, 3] on the basis of self-reported questionnaires, clinical outcomes scales, and wound closure studies. Previous work by the authors optimized new technology platforms for quantitative assessment of residual limb skin health and circulation in response to elevated vacuum suspension. Non-invasive measurement protocols were developed that leverage out-of-socket skin health tests (transepidermal water loss (TEWL), surface electrical capacitance (SEC), cutometry (CTY), and torsional ballistometry (TB)), out-of-socket circulation imaging (hyperspectral (HI) and laser speckle imaging (LSI)), and in-socket probe-based circulation tests (transcutaneous oxygen measurement (TCOM), laser doppler flowmetry (LDF)). These techniques were employed to characterize residual limb health in response to long-term use of a vacuum suspension socket.

METHOD

Subjects: All experiments were approved by The Ohio State University Institutional Review Board. Ten unilateral amputee subjects (5 transfemoral and 5 transtibial) were enrolled in the study.

Apparatus: Residual limb skin health was assessed by measuring skin water loss/hydration (TEWL, SEC) and elasticity (CTY, TB) at areas of high and low socket stress. Out-of-socket circulation in the sound limb and residual limb was quantified using HI (skin oxygenation) and LSI (perfusion). In-socket residual limb circulation was quantified by TCOM (skin oxygenation) and LDF (perfusion).

Procedures: A crossover design was employed, such that half of the subjects were randomized to begin the study with their current, non-vacuum prosthesis (Group A) while the other half began testing with the vacuum socket (Group B). After 16 weeks, subjects in Groups A and B crossed over to use either the vacuum socket or their original prosthesis respectively. During each 16 week interval, skin health and circulation measurements were acquired at baseline (week 1), mid-point (week 8), and final (week 16) time points.

Data Analysis: TEWL, SEC, CTY, and TB data were exported from DermaLab™ and MApp v1.10.2000 software immediately after socket and liner removal and after equilibration with air for 15 minutes. HI and LSF data were analyzed using custom MATLAB code that averaged signal intensity over a 2.5cm x 2.5cm FOV. Raw data from the LDF and TCOM probes were analyzed using semi-automated MATLAB code as the mean ± SD value recorded during a 1min period under defined resting positions and during activity (treadmill walking). All data were analyzed using a student's t-test (SigmaStat 12.0). Skin health data were expressed as mean ± standard error of the mean and statistical significance was established if $p<0.05$.

RESULTS

The use of vacuum socket technology reduced both skin surface hydration and water loss compared to non-vacuum controls in Group A in areas of high socket pressure. Within Group B, SEC values were significantly reduced in areas of low pressure with vacuum use and these changes persisted even after cross-over to non-vacuum conditions. Differences in skin biomechanics were also found between the two suspension systems. Reactive hyperemia (increase in blood flow after period of occlusion) was consistently observed when comparing pre- to post-activity StO_2 values from the residual limb of amputees. After 16 weeks of use, however, reactive hyperemia was significantly attenuated in subjects under elevated vacuum suspension conditions as compared to suction controls. While not statistically significant, there was a general trend for reactive hyperemia to increase over the 16 weeks under suction conditions.

DISCUSSION & CONCLUSION

This work represents first efforts to quantitatively assess skin health and circulation in response to elevated vacuum suspension. The results suggest vacuum suspension leads to improved circulation and skin health. Further work is needed to explore these findings in more detail with a larger study population.

ACKNOWLEDGEMENT

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