FALLS IN PERSONS WITH UPPER LIMB LOSS

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INTRODUCTION

Natural arm dynamics play a critical role in dynamic balance, for steady-state walking by minimizing body angular momentum [1] and when recovering from a perturbation through ballistic movements to redirect body mass [2]. This has considerable implications for fall risk in persons with upper limb loss. Fall frequency has been documented for individuals with lower limb loss [3], but this health hazard has not been explored in persons with upper limb loss. The purpose of this pilot study was to investigate fall frequency, balance confidence, and predictors of falls in persons with upper limb loss at or proximal to the wrist.

METHOD

Subjects: Data were collected on persons at least 18 years of age with limb loss at or proximal to the wrist.

Apparatus: A 35 multiple-choice, English-language online survey (SurveyMonkey, CA), released 4/6/2016 collected information on prosthesis use, fall history and circumstances, limb loss, body and health characteristics, and balance confidence (Activities-specific Balance Confidence (ABC) Scale [3]).

Procedures: Subjects accessed the survey at the web address advertised through OANDP-L, AMP-L, and prosthetic clinics, and provided anonymous responses following provision of informed consent. Respondents were permitted to skip any question.

Data Analysis: Summary statistics were prepared for all data. A backward step-wise logistic regression analysis assessed the impact of relevant variables including age, upper limb loss characteristics (most proximal level, time since loss, cause), prosthesis use inside or outside of the home, and presence of lower limb loss on fall classification: frequent fallers (≥2 in the past 12 months), and non-fallers (≤1). Incomplete records were removed for regression analysis.

RESULTS

At the time of analysis, data had been collected on 56 subjects. Some variables were analyzed on a reduced sample as respondents did not answer every question. Summary statistics are displayed in Table 1. Overall, 44% of respondents (n=55) reported a fall in the past year, 67% of which fell more than once and 29% within the last six months. Falls occurred while walking indoors (40%), outdoors (5%), on stairs (40%), during domestic chores (10%), and during sport (25%). Falls resulted mainly from trips (50%), slips (30%), or a push/pull (10%). Seven subjects experienced lower limb loss (ranging from partial foot to hip disarticulation). The model (n=43, 12 fallers, $\chi^2(4)=29.542$, $p<0.001$) correctly classified 91% of cases and explained 72% of outcome variance. Respondents were more likely to fall if they were older (p=0.055), had less time since limb loss (p=0.028), and used an upper limb prosthesis (p=0.033). Amputation cause was significant (p=0.040), but did not contribute greatly to explaining model variation.

Item	Category	Count
Sex	*Male*	22
	Female	28
Age (yrs)	40±17 [21-78]	50
Body Mass Index	25±9 [12-55]	49
Upper limb loss		
Time since loss	28±17 [1-78]	48
Cause	*Congenital*	27
	Other	25
Number	*Unilateral*	43
	Bilateral	7
Level	*Shoulder Disarticulation*	2
	Transhumeral	10
	Elbow Disarticulation	1
	Transradial	27
	Wrist Disarticulation	13
Prosthesis use		
Type used (inside and/or outside the home)	*Cosmetic*	13
	Body-powered	25
	External/electric	18
	Hybrid (body+ external)	2
	Passive w/ terminal device	8
	Sport/Recreation	14
	None	21
Use (hrs/day)	9±7 [0-19]	32
Use (days/week)	5±3 [0-7]	33
ABC Score (%)	88±17 [30-110]	47

Figure 1. Summary statistics; mean ± 1 StDev [range].

DISCUSSION

Results suggest that although persons with upper limb loss do not generally suffer from low balance confidence, they report a high prevalence of falls that is only 8% less than that for lower limb amputees [3]. These findings suggest an undocumented health hazard in this patient group. Falls appear to result from common risks such as slips and trips, but risk of repeated falls may be elevated due to variables specific to upper limb loss and prosthesis use in addition to the known factor of age. Sample size was small and this should be considered for interpretation.

CONCLUSION

Falls may be an important health concern for persons with upper limb loss and research should further explore possible factors related to risk.

CLINICAL APPLICATIONS

Although balance confidence in patients with upper limb loss is high, they may benefit from closer monitoring to identify prevalence and risk of falls. Such monitoring could create awareness of this risk and identify patients in need of targeted intervention.

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Symptom Severity and Prosthesis Use; Exploring the Pain Experience Using the Disabilities of the Arm Shoulder and Hand (DASH)

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INTRODUCTION

The pain experience of amputees has been identified as an important factor in relation to prosthesis use (1), and as an outcome that can change as a result of prosthesis use. The authors have previously reported on functional outcomes recorded using the Disabilities of the Arm Shoulder and Hand (DASH) outcome measure (2), however the aim of the study is to explore the effect on specifically the self-reported symptom severity score of the DASH as a result of prosthesis use.

METHOD

The cohort consisted of 25 Individuals of various age and gender reporting on outcomes via an online platform comprised of the DASH questionnaire in addition to questions requesting level of absence, cause of limb absence, and various other questions to establish if the population was representative. The entire cohort was current prosthesis users. The demographic information allowed the effect of prosthesis use on the symptom severity score to be analysed across sub groups.A Wilcoxon signed rank test was used by Touch Bionics in addition to the descriptive data to ensure that change in the responses was not dispersed, and to provide more detail about the nature of change across the group. Presented below are the results for the partial hand subgroup. These data will be compared for the overall pain rating across subgroups including partial hand, trans-radial, above elbow, and congenital. The congenital subgroup will act as a control.

RESULTS

Pain rating	Pre fitting		3 months	
	Patients	%	Patients	%
None	9	36.0%	13	52.0%
Mild	8	32.0%	8	32.0%
Moderate	6	24.0%	3	12.0%
Severe	2	8.0%	1	4.00%
Total	25	100%	25	100%

Table 1. Prefitting and 3 months Wilcoxon signed ranks test-overall pain rating

Wilcoxon signed Ranks Test Full cohort (n = 25 patients)			
3 months – Pre fitting	N	Mean Rank	Sum of Ranks
Negative Ranks	8a	5.13	41.00
Positive Ranks	1b	4.00	4.00
Ties	16c		
Total	25		

Table 2

(A) 3 months rating < prefitting rating

(B) 3 months rating > prefitting rating

(C) 2 months rating = prefitting rating

Test (statistic Z):	
Z	-2.31
Asymp. Sig. (2-tailed)	**.021**

Table 3. Statistical Z.

DISCUSSION

Resnik et. al. discuss the pain experience and implications for upper limb prosthetic rehabilitation. The authors aimed to establish if the use of a prosthesis has an impact on the levels of pain reported via the DASH and if this varies across levels of absence or origin of limb absence.

CONCLUSION

The self-reported measure of pain recorded by question 24 of the DASH showed a statistically significant reduction in pain symptoms from pre to post prosthesis use over the cohort. This positive effect was also observed for questions relating to pain when performing a specific activity and stiffness. These results indicate that powered partial hand prostheses can provide benefits to the pain experience of partial hand amputees.

CLINICAL APPLICATIONS

Routine administering of validated clinical tools such as the DASH in prosthetic clinical settings both pre and post fitting help validate and justify the use of advanced upper limb prosthetic devices in tasks of everyday living and provide meaningful outcome information to the clinician and other relevant entities.

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CASE COMPARRISON OF ELECTRIC DIGITS AND 3D PRINTED BODY POWERED HAND PROSTHESES

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INTRODUCTION
Medical applications of 3D printing are expanding rapidly. Popular press has generated growing patient interest in low cost 3D printed hands as an alternative to conventional prosthetics. Comparison is commonly made between electric prosthetic finger systems and 3D printed body powered hands with regard to cost in particular. Comparing such devices is inherently problematic as one is body powered whereas the other is electric. 3D printing is a manufacturing process that has the potential to reduce cost and increase speed of production. It does not however alter basic prosthetic principles and has potential issues of durability. The differences in function of these systems is not readily apparent to the public consumer of this information. The authors aimed to examine how these two systems compare in standardized functional testing as well as subjective evaluation in a single case. The hypothesis was that the electric digits would outperform a 3D printed body powered hand in all measures with the exception of response speed for light manipulation tasks.

METHOD
Subject: One 48 year old male with partial hand amputation of the non-dominant left hand at the transcarpal/transmetacarpal level.

Apparatus: A Raptor Reloaded 3D printed body powered prosthesis was printed via a MakerBot Replicator. The patient was previously fit and currently is a user of a 5 finger iDigit system.

Procedures: The subject was fit with a 3D printed wrist driven hand, received training in its use, and was asked to wear the device at least one hour per day for two weeks. The subject then performed the Southhampton Hand Assessment Procedure (SHAP) while wearing each of the two devices. The subject also completed 4 trials of the box and blocks test using the 3D printed hand and 3 trials using iDigits. A semi-structured interview with subjective ratings was also performed.

Data Analysis: Normalized scores of the SHAP trials were obtained using the online software provided.

RESULTS
For the trials of the SHAP the iDigits resulted in higher scores in all grasp patterns than the 3D Hand with an index of function score of 75 versus 25, respectively. Norms for the SHAP are between 95 and 100. In semi-structured interview the subject rated the iDigits higher in all categories including comfort, durability, function, and aesthetics with the narrowest margin being aesthetics.

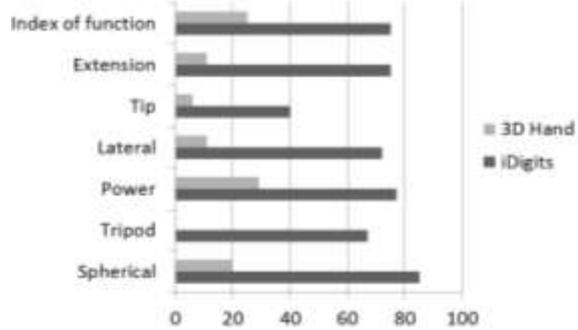

Fig. 1 Normalized scores of the SHAP trials.

DISCUSSION

The study produced results that were in alignment with the original hypothesis. The electric digits had significantly better performance for all grip and pinch types as well as the overall index of function. The wrist driven 3D device performed comparably in large lightweight grasp and slightly higher in one trial of the box and blocks.

The limitation of a single case study is understood and conclusions from this should be weighed against the sample size. Additionally the subject had more experience with the electric digit system and this could have contributed to the disparity of the results.

CONCLUSION

In this one case the results clearly demonstrated the functional advantages of the electric system vs. a wrist driven system for the partial hand level. Further study with larger number of subjects as well as comparison of other non 3D printed body powered devices to 3D printed devices is indicated to improve clinical relevance.

CLINICAL APPLICATIONS
This study is relevant to clinicians providing upper limb prostheses, education, or training. Studies such as this, along with longer trials for subjective and quality of life improvements may provide more significant results and guidance for best practices.

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USING MEANINGFUL DATA TO OPTIMIZE THE QUALITY OF LIFE FOR PERSONS WITH PARTIAL HAND AMPUTATION

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INTRODUCTION

With recent prosthetic advancements and the increasing prosthetic options for partial hand (PH) amputations (PHA) over the past decade, some research has been conducted to evaluate the needs of this subgroup of the upper limb amputation (ULA) patient population (Desmond 2002). However, a dearth of research has been conducted to evaluate differences between varying subgroups of ULA patients; more specifically, how PHA patients may differ from higher ULA patients.

Anecdotal evidence and some preliminary work has found that PHA patients exhibit elevated levels of perceived distress in comparison to higher ULA patients (Phillips 2012). However, literature in this area is few and far between.

The study aimed to advance the literature by evaluating odds of positive screens on various measure of psychological wellness (e.g., PTSD, depression) between subgroups of ULA patients secondary to clinical team experiences indicating the need to objectively evaluate patient needs and inform patient specific care recommendations. We hypothesized psychological variables responses are unique to ULA subgroups.

METHOD

Subjects: Sample 263 (M_{age} = 44.35; 67.3% male) from the Wellness Inventory (WI) with varying levels of UL amputation receiving prosthetic rehabilitation.

Apparatus: The WI consists of seven validated screening instruments, including depression, PTSD, pain interference and substance use (i.e. alcohol, illicit drug use, overuse of prescription medication).

Procedure: Subjects participated in a battery of validated outcome measures at relevant prosthetic fitting and training stages as standard of care in seven out-patient rehabilitation centers.

Data Analysis: A series of hierarchical logistic regressions were conducted to assess if level of amputation (PHA vs. ‘higher ULA’) increased odds for screening positive on psychological wellness measures in the WI. Analyses controlled for pertinent demographic variables (e.g. age, gender).

RESULTS

Results from the analyses found that membership in subgroup did not significantly increase odds of positive screens for depression or any of the substance use variables. However, belonging to the PHA subgroup significantly increased odds of a positive screen for PTSD [Odds Ratio (OR) = 2.04, 95% CI: 1.11 –
3.77, p = .002] and for endorsement of pain interference (OR = 2.96, 95% CI: 1.63 – 5.39, p < .001).

Wellness Screen	Odds Ratio (95% CI)	p-value
PTSD	2.04 (1.11, 3.77)	**.022**
Depression	1.26 (.772, 2.06)	.353
Pain Interference (Yes/No)	2.96 (1.63, 5.39)	**<.001**
Alcohol	1.17 (.70, 1.95)	.559
Overuse of Prescription Drugs	.94 (.43, 2.06)	.884
Illicit Drug Use	.92 (.36, 2.38)	.864

Figure 1. Comparison of upper limb amputation groups on psychological outcome measures, controlling for age and gender.

DISCUSSION

This study found that level of amputation increased odds for screening positive for several psychological well-being measures. In fact, our data suggest that the odds of a PHA patient screening positive for PTSD were twice those of a ‘higher ULA’ patients; same for pain interference. Future work should (a) consider level of amputation as a meaningful predictor or control variable and (b) consider investigating the interplay between psychological variables within various ULA subgroups.

CONCLUSION

Our findings suggests that level of amputation may play an important role in understanding and predicting psychological well-being among ULA patients, and may be particularly meaningful for PHA patients. Further research to further evaluate this potential influence on clinical outcomes along with methods to address the patient population specific need is necessary.

CLINICAL APPLICATIONS

As there are more prosthetic fitting options for PHA than in the recent past, clinicians providing prosthetic rehabilitative services to this patient population subgroup should consider these findings to meet the needs of individuals.

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USING MEANINGFUL DATA TO OPTIMIZE THE QUALITY OF LIFE FOR PERSONS WITH PARTIAL HAND AMPUTATION

"Conyers, D.W., CP, FAAOP[1], Ryan, T.R., OTR, MOT[1], Hsu, C.J, MOTR/L, MSOT[1], Kearns, N.T. CSP[2], Miguelez, JM CPO, FAAOP[1]
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Phillips et al. JPO, 24(2), 93-97, 2012.

Contact Reflex Improves Fragile Grasping while Blindfolded

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INTRODUCTION

While able-bodied individuals can perform complex manipulation tasks without looking at their hands, myoelectric prosthetic hand users rely heavily on visual feedback to control the closing speed and stopping force of their prosthesis. Reducing the visual attention required to operate a myoelectric prosthesis would make using these devices more intuitive and natural.

In this work, highly sensitive and compliant tactile sensors (NumaTac, SynTouch) were integrated into a myoelectric prosthetic hand. When opposing contact is detected by the sensors during a grasp, the gain of the EMG signals delivered to the myoelectric controller is reduced, a process similar to a natural spinal inhibitory reflex. This improves the control of low force grasps without compromising speed or the ability to achieve maximum forces. This study explores subject performance in a bimanual fragile grasping task with and without vision.

METHOD

Subjects: One 23-year-old male transradial congenital amputee and three able-bodied individuals with no amputations.

Apparatus: Two prosthetic hands, an unmodified OttoBock VariPlus Speed (VPS), and a VariPlus Speed that has been modified with NumaTac-sensors and a contact-detecting reflex (NT).

Procedures: Each subject was asked to pick up a fragile object (saltine cracker) with their dominant hand, pass to their prosthetic hand (or non-dominant hand for able-bodied subjects), then place the cracker in a cup without breaking it. Each timed trial consisted of 10 cracker transfers. Amputee performance with each of the prostheses was compared to the average task performance of three able bodied individuals for each visual condition (AB). This was performed with and without a blindfold for all cases.

Data Analysis: Five trials were recorded for each condition to find average speed and accuracy and comparisons were made between the VPS hand, NT hand, and able-bodied individuals (AB).

RESULTS

In all cases, loss of visual feedback inhibited speed of fragile item passing. For the prosthesis user, bimanual passing with the NT hand was found to be significantly faster and showed fewer grasping failures (cracker breaks) when compared with the unmodified VPS hand. In addition, the blindfold hampered the VPS task speed significantly more than either the NT or AB test conditions. The blindfold slowed AB speed by an average of 2.2 seconds, NT by 2.7 seconds, and VPS by 18.2 seconds.

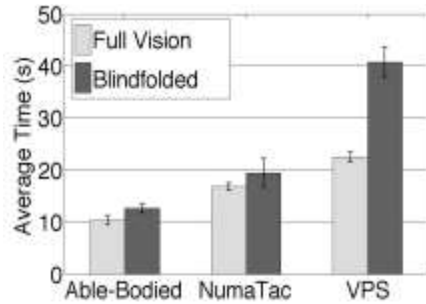

Figure 1. Average bimanual task performance speeds for each hand with full vision and while blindfolded.

DISCUSSION

When using a traditional myoelectric prosthesis (VPS), blindfolding makes the grasping task significantly more difficult, demonstrating that users are relying heavily on visual feedback. However, with the reflex-enabled hand (NT), the loss of performance when blindfolded was comparable to able-bodied subjects (AB). This suggests that reflex-enabled and able-bodied grasping require a similarly low amount of visual attention. Additionally, fragile grasping with the NT hand was faster blindfolded than the VPS hand without a blindfold. Future research will be aimed at validating methods of evaluating visual and cognitive burden, and the conduction of a clinical take-home study to evaluate the utility of a myoelectric contact reflex in activities of daily living.

CONCLUSION

Contact-detecting sensors are a simple yet effective advancement in prosthetic research. They enable prosthesis users to perform faster and more accurate fragile grasps, greatly reducing the need for visual feedback while grasping, which may increase the utility and ease of use of prosthetic hands.

CLINICAL APPLICATIONS

Contact detecting sensors may be incorporated into prosthetic hands in the future to restore a more natural and intuitive grasping ability for amputees using myoelectric prosthetic hands. Additionally, the experimental method may be adapted into an outcome measure to assess the importance of visual feedback for the use of different prosthetic hands.

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USING MEANINGFUL DATA TO OPTIMIZE THE QUALITY OF LIFE FOR PERSONS WITH UPPER LIMB AMPUTATION

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INTRODUCTION

Successful outcomes in upper limb prosthetic rehabilitation are dependent upon many factors, some of which have the potential to negatively impact recovery from traumatic amputation and the integration of prosthetic technology into daily living.

Within the field, prosthetic wear time is frequently considered a measure of "success." Clinicians must consider patient specific factors, such as level of amputation, psychological, physical, cognitive, and social impact when making clinical recommendations.

Evaluation of relevant data is invaluable to determine best practices in support of patients' prosthesis wear and use to meet their rehabilitation goals. Some research suggests persons with higher levels of ULA choose to wear their prosthesis less than those with lower level ULA (Biddiss, 2007). Research also suggests psychological and cognitive influences play a role in wear time (Phillips, 2012). Epidemiological and evidence-based research studies to account for these influences are few and outdated. This study aims to identify and assess the influence of level of amputation and perceived quality of life with the potential to impact prosthetic rehabilitation.

METHOD

Subjects: Samples included 118 (M age = 43.61; 72.9% male) from Comprehensive Arm Prosthesis and Rehabilitation Outcome Questionnaire - Revised (CAPROQ-R) and 263 (M age = 44.35; 67.3% male) from Wellness Inventory (WI) with varying levels of UL amputation receiving prosthetic rehabilitation.

Apparatus: CAPROQ-R assesses physical and functional factors influencing prosthetic outcomes. The WI consists of 7 validated screening instruments, including the *Orthotics and Prosthetics Users' Survey Quality of Life Scale* (OPUS).

Procedure: Subjects participated in a battery of outcome measures at pertinent fitting stages within the prosthetic fitting and training process as standard of care in 7 out-patient rehabilitation centers.

Data Analysis: ANOVAs were conducted to assess differences in (1) hours per day patients wore their prosthesis and (2) activity restriction and emotional reactions scores from the OPUS between three levels of amputations: partial hand (PH), elbow and below (BE), and above elbow (AE).

RESULTS

CAPROQ-R: Results showed significant differences by group, [$F(2, 115) = 5.08$, $p = .008$, $\eta^2 = .081$)]. Post hoc analyses found daily wearing times for PH patients ($M = 6.65$, $SD = .74$) were significantly lower than both EB ($M = 9.42$, $SD = .53$, $p = .003$) and AE patients ($M = 9.44$, $SD = 1.01$, $p = .027$). No other differences were significant ($ps > .05$).

Wellness Inventory: Results for the analysis of activity restriction found no significant differences between the groups, [$F(2, 243) = 1.73$, $p = .180$, $\eta^2 = .014$].

Results for the analysis of emotional reactions showed significant differences between groups, [$F(2, 259) = 3.23$, $p = .041$, $\eta^2 = .024$)]. Post hoc analyses found emotional reactions scores for PH patients ($M = 13.65$, $SD = .63$) were significantly higher than AE patients ($M = 10.84$, $SD = 1.08$), $p = .025$. No other differences were significant.

DISCUSSION

Persons with AE amputation wore their prosthesis *more* than PH patients and at the same level as those with wrist-elbow amputation, which is inconsistent with some research and clinical perceptions of prosthesis wear habits. Although patients did not differ in perceived daily life restrictions, PH patients reacted more emotionally to their condition. Future work should investigate emotional reaction and areas of "wellness" correlated to prosthetic wear time.

CONCLUSION

These findings suggest that patients' emotional reaction to their condition may play a unique role in understanding wear time for patients.

CLINICAL APPLICATIONS

Understanding factors influencing prosthesis wear time may guide successful UL prosthetic rehabilitation practice. Given our findings, specialists should incorporate assessment of psychological 'wellness' into the rehabilitation process.

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A Double-Blind Study of a Bimodal Ankle-Foot Prosthesis for Improved Balance and Mobility

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INTRODUCTION

Many individuals with lower-limb amputation experience reduced balance and balance confidence, which can negatively impact participation in social activities and quality of life. Previous work suggests that in order to restore balance and balance confidence, ankle-foot prostheses should be designed with a flat effective rocker shape for standing (Hansen and Wang, 2010). However, most commercially-available ankle-foot prostheses are designed with a curved effective rocker shape for walking. To address the demands of both standing and walking, our group has designed a novel bimodal ankle-foot prosthesis (Fig. 1 inset; Hansen and Nickel, 2013) that can accommodate both functional modes through the use of a rigid foot plate and an ankle that can lock (resulting in a flat effective rocker shape for standing) and unlock (resulting in a curved effective rocker shape for walking).

The primary objective of this study was to determine if this design could improve the standing balance of lower-limb prosthesis users. We hypothesized that subjects would exhibit improved balance during quiet standing tasks when the ankle was locked compared to when it was unlocked, and that this effect would be exaggerated in the absence of visual feedback.

METHOD

Subjects: Data were collected on 17 subjects (16 male) with unilateral, transtibial amputation (age 58±15 years; mass 93±27 kg; height 1.8±0.07 m).

Apparatus: Upon enrollment, subjects were asked to complete the Activity-Specific Balance Confidence (ABC) Scale and the Prosthetic Limb Users Survey of Mobility (PLUS-M). A NeuroCom Clinical Research System (Clackamas, OR) was used to assess static postural stability between conditions.

Procedures: Prior to data collection, subjects practiced the first two conditions of the Sensory Organization Test (i.e., quiet standing with eyes open and closed) with their usual prosthesis. A certified prosthetist then fit subjects with the bimodal ankle-foot prosthesis and either locked or unlocked the ankle (testing order was randomized and blinded to the subjects and the investigators collecting data). Testing was then repeated with the ankle locked and unlocked. Following testing, subjects were asked to provide feedback about the two ankle modes.

Data Analysis: Equilibrium scores (a measure inversely proportional to body sway) were averaged across conditions and compared using a repeated measures ANOVA with two within-group factors (MODE: locked and unlocked and EYES: open and closed). Post-hoc Bonferroni multiple comparisons were used given a significant main effect ($p<0.05$).

RESULTS

Subjects scored an average of 81±13 points (range: 56-96) on the ABC Scale and an average of 4±1 points (range: 3-5) on the PLUS-M. Statistical analysis revealed a significant interaction term between MODE and EYES ($p=0.03$), in which subjects exhibited a significant decrease ($p=0.01$) in equilibrium scores when standing on the unlocked (88±3) versus locked ankle (91±3) with their eyes closed (Fig. 1). No statistical differences were noted between the locked and unlocked ankle when subjects stood with their eyes open ($p=0.1$). Overall, 8 subjects said they felt more balanced and 9 subjects said they felt equally balanced while standing with the locked ankle compared to the unlocked ankle. In addition, 13 subjects expressed interest in trying this system for a longer period of time in the future.

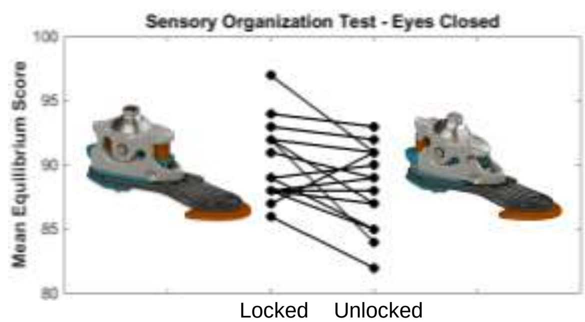

FIGURE 1. Mean equilibrium score for subjects standing with their eyes closed while using the locked and the unlocked bimodal ankle-foot system.

DISCUSSION

Preliminary results suggest that in the absence of visual feedback, the locked bimodal ankle-foot system may improve standing balance in a group of experienced, relatively active lower-limb prosthesis users. However, given the modest decrease in equilibrium scores between the locked and unlocked conditions, future testing of this system should focus on new amputees and lower mobility users.

CLINICAL APPLICATIONS

Commercial implementation of this design could lead to improved standing balance and balance confidence among lower-limb amputees, improving participation in social activities and quality of life.

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Comparison of Self-report and Clinician Measured Body Mass Index Calculations for Lower Limb Amputees

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INTRODUCTION

Weight gain is typical following lower limb amputation, with the likelihood of obesity increasing the more proximal the lower limb amputation at a rate of 37.9% and 48.0% for those with unilateral transtibial and transfemoral amputation, respectively.[1] Body Mass Index (BMI) is a measure of weight adjusted for height (kg/m^2) and has been found to be a surrogate measure of body fat, predictor of obesity, and indicator of type 2 diabetes, hypertension, and cardiovascular disease in adults.[2,3] More than one-third (35.7%) of American adults are considered obese (BMI > 30).[3] For persons with lower limb amputation this calculation factors in the weight and length of the missing limb using a mathematical formula. The Amputee Coalition and members of the Scientific and Medical Advisory Committee (SciMAC) developed a BMI Calculator for People with Limb Loss. The tool is available online and can rapidly generate a BMI score.

The purpose of this study is to determine the validity of using self-reported height and weight and an estimated residual limb length for BMI calculations when compared to clinician measured anthropometric values.

METHOD

Subjects: A convenience sample of 72 subjects were recruited at the 2016 Amputee Coalition National Conference in Greensboro, North Carolina. Eligible subjects were between 18-80 years of age, with a unilateral transtibial, knee disarticulation, or transfemoral amputation.

Procedures: Subjects completed the online Amputee Coalition BMI Calculator (BMI_s) at intake using self-reported height, weight, and level of amputation. The formulas to calculate BMI_s with this tool are:

$$BMI_s = [W_e(\mathrm{lb})/\mathrm{height\ (in)}^2]\ \mathrm{x}\ 703$$

$$W_e = W_0/(1 - \mathrm{P})$$

Figure 1. BMI_s Formulas. Where W_e = estimated weight, W_0= weight without the prosthesis, and p= percentage of total body weight of missing limb (TTA = 3.26, TFA= 9.96)

The research staff then measured height, weight, residual limb length, and sound limb segment length using standard equipment and calculate BMI_c.

$$BMI_c = [W_e(\mathrm{kg})/\mathrm{height(m)}^2]$$

$$W_e = W_{wp} - \mathrm{W}_{pro}/(\mathrm{P} - (\mathrm{RL/intact}\ )$$

Figure 2. BMI_c Formulas. Where W_e = estimated weight, W_{wp}= weight with the prosthesis, W_{pro}= weight of the prosthesis, and P= percentage of total body weight of missing limb (TTA = 0.985, TFA= 0.941), RL= residual limb length, intact= sound limb segment length (tibia or femur)

Data Analysis: The two methods of calculating BMI were compared using correlation analysis and paired t-tests. SPSS Software version 21 (IBM corp., Armonk, NY).

RESULTS

The average BMI_c was 29.95 (range 15.4-55.8). Three subjects had calculated BMI < 18.5, indicating underweight status. Fifteen subjects had a calculated BMI in the normal range (18.5-24.9 kg/m^2). Eighteen subjects (25%) were classified as overweight (BMI 25-29.9), and 36 subjects (50%) were classified as obese.

The two methods of calculating BMI were highly correlated r = 0.95, p<.001. There was no significant difference in calculated BMI between the self-reported value and the clinician administered measurements (paired t-test, p=0.36). The clinician administered BMI_C calculations were an average of 0.25 kg/m^2 higher.

DISCUSSION

The BMI equation developed by the Amputee Coalition using self-reported height, weight, and level of amputation produced similar BMI for unilateral lower limb amputees when compared to traditional methods. The clinician measured calculations required significantly more time to administer. Surprisingly, the rate of obesity in this sample of unilateral lower limb amputees is much higher (50%) than the prevalence in the US adult population (35.7%).[3]

CONCLUSION

The Amputee Coalition BMI Calculator is a quick and valid method for calculating BMI in unilateral lower limb amputees

CLINICAL APPLICATIONS

Healthcare providers can use the Amputee Coalition BMI Calculator to generate valid BMI calculations for unilateral lower limb amputees while saving valuable clinical time.

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GAIT SYMMETRY IN TRANSFEMORAL AMPUTEES

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INTRODUCTION

Individuals with unilateral transfemoral amputation (UTFA) may regain some degree of independent ambulation by wearing a prosthesis. However, previous studies show that they still experience gait asymmetries (Jaegers et al., 1995, Sjodahl et al., 2002). The asymmetry limits walking ability and also leads to secondary physical conditions, such as joint pain and osteoarthritis in both limbs (Gailey et al., 2008). Recent evidence indicates that adaptation of gait symmetry on a split-belt treadmill can be transferred to over-ground walking in people with stroke (Reisman et al., 2009). This suggests that gait training using a split-belt treadmill is a potential training method to assist the recovery of gait symmetry. Thus, the purpose of this study is to identify the effects of a split-belt treadmill gait training (STGT) program on symmetric walking in people with UTFA.

METHOD

Subjects: A 35 year-old woman (height: 160cm, weight: 45kg) with congenital UTFA participated in this study. The subject used a suction socket prosthesis with Total Knee and a Talux foot.

Apparatus: Split-belt treadmill (Bertec, Co., OH) and ProtoKinetics Zeno Walkway (ProtoKinetics, Havertown, PA) were utilized for gait training and testing, respectively.

Procedures: The subject completed a 2-week STGT program (3 sessions/week, 30 minutes/session). Over-ground walking was examined prior to training (baseline), after completing the STGT program (posttest), and 1 month after completing the training program (retention). A 6-minute walk test was also performed to assess changes in exercise tolerance over the three test periods.

Data Analysis: Step length, swing phase, and double limb support phase symmetries were analysed by calculating a symmetry Index (%): [(prosthetic side – sound side) / 0.5(prosthetic side + sound side)] x 100. Note that 0% indicates a perfect symmetry and negative values represent that the subject took a longer step or a prolonged phase time with the sound leg compared to the prosthetic one.

RESULTS

The subject demonstrated improvements in gait symmetries during comfortable walking following the STGT training (Table 1). Step length symmetry changed from 2.7% to -0.5% after training and the change was maintained at 1 month follow-up. Double limb support phase symmetry also improved from 7.2% to 2.6% following training and the improvement was retained at the retention test. Swing phase symmetry changed from 20.3% to 17.3% after training, but the change was not maintained at the retention test.

Symmetry Index	Baseline	Posttest	Retention
Step Length	2.7±1.5	-0.5±2.5	-1.3±2.0
Swing Phase	20.3±0.8	17.3±1.4	21.7±1.5
DLS Phase*	7.2±8.9	2.6±11.0	-0.2±9.2

Table 1. Changes in gait symmetry indices (%) over three tests. *DLS phase: double limb support phase

Exercise tolerance (6-minute walk distance) noticeably increased from 454.4m to 577.7m following training. The distance was fairly preserved at 1 month follow-up (525.4m) (Figure 1).

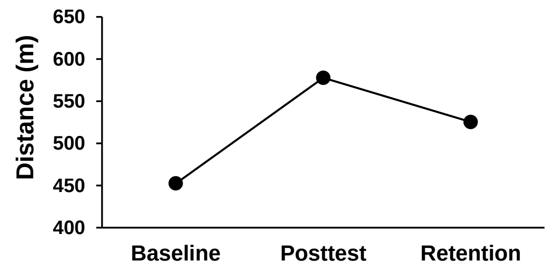

Figure 1. Changes in exercise tolerance (6-minute walk distance) over three tests.

DISCUSSION

The preliminary results of our study show that a person with UTFA could improve gait symmetry following a short term gait training using a split-belt treadmill. The results are comparable to a previous stroke study (Reisman et al., 2009). Moreover, the improvement in gait symmetry might help increase the level of exercise tolerance during over-ground walking.

CONCLUSION

Adaptation of gait symmetry during STGT can be carried over to over-ground and also increase exercise tolerance in a person with UTFA.

CLINICAL APPLICATIONS

The STGT could be utilized as a potential treatment approach to improve the efficiency of walking in people with UTFA.

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GAIT SYMMETRY IN TRANSFEMORAL AMPUTEES

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Visual Localization for Prosthetic Lower Limb Control

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INTRODUCTION

A major hurdle for robotic lower limb prostheses is determining which terrain-specific control mode is appropriate for a given moment. Currently available methods for automatic mode selection are based on measuring the state of the device or body, such as acceleration or forces. However, mechanical sensors do not offer an easy window into the future intent of the user. In order to achieve this, there continues to be interest in using electromyogram (EMG) signals from the residual limb, following decades of research. While EMG shows great promise, it is also challenging to deploy due to changes in skin conditions (Hoover et al. 2012), crosstalk, electrode lift off and motion artifacts (Li et al. 2011).

Independent of research into prosthesis control, there has recently been great progress in estimating the location of a device equipped with cameras (Frese 2010). While there remain hurdles, localization has reached a critical point of usefulness but has yet to be leveraged for prosthesis control. The location of the prosthesis can provide a novel means for anticipatory mode control with a different set of engineering tradeoffs from mechanical and EMG sensing. We demonstrate vision-based localization of the limb during walking on varied terrain. We use this location to estimate terrain and anticipate transitions.

METHOD

Performance was evaluated on eight non-amputee subjects wearing a commercially-available “Tango” localization device on the shank of the leg. Subjects performed laps around a locomotion course with stairs, a platform, and a ramp. Laps were performed under two walking speeds (averaging 1.67 and 1.15 m/s) and three “exposure conditions.” Exposure conditions are related to how much prior exposure the localization system has had to the environment. Ground truth of location was collected using a retroreflective marker based motion tracking system. We quantified positional tracking accuracy, awareness of the moment-to-moment terrain, and the detection of terrain transitions. We investigated the performance of four classifiers that use location estimates to classify terrain. Three classifiers used height estimates in addition to location, and one classifier included a time history. Four terrains and six terrain transitions were tested.

RESULTS

The system localized position within 20 centimeters for the faster walking condition and 10 centimeters for the slower. Classification utilizing both height estimates and time history provided terrain awareness at least 95% of the time, and accurately detected most terrain transitions within 40 milliseconds.

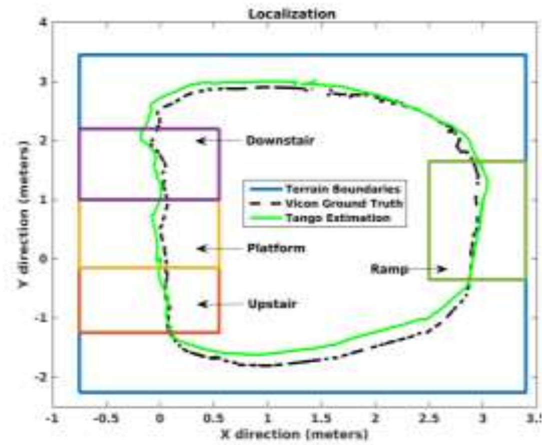

Figure 1. Localization on multi-terrain course.

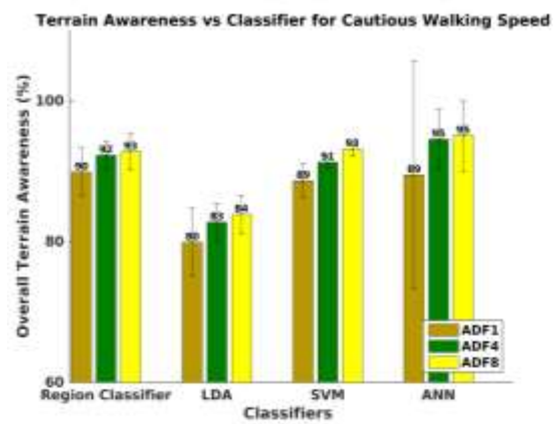

Figure 2. Terrain classification accuracy. Performance of the four classifiers is depicted as a group of three bars, one for each exposure condition. Increasing exposure to the environment resulted in improved performance.

DISCUSSION

These results demonstrate the promise of localization via visual sensors for control of robotic lower limb prostheses.

CLINICAL APPLICATIONS

Rapidly improving localization technology could unlock the full benefits of powered limbs and enable more capable and safer prescribed prostheses.

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ABILITY OF EPIDERMAL SENSORS TO MEASURE LOWER LIMB TEMPERATURE DURING ACTIVITY WITH A PROSTHESIS SIMULATOR

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INTRODUCTION

Clinicians and researchers lack easy-to-use instruments to evaluate the socket-limb interface in a non-invasive manner during every day activities[1]. Interface temperature and pressure are critical considerations in socket design, fit, comfort, and residual limb health[1,2]. Hafner & Sanders[2] suggested that incorporating sensing and monitoring technologies within prostheses could create opportunities for exchange of timely, relevant, and meaningful health information between patients, their prosthetists, and other healthcare providers. Unfortunately, instruments currently available to measure inside the socket include wires, cables, bulky/rigid sensors, or require mounting through holes in the socket, which is not clinically practical. Recent development of thin, flexible, wireless, 'skin-like' epidermal sensors[3] may be one way to address these problems, leading to the development of a residual limb monitoring system. The purpose of this study was to assess temperature readings from these epidermal sensors by comparing them to thermocouples, which have been previously used to collect data from the socket-limb interface[4].

METHOD

A prosthesis simulator was fabricated by a certified prosthetist to fit the left leg of an able-bodied individual (female, 26 years, 162.6 cm, 56.3 kg). The simulator comprised the following components: a gel liner (Ottobock, Germany), a prosthetic sock, and a transtibial vacuum-suspension socket. Data were collected simultaneously from both legs using 8 thermocouples (Omega Engineering, Stamford, CT) and 8 epidermal temperature sensors (Materials Research Lab, UIUC) placed on top of the thermocouples on 4 sites on each leg: tibial tubercle, fibular head, distal tibia, and medial gastrocnemius. Data were collected during: (1) 5 min. of seated rest with bare limb, (2) donning of simulator, (3) 10 min. of seated rest with simulator donned, (4) 30 min. of treadmill walking at 0.53 m/s, (5) 5 min. of seated rest with simulator donned, (6) 30 min. of treadmill walking at 0.53 m/s, (7) 30 min. of seated rest with simulator donned, (8) doffing of simulator, and (9) 25 min. of seated rest with bare limb.

RESULTS

Temperature readings from both sensor types at all locations corresponded reasonably well (±1.1°C) but were generally better on the contralateral limb (Figure 1). Temperature from the limb within the simulator were generally greater than the contralateral limb. Contralateral limb temperatures were generally constant throughout testing while temperature within the simulator continuously increased by 5-7°C once donned and did not return to near initial temperature until the simulator was doffed. Donning the gel liner caused a drop in temperature, while doffing the simulator caused an instant drop in temperature. The epidermal sensors were durable to socket conditions and did not cause any adverse skin problems.

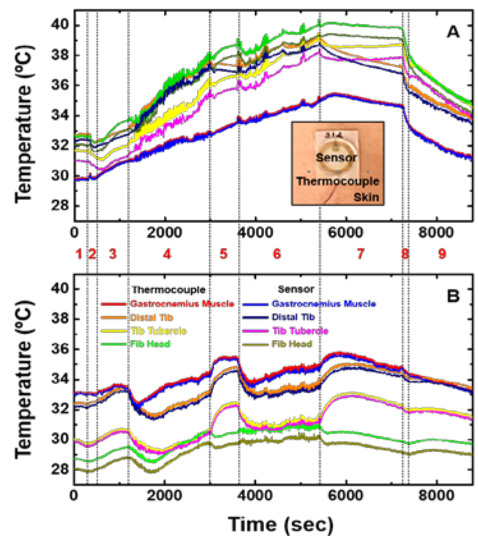

Figure 1. Temperature recorded: (A) on the leg under the simulator and (B) on the contralateral limb. Phases 1-9 correspond to activity described in the method.

DISCUSSION

Thermocouples have been used previously to measure transtibial residual limb temperature using a similar protocol[4]. Our data compared well and was similar both in magnitude and pattern to that previously published for transtibial amputees[4]. While these initial results suggest that the epidermal sensors are suitable for assessing temperature from within a prosthetic socket, additional work is needed to better understand the variation in correspondence between the two sensors at different locations.

CONCLUSION

Epidermal sensors provided temperature magnitudes and trends during initial testing that are reasonable.

CLINICAL APPLICATIONS

Using epidermal sensors to monitor residual limb conditions within prosthetic sockets may lead to improved healthcare for persons with limb loss.

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THE EFFECT OF CLEAT PLACEMENT ON FORCE GENERATION IN A CYCLIST WITH A TRANSTIBIAL AMPUTATION: A PILOT STUDY

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INTRODUCTION

Cyclists commonly implement a pedaling system that involves clipping a cleat fixed to the bottom of a shoe into a notch within a pedal. When accomplished, a cyclist can pedal more efficiently (Hull 1982).

Individuals with a transtibial amputation are unable to generate force with muscle groups distal to the knee and lack important range of motion at the foot and ankle. As a result, optimal cleat placement may be necessary for maximal performance (Childers, 2011).

The aim of this study was to analyze peak force production at three different cleat positions on the plantar aspect of a transtibial amputee's cycling shoe. It was hypothesized that manipulation of the cleat/pedal connection and alignment would influence the subjects' ability to generate force.

METHODS

Subjects: An adult transtibial amputee was recruited for participation (height: 1.87 m; mass: 85 kg; years since amputation: 9; etiology: MVA). There were no notable comorbidities and range of motion and manual muscle testing values were within normal limits. The subject utilized a patellar tendon bearing style socket with a gel liner and suction suspension.

Apparatus: An aluminum footplate test fixture was fabricated and a cycling cleat was fixed to the forefoot, midfoot, and hindfoot positions. The footplate was attached in lieu of the subject's prosthetic foot to the existing prosthesis, and the iPecs System® was used to measure forces (Koehler, 2014).

Procedures: The subject completed steady state and maximal exertion trials on a bicycle suspended in a trainer in all three cleat positions. Force generation data were collected for two minutes during each trial.

Data Analysis: Force values were analyzed, and peak forces were calculated from the maximum push phase of 70 maximal exertion revolutions and 40 steady state revolutions. Values were averaged for each cleat position and standard deviation was calculated.

RESULTS

The subject produced the highest average peak force for steady state and maximal exertion trials at the forefoot position (steady state: 318.0 ± 20.9 N, maximal exertion: 476.0 ± 48.2 N; Figure 1).

The subject produced the lowest average peak force during steady state and maximal exertion trials at the hindfoot position (steady state: 250.0 ± 10.5 N, maximal exertion: 349.0 ± 27.7 N; Figure 1).

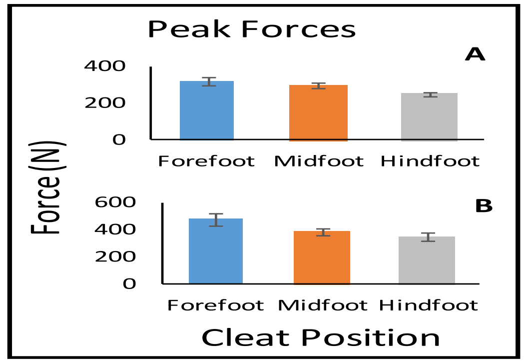

Figure1: Peak forces at Steady State (A) and Maximal Exertion (B).

DISCUSSION

The rigid, extended lever arm in relation to the pylon in the forefoot configuration increased force generation potential, in support of our hypothesis.

Additionally, the subject stated the forefoot position felt most natural. Because of this, it was assumed overall comfort at the forefoot position may have led to increased force generation. It was noted that during both trials, tensile force was not generated in the pylon during upstroke.

The subject may have maintained compressive force through the prosthesis during cycling to maintain good fit and suspension of his prosthetic socket. Further research is needed to confirm this assumption.

CONCLUSION

The results of this study suggest greatest force can be generated at the forefoot position of a clipless pedal configuration. This configuration should allow a cyclist with a transtibial amputation to pedal more efficiently by producing optimal force without sacrificing comfort and/or altering the natural biomechanics inherent in cycling.

CLINICAL APPLICATIONS

Determining whether maximal force production occurs at the forefoot, hindfoot, or midfoot is clinically relevant because maximal force production may allow an amputee to ride faster, longer, and more efficiently, leading to a more enjoyable experience.

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A Case Study demonstrating the benefit of the Össur Proflex foot to a user with a uni-lateral transtibial amputation

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INTRODUCTION

The Proflex foot from Össur represents an interesting design that shows promise to deliver more push-off than traditional energy storage and return prosthetic feet (Heitzmann et al., 2015). However, traditional evaluation of prosthetic foot push off power has been done using inverse dynamics in which a critical assumption is that the ankle joint center of rotation does not move. The design of the Pro-Flex foot itself includes a linkage system in combination with deformable carbon fiber sections and the instant center of rotation between the shank and foot segments is not constant and likely not consistent with the assumptions made for inverse dynamics calculations. This is a problem with any prosthetic foot that relies on the deformation of the foot to provide movements (Sawers & Hafner, 2011).

The unified deformable (UD) segment model overcomes the problem of calculating prosthetic foot push-off power by calculating total power generated below the knee joint and is not dependant on ankle joint center movement (Takahashi et al., 2012).

The purpose of this study was to 1) define if the fixed ankle joint center assumption inherit with traditional calculation of ankle joint power was acceptable when evaluating the Össur Proflex which uses a deformable carbon fiber heel and forefoot sections in conjunction with a linkage system, and 2) evaluate the performance of the Össur Proflex foot to generate more push-off power than a variflex foot.

METHOD

When providing your methods, you should use the standard presentation adopted in scientific papers.

Subjects: A person with a uni-lateral transtibial amputation (82 kg, 1.65 m, 55 y/o, K3) provided informed consent for this IRB approved study.

Apparatus and procedures: The participant walked at on an instrumented dual belt treadmill for four different conditions (0.7, 1.1, and 1.3 m/s at 0 pitch angle and 1.1 m/s at 7.5 degree incline) while first wearing the Össur Variflex foot that he currently uses and then a Össur Proflex foot. The order of conditions were randomized. The Human Body Model markerset was modified to include three additional markers on the both shanks to allow simultaneous calculation of ankle power with traditional inverse dynamics and the UD model. Kinematic data (100 Hz) and ground reaction force data (1000 Hz) was collected in Vicon Nexus 2.2.

Data Analysis: Data was processed in Visual3D.

RESULTS

Traditional methods of assuming a fixed ankle joint center and using inverse dynamics tended to overestimate push-off power compared to the UD model (Figure 1). The Proflex foot delivered more push-off power than the variflex foot but not as much as the sound limb ankle joint (Figure 1).

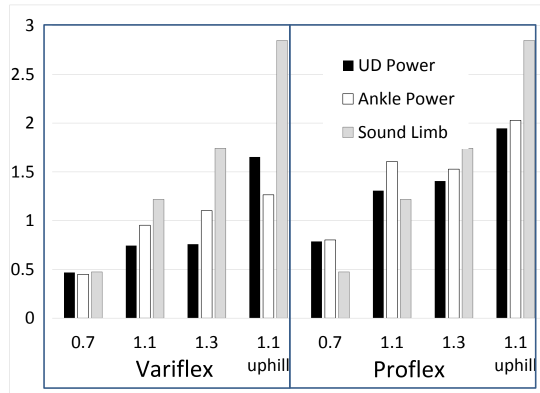

Figure 1. The Proflex foot consistently delivered more push off power than the variflex foot. The proflex foot was able to deliver similar power output to the sound limb at slow speeds but not faster (normal walking speeds) and uphill. Vertical axis is in Watts/kg sec.

DISCUSSION & CONCLUSION

The use of traditional inverse dynamics to calculate ankle joint power can show similar peak power output to a normal/intact foot/ankle system and this may lead to inaccurate interpretation of prosthetic foot performance.

Therefore the evaluation of any deformable prosthetic foot should use the UD model that does not depend on assuming a fixed ankle joint center. The true effect on knee osteoarthritis risk was unclear and more data will be necessary before any definitive statements can be made on how the additional push-off provided by the Proflex foot could reduce secondary health complications.

CLINICAL APPLICATIONS

Improving the methods to evaluate prosthetic feet will better demonstrate the biomechanical advantages of energy storage and return feet.

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ACKNWOLEDGEMENTS

The Össur Proflex foot was provided by Össur ehf

TURNING BIOMECHANICS OF LOWER-LIMB PROSTHESIS USERS WITH A HISTORY OF FALLS

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INTRODUCTION

Turning and curved-path walking are challenging for prosthesis users. The Figure-of-8 Walk Test (F8WT) combines straight and curved-path walking, can be conducted in small spaces, and requires participants to turn towards the prosthesis and sound limbs (Hess, 2010). Turn biomechanics can be measured with small, wearable sensors and the data obtained may help to differentiate between fallers and non-fallers. The purposes of this study were to (1) establish test-retest reliability of the instrumented F8WT and (2) investigate turn biomechanics of unilateral lower-limb prosthesis users with and without a history of falls.

METHOD

Subjects: Sixty-eight unilateral transtibial (TT) and transfemoral (TF) prosthesis users were enrolled in this IRB approved study. The TF group included one knee and one hip disarticulation. Nine participants repeated the experimental protocol to obtain test-retest reliability.

Apparatus: Fall history over the past year was self-reported by participants. Four wireless triaxial inertial measurement units (Opal, APDM, Inc., Portland, OR) were secured to the sternum, lumbar spine, and feet using elastic straps. Each sensor recorded at 128 Hz.

Procedures: Participants walked as quickly and smoothly as possible around a pair of cones (spaced 1.525 m apart) in a figure-of-8. Two laps were performed without pausing.

Data Analysis: Angular velocity in the transverse plane at the lumbar spine (L5) was measured with the gyroscope. Outcome measures were peak angular velocity when turning towards the prosthesis (p-turn), peak angular velocity when turning towards the sound limb (s-turn), and turn asymmetry index (turn-ASI) (Herzog, 1989).

Test-retest reliability of the outcome measures were examined using intraclass correlation coefficients (ICC(2,1)). Mann Whitney U tests were used to compare TT fallers and non-fallers and TF fallers and non-fallers. Alpha was set to .05 *a priori*.

RESULTS

Outcome measures were reliable: p-turn (ICC = .910), s-turn (ICC = .830), and turn-ASI (ICC = .780). No significant differences were identified between TT fallers and non-fallers. TF non-fallers resulted in significantly greater turn-ASI (30.4% ± 21.9%) ($p = .008$) as compared to fallers (12.9% ± 20.6%) (Figure 1).

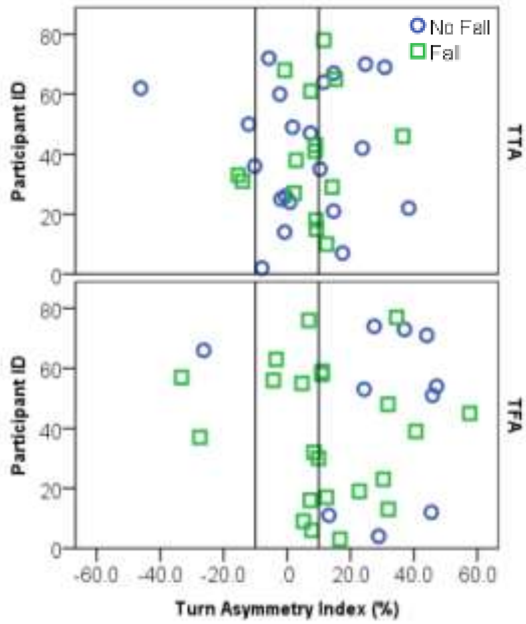

Figure 1. Scatterplot of turn-ASI for TT (n = 35, fallers = 14) and TF (n = 33, fallers = 22) prosthesis users. Vertical lines are ± 10% which is considered symmetric.

DISCUSSION

TF non-fallers had greater asymmetry when turning towards the sound limb. Turns and curved-path walking towards the sound limb require decreased stride length of the sound limb and increased stride length of the prosthetic limb, while simultaneously shifting the body's center of mass to the sound limb (Hess, 2010). This asymmetry may be a successful protective mechanism in TF prosthesis users to prevent falling.

CONCLUSION

The instrumented F8WT is a reliable test for unilateral lower-limb prosthesis users. TF non-fallers have significantly greater turn asymmetry when turning towards their sound limb as compared to TF fallers.

CLINICAL APPLICATIONS

The instrumented F8WT allows quantification of turn and curved-path walking performance and may provide greater resolution to identify fall risk when combined with traditional clinical outcome measures.

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Variable Stiffness Torsion Adaptor: Pilot Study with Transtibial Amputees

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INTRODUCTION

Complex gait maneuvers with large transverse plane motion such as turning account for a significant portion of daily steps (Glaister, 2009; Srisuwan, 2016). Transverse rotation adapters have been shown to have beneficial effects (Su, 2010; Buckley, 2002; Segal, 2014), but their stiffness is only adjustable by a prosthetist and are unable to adapt to the varying activities of daily living. A variable stiffness torsion adaptor (VSTA) may be beneficial for individuals capable of complex gait (Pew, 2015).

The aim of this research is to determine if the VSTA can reduce residual limb torsional loads without impeding mobility.

METHOD

Subjects: Five male, unilateral, transtibial amputees (mean ± standard deviation; age: 53 ± 14 years, mass: 87 ± 12 kg, height: 1.82 ± 0.05 m) provided informed consent to participate in this institutional review board-approved study.

Procedures: A certified prosthetist fit each participant with the study prosthesis which included their as-prescribed socket and suspension, an iPecs load sensor (College Park), the VSTA, and a Vari-Flex Low Profile (Össur) foot.

Self-selected walking speed (SSWS) was determined while traversing a 20 m hallway. Peak transverse plane moments were measured while subjects performed five walking tasks at SSWS: straight walking, 90° spin turn, 90° step turn, 180° turn, and the L Test of Functional Mobility (Deathe, 2005). Subjects were blinded to the VSTA stiffness which was block randomized to three fixed conditions: compliant (0.30 Nm/°), intermediate (0.57 Nm/°), and stiff (0.91 Nm/°) for five repeated trials of each of the five activities (75 total trials per subject).

Data Analysis: A linear mixed effects model with random effects for intercept and slope within individual subjects (Matlab) was used to determine if differences due to stiffness were statistically significant ($p<0.05$).

RESULTS

Significant reductions in peak transverse plane moments (Table 1) between the *stiff* and *compliant* settings occurred for all three turning maneuvers. The 90° spin turn and the 180° turn had an average reduction of 40 Nmm/kg while the 90° step turn had an average reduction of 14 Nmm/kg, or 23%, 40%, and 22% respectively. Smaller reductions, some statistically significant, occurred between other stiffness settings (Table 1).

	Compliant	Intermediate	Stiff
Straight Walk[c]	82±24	70±18	88±20
90° Spin Turn[a,b]	132±18	151±22	172±25
90° Step Turn[b,c]	-51±13	-51±12	-65±13
180° Turn[a,b,c,]	-65±6	-85±9	-109±18

Table 1. Peak transverse plane moment normalized by body mass (Nmm/kg). Internal rotation is positive, external rotation is negative. [a]Compliant v Intermediate p<.05, [b]Compliant v stiff p<.05, [c]Intermediate v stiff p<.05.

The mobility metrics (Table 2) exhibited no significant differences between stiffness settings for either self-selected walking speed or the L Test of Functional Mobility.

	Compliant	Intermediate	Stiff
SSWS (m/s)	1.3±0.0	1.4±0.0	1.3±0.0
L Test (s)	22.1±0.5	22.4±0.8	22.3±0.7

Table 2. Mobility measures.

DISCUSSION

These results (n=5) suggest that activities requiring high levels of transverse plane motion (90° spin, 90° step, and 180° turns) had significantly reduced peak transverse plane moments at the socket for the *compliant* stiffness versus the *stiff* stiffness. Additionally, use of the VSTA did not impede mobility (SSWS or L Test of Functional Mobility) across the three stiffness conditions.

CONCLUSION

These pilot study results suggest the development of a variable stiffness torsion adapter with a controller that can detect transverse plane motion and select the appropriate transverse plane stiffness is warranted.

CLINICAL APPLICATIONS

A variable stiffness torsion adapter might reduce residual limb injuries in persons with lower limb amputation who are capable of complex gait maneuvers.

ACKNOWLEDGEMENT

Supported by: Dept. of Veterans Affairs, Rehabilitation Research and Development Service (A9243C and A9248-S), Dept. of Education (GAANN P200A130025), and Dept. of Defense (W81XWH-09-2-0144).

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Perspiration and Secure Suspension for Lower Limb Amputees in Demanding Environments

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INTRODUCTION

Lower limb amputees often complain about uncomfortable residual limb skin temperatures, accumulation of perspiration inside their prostheses, and loss of confidence in suspension security (Klute, 2014; Klute, 2016; Hagberg, 2001). This study compared a prosthesis designed to unobtrusively expel perspiration with a standard-of-care prosthesis in hot and humid environments.

METHOD

Subjects: Five transtibial amputees provided informed consent to participate in this institutional review board-approved protocol (49±12 yo, 93±14 kg, 1.82±0.06 m, 19±15 years post-amputation, n=4 trauma, n=1 secondary to infection). All participants considered themselves moderately active community ambulators.

Procedures: Subjects (n=5) were fit a modified patellar tendon bearing socket and two study suspensions: (1) a distal PIN locking liner and (2) an innovative suspension that included a pump to induce dynamic air exchange (DAE) between the liner and the residuum, allowing expulsion of any accumulated perspiration. Subjects were randomized to study prosthesis and asked to walk at their self-selected speed on a treadmill in an environmental chamber at 50% relative humidity (RH) and 20, 30, and 35° C, presented in random order. A 26 cm^2 absorbent patch was also placed on the lateral calf of the contralateral limb. While in the chamber, subjects rested while seated for 30 min, then walked for 30 min or until they lost confidence in the security of their prosthetic suspension, and then rested outside the chamber (~50% RH, 20° C) while seated for 30 min. Perspiration amounts were measured by tare weight (g) at the end of the protocol. Liner slippage (n=2) was measured by marking the skin at the proximal border of the liner prior to the protocol and measuring the distance (mm) between the mark and the liner at the end of the protocol.

Data Analysis: A linear mixed model was used to determine if differences in contralateral limb perspiration were statistically significant ($p<0.05$). Others were not statistically analyzed.

RESULTS

No subject lost confidence in the security of their suspension; all walked for 30 min in all conditions. One subject experienced pistoning at 30 and 35° C while wearing the PIN, but was confident to continue the protocol. Liner slippage (n=2) was greater for the DAE than PIN at 20° C but greater for PIN than DAE at 35° C (Table 1). The DAE accumulated more perspiration (Table 2) and resulted in more total perspiration (accumulated + expelled) than PIN at each temperature. Individual results were highly variable as indicated by the large standard deviations. The DAE prosthesis expelled 51, 11, and 20 percent of the total perspiration at 20, 30, and 35° C, respectively. No difference in contralateral limb perspiration was observed across temperature ($p>0.05$).

	20° C	**30° C**	**35° C**
PIN	5±5	17±19	46±34
DAE	21±29	17±23	33±43

Table 1. Liner slippage (mean ± standard deviation) from two subjects (mm).

	20° C	**30° C**	**35° C**
Accumulated in PIN	0.0±0.1	0.6±0.8	1.3±1.8
Accumulated in DAE	0.3±1.0	2.0±2.8	4.1±5.9
Expelled by DAE	0.3±0.2	0.3±0.2	1.0±1.4
Contralateral limb PIN	0.2±0.1	0.5±0.5	0.5±0.3
Contralateral limb DAE	0.5±0.9	0.3±0.2	0.5±0.4

Table 2. PIN and DAE perspiration (mean ± standard deviation) from five subjects (g).

DISCUSSION

Even at 35° C, all subjects were able to walk for 30 min without losing adherence, suggesting a more demanding protocol is needed to identify loss of suspension thresholds. The DAE liner slipped more than PIN at 20° C, but the PIN slipped more than DAE at 35° C, suggesting the heavier DAE may be beneficial in more demanding conditions. The DAE expelled a portion of the accumulated perspiration at each temperature, but subjects perspired more while wearing it compared to the PIN.

CONCLUSION

These interim results suggest that despite greater perspiration while wearing the DAE, it may provide greater adherence (less slippage) in demanding conditions. Enrolling additional subjects is warranted.

CLINICAL APPLICATIONS

Dynamic air exchange technology may improve the mobility and comfort of individuals who need to maintain a secure suspension in demanding conditions.

ACKNOWLEDGEMENT

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CHANGES IN PRESSURE DISTRIBUTION WITH AN ADJUSTABLE SOCKET

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INTRODUCTION
An appropriate distribution of pressure within a prosthetic socket is essential for biomechanical control, containment, comfort, and maintaining skin integrity. (Brienza, 2001). Pressure distribution is dependent on socket configuration, shape, volume, and the socket materials. Prosthetists justify socket billing based on their view that shape and construction of the socket affect distribution of forces on the residual limb and clinical outcomes. However, little research has been done to quantify and validate this assumption.

Our hypothesis is that targeted shape changes in an adjustable socket will result in changes to the pressures applied by the socket onto the residual limb during gait.

METHOD
Strain gauges and thin force sensors were integrated into an adjustable ischial containment socket. The strain gauge was incorporated into the socket's closure system. Force sensors were attached to the socket's distal end, along the long axis of the socket and at the ischial containment aspect of the socket. These sensors effectively mapped pressure distribution within the socket and the tension within a proximal strap. Triplanar motion sensors were incorporated to the socket to measure socket movement. Sensor data were recorded while the patients performed functional tests.

A convenience sample of 10 randomly selected patients were instructed to find a perceived neutral fit then increase and decrease the tensioner by 25 lbs. to create a tight/smaller volume and loose/larger volume variable. Adjustment of the tension value for this adjustable socket system directly correlates with socket shape and volume. L-test, two-minute walk test, and FSST functional outcomes measures were conducted at these variables and associated with sensor data. Patients also recorded a Socket Comfort Score at the conclusion of functional outcomes measures at each variable.

RESULTS
Data analysis across different users showed statistically significant trends. Taking the neutral position as baseline, the patients generated greater pressure in the proximal and ischial containment aspects of the socket, while reducing pressure on the distal end by tightening the closure system and thereby reducing socket volume. Conversely, when the patients loosened the closure system, the pressure in the proximal and ischial containment aspects of the socket decreased, and the pressure on the distal end increased.

When performing outcome measures, a loose closure system generated greater data variability for a given sensor (a large difference between high and low values). When the closure system was tightened, the average pressure increased in the proximal sensors, and sensor data variability was lowest.

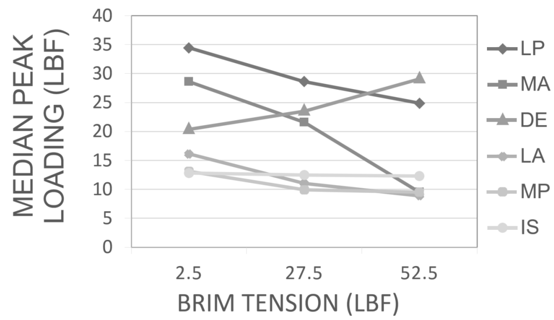

Figure 1: Effect of Varying Brim Tension on Pressure Readings within the Socket

DISCUSSION
By increasing the tension in the closure system, patients could change the relative pressure distribution. When the closure system was loose, patients experienced higher distal pressure. When the socket tension was tight, pressure in proximal and ischial containment aspects of the socket increased.

Functional outcome scores and socket comfort scores were lowest at the loose setting. This correlates with the increased variability in pressure distribution data during functional outcomes measures. These results indicate decreased biomechanical control and higher peak pressures when the socket fit was loose. Conversely, when the closure system was tight, variability in pressure readings decreased for each sensor, indicating good connectively between the limb and socket. Functional tests performed with the tightened brim yielded better outcomes, which can be explained with better connectivity and thus better biomechanical control.

CONCLUSION
Results indicate a direct correlation between socket shape and resultant forces on the residual limb, functional outcome measures, as well as Socket Comfort Score. Future studies will be directed to increasing the number of patients tested to further validate this correlation.

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

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A Computational Tool to Assess Limb-Socket Interface

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INTRODUCTION

Prosthetic fit and liner selection are two of the most fundamental and important features of a prosthesis. Changes in socket fit (Sanders, 2005) and liner product (Ali, 2012) can produce changes in contact pressures by as much as 25%. However, it is not well established what variations occur from person to person due to differences in the shape and size of a residual limb. By understanding how loads are transmitted through different residual limbs, practitioners may be able to better anticipate and develop improved strategies to accommodate patients experiencing mechanically induced skin breakdown.

METHOD

Magnetic resonance images (MRI) were taken of three residual limbs characterized as cylindrical, short-conical, and long-conical. One participant using a uniform thickness liner in their prescribed prosthesis was recruited for each limb shape.

Participants were first fit with a new liner (Ossur Dermo) of a 6mm uniform thickness profile. The participants' prescribed sockets were digitized, and then a series of custom-designed, MRI-compatible prosthetic sockets were fit until a single socket was found that achieved a comfortable fit with no socks.

Using the custom-designed sockets, participants were scanned to capture the geometries of the limb, liner, prosthetic socket, and distal air gap. From these scans, finite element models were created to evaluate the influence of limb shape, socket size, and liner material on load transmission pathways.

RESULTS

A small range in participant weight (84-92 kg) meant that limb shape (Fig. 1) varied significantly compared to ambulatory load. The range of limb circumference and tibial length were 30-38cm and 13-19cm.

Figure 1. Coronal views illustrating the characteristic shapes of short-conical, cylindrical, and long-conical.

All limbs exhibited multiple pathways of major load transmission. The patellar tendon was a common pathway to all limbs, while the others were specific to general limb shape (Fig. 2).

The short-conical limb was true total surface bearing, with a major pathway on the anterior-lateral aspect.

The cylindrical limb transmitted loads through the curved surfaces of the brim and distal socket.

The long-conical limb transmitted loads through bony features on the proximal medial and lateral aspects.

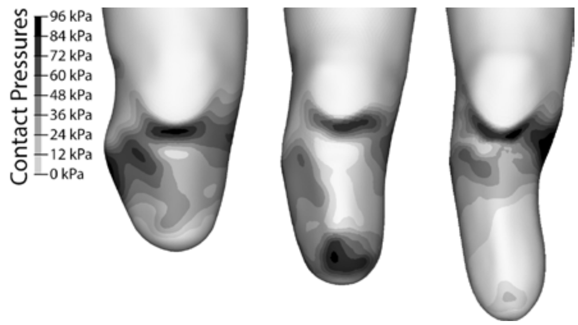

Figure 2. The cylindrical limb (middle) was not able to effectively transmit loads through desirable pathways on the anterior aspect, showing an adverse focal pressure over the anterior-distal tibia.

DISCUSSION

When queried before and after the study, the participant with the short-conical limb reported the highest satisfaction with his prescribed prosthesis. Despite his limb's short length, this model had the lowest peak and best distributed contact pressures.

Conversely, the participant with the cylindrical limb replaced his prescribed prosthesis shortly after the study concluded, because of an inflamed bursa and skin breakdown over the distal tibia.

The participant with the long-conical limb reported the lowest satisfaction with his prescribed socket, but did not have it replaced. This was reflected in the model, which showed peak pressures 21% and 28% higher than the cylindrical and short-conical limbs.

CLINICAL APPLICATIONS

Each limb-socket geometry had a specific set of pathways for transmitting ambulatory loads. The short-conical limb presented angled surfaces for distributed load transmission on all aspects, while the two remaining sockets had at least one overhanging surface that was unable to support any load. These sockets used internal curvatures to transmit loads at the cost of increased localized peak stresses. Further research will help determine socket adjustments and liner selections that can improve localized stresses.

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Scientific Symposium
March 1-4, 2017

The Effect of Transfemoral Prosthetic Interface Design on Gait Biomechanics Using a CAREN System: IRC Compared to Sub-Ischial

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INTRODUCTION

Prosthetic socket design is evolving and the introduction of new materials and techniques allow for alternative designs. The addition of a vacuum assisted suspension has been reported to allow lower more comfortable trim lines. Lowering these trim lines for the transfemoral prosthetic socket interface reportedly increases comfort and range of motion. Additionally, these alternative trim lines decrease pressure and show equivalence in the areas of gait, skeletal kinematics, mobility and balance compared to the standard of care ischial ramus containment (IRC). However, it is unknown whether lowering trim lines and eliminating IRC will compromise gait biomechanics. This preliminary project proposal will examine the biomechanical gait effects of a transfemoral amputee using a Computer Assisted Rehabilitation ENvironment (CAREN). This project compared the effect of IRC to Sub-Ischial vacuum assisted suspension (VAS) transfemoral interface design on gait biomechanics using a CAREN system on a single case matched subject.

METHOD

Subjects: One amputee subject, a 37y Right TFA Female was used.*Apparatus*: This experiment was conducted on the CAREN system.

Procedures: Two different TFA interface designs were fit; IRC and VAS Sub-Ischial. Both reported as a socket comfort score =10, and then compared. . The subject experienced scenarios based on the CAREN's ability to simulate different walking conditions and perturbations. The five randomized scenarios (Foot Slip, Tread Deceleration, Missing Step, Height Change, Unstable Ground) at 3 different speeds was observed and carried out as one experiment.

Data Analysis: The subject's motion was recorded using reflective markers placed on the subject according to the human body model. The motion capture and force data was continuously recorded for the duration of the trial.

RESULTS

The IRC interface with suction suspension pistoned 5mm more than the VAS Sub-Ischial interface from swing to stance phase. The subject's Center of Mass (COM) displaced 2cm less on the IRC interface than the VAS Sub-Ischial interface during gait. The subject reported improved socket comfort (SCS VAS=10, IRC=7) and less pain (VAS=0, IRC 4) on the VAS interface design, during the experiment.

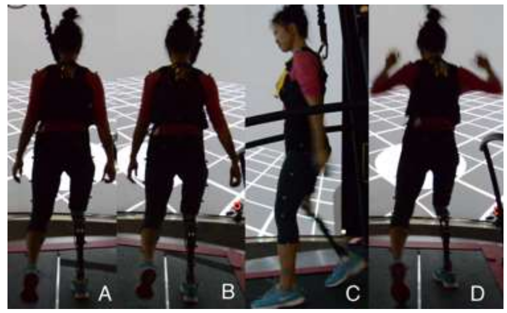

Figure 1. Amputee subject on the CAREN system, which can simulate perturbation and walking scenarios by A) Rolling to the left, B) Rolling to the right, C) Pitching down (or up), and D) Creating a foot slip scenario by suddenly stopping one side of the treadmill. These are just 4 examples of the many scenarios it can simulate. Coupled with a visual environment CAREN can safely record video and biomechanical analysis of an intervention's effectiveness in a multitude of environments.

DISCUSSION

The CAREN is a new outcome measure instrument, which has the ability to offer many gait and perturbation scenarios through a split belt treadmill, 6 degrees of freedom and visual environment, while collecting biomechanical data and video. There is a scarcity of evidence regarding the effect of TFA interface design, particularly newer technology such as a VAS Sub-Ischial. This pilot study of a single control matched case demonstrated TFA interface design can have an effect on gait biomechanics, pain and socket comfort. A larger, funded clinical trial could provide answers as to population relevant interpretations of TFA interface design.

CONCLUSION

In a single case, TFA interface design effected pistoning, pain and socket comfort; improving for the VAS Sub-Ischial. TFA interface design effected center of mass displacement; improving for the IRC

CLINICAL APPLICATIONS

The CAREN represents the ideal instrument to evaluate biomechanics when simulating walking and perturbation scenarios.

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HYBRID VACUUM PUMP FOR VACUUM-ASSISTED SUSPENSION IN TRANSFEMORAL PROSTHESES

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INTRODUCTION

Evidence suggests that vacuum assisted suspension (VAS) reduces relative motion between the residuum and prosthetic socket to improve force transmission, comfort and soft tissue health (1, 2). VAS is achieved through evacuation of air between the liner-clad residuum and prosthetic socket by vacuum pumps. Commercial pumps often have a tall build height and can be noisy (electric) or require extended time to generate vacuum (mechanical). There is need for a low-profile pump for use with transfemoral prostheses that works quietly and quickly generates vacuum when desired while conserving battery life. This study describes a hybrid vacuum pump, known as Northwestern University Hybrid Integrated Prosthetic Pump Initiative (HIPPI), that was developed to address this need by integrating electric and mechanical function into a single design (Patent US9066822, Pending 62/214,560) (3).

METHOD

The HIPPI concept relies on combined electric and mechanical function to create vacuum within the liner-socket interface. Two prototypes were developed (first with a bladder and then with a diaphragm); the bladder pump, was evaluated on the bench, and during walking using prosthesis simulators as well as a transfemoral prosthesis.

Subjects: Able-bodied individual (simulator test) [35 years, 185 cm, 78 kg]; unilateral transfemoral amputee (prosthesis test) [54 years, 183 cm, 97.5 kg].

Apparatus: A digital pressure gauge (DigiVac, Matawan, NJ) monitored vacuum during all testing with the bladder pump.

Procedures: Bench testing: A hydraulic machine (Instron, Norwood, MA) subjected the HIPPI to 300 cycles of 10 mm displacement. Simulator testing: Subject walked (0.53 m/s) for 10 min after the electric pump generated 17 in-Hg. Prosthesis testing: Subject walked (0.53 m/s) for 10 min after the electric pump generated 17 in-Hg using two pumps: 1) LimbLogic electric pump (Ohio WillowWood, Mt. Sterling, OH), and 2) HIPPI bladder pump.

RESULTS

Bladder and diaphragm pump prototypes and vacuum gauge pressure results for the different conditions of testing the bladder prototype are shown in Figure 1.

DISCUSSION

Testing demonstrated that the HIPPI bladder prototype can rapidly generate vacuum through the electric system, and sustains vacuum during walking through the mechanical system to minimize electric reactivation and maximize battery life. Off-axis loading of the bladder during walking encouraged a redesign that included a diaphragm component that, due its cup architecture, provided for more reliable function.

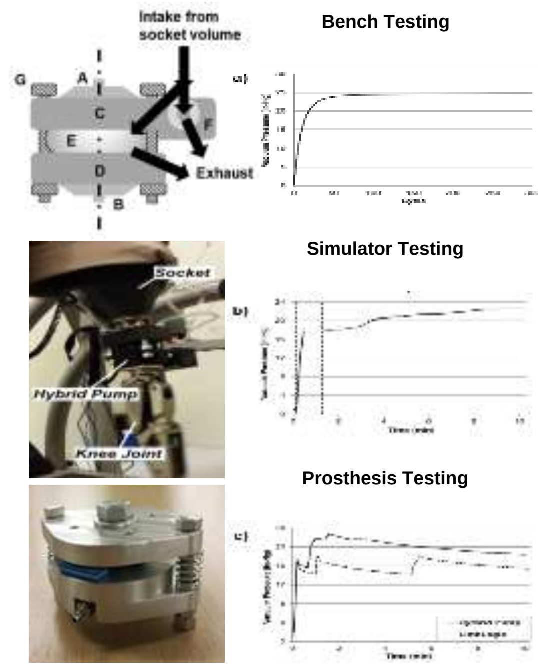

Figure 1. Top Left: HIPPI schematic (bladder pump): A&B) pyramid adapters, C&D) housing plates, E) bladder, F) electronics, and G) guide posts. Solid arrows indicate air flow. Middle Left: Transfemoral prosthesis installation. Bottom Left: HIPPI diaphragm prototype. Right: Vacuum gauge pressure for different testing conditions. For simulator testing, first and second dashed vertical lines represent initiation of the electric system and walking, respectively.

CONCLUSION

Testing has confirmed proof-of-concept that the HIPPI can generate VAS in transfemoral prostheses.

CLINICAL APPLICATIONS

The HIPPI has utility for users who experience excessive time to create sufficient vacuum when using only a mechanical pump (e.g., elderly) and risk incurring residuum trauma, or who desire immediate use of their prosthesis post-donning (e.g., engaging in sporting activity or the military).

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QUANTIFICATION OF RECTIFICATIONS FOR THE NORTHWESTERN UNIVERSITY FLEXIBLE SUB-ISCHIAL VACUUM (NU-FlexSIV) SOCKET

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INTRODUCTION

The fit and function of a prosthetic socket depends on the prosthetist's ability to properly design the socket's shape to distribute load comfortably over the residual limb. Traditionally, the prosthetist achieves the desired shape by either removing or adding plaster to specific regions on a positive plaster model of the residual limb. As proposed by Sidles et al.[1] rectification maps can be used as a tool to teach prosthetists how to modify a positive mold for specific socket designs. We recently developed a new socket technique for persons with transfemoral amputation named the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket[2]. The aim of this study was to quantify the rectifications required to fit the NU-FlexSIV Socket in order to teach the technique to certified prosthetists as well as provide a central fabrication option via Computer Aided Design-Computer Aided Manufacture (CAD-CAM).

METHOD

The following steps were taken to quantify the rectification process for the NU-FlexSIV Socket: (1) create a pair of negative cast molds (NCMs) of unrectified and rectified positive molds, (2) digitally scan each pair of NCMs, (3) align each pair of NCM scans using a closest point algorithm, and (4) calculate the difference in depth at each point between each pair of NCM scans. The average of the differences in depths across each pair of NCM scans was used to create an average rectification template[3]. The average template was shared with a central fabrication facility to assess how it performed when used to fulfill requests for CAD-CAM fabrication of the NU-FlexSIV Socket.

RESULTS

30 unrectified and rectified cast pairs from NU-FlexSIV Sockets that were successfully fit in clinical practice were collected and scanned to create 30 color-coded rectification maps. The rectification maps confirmed that for the NU-FlexSIV Socket, plaster from the positive mold was primarily removed from the proximal-lateral and posterior regions; no plaster was added (Figure 1). The average template was used to fabricate fifteen NU-FlexSIV Sockets for five certified prosthetists (CPs). Feedback from the central fabrication facility indicated that the template worked reasonably well for the initial check socket; typically, the only adjustment needed was to add a pad to tighten up the proximal medial-lateral dimension.

Awarded and administered by the U.S. Army Medical Research and Materiel Command Acquisition Activity (#W81XWH-10-1-0744).

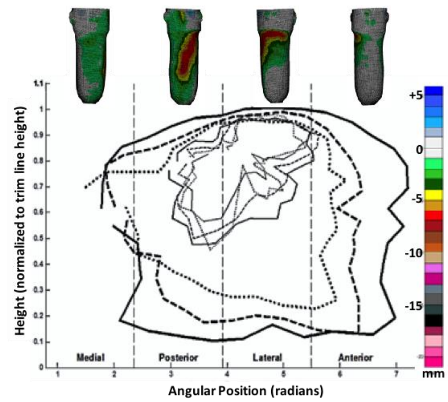

Figure 1 Illustrative color-coded rectification map shown above contour plot of the average template.

DISCUSSION

Rectification maps quantified the depths and contours of the modifications that were made for the NU-FlexSIV Socket. The exemplar rectification map was used as part of a series of 2-day hands-on continuing education workshops to teach CPs the rectification process required to fit and fabricate the NU-FlexSIV Socket[2]. 28 of the 30 CPs who participated in these courses successfully fit a check socket version of the NU-FlexSIV Socket on their first attempt and described the process as *"straight forward, reproducible"* [2]. Initial experience using the average template as part of central fabrication of the NU-FlexSIV Socket suggests that the template currently underestimates the magnitude of material removal needed in the proximal-lateral region. The 30 cast pairs used to create this initial template were collected during a period when the technique was not at full maturity and likely incorporate greater variability than the current technique. Having taught a fully mature version of the technique successfully, we are currently collecting more cast pairs to help refine this aspect of the average template.

CONCLUSION

Rectification maps and a template quantified rectifications needed to fit the NU-FlexSIV Socket.

CLINICAL APPLICATIONS

Rectification maps and template help communicate an important step in the fabrication of the NU-FlexSIV Socket facilitating dissemination of the technique and providing an alternative fabrication option via CAD-CAM and central fabrication.

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Improving Upper Limb Function in Chronic Stroke Utilizing Custom Myoelectric Bracing: A Case Report

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INTRODUCTION

Every year in the U.S. approximately 795,000 people experience a stroke. 85% of that group exhibit hemiparesis, and between 55-75% of survivors continue to experience upper extremity (UE) functional limitations even after 6 months (Wolf et al., 2006). For many people, traditional interventions may not result in restored bilateral function, and leave them seeking alternative solutions. This case report highlights one such alternative – the MyoPro® custom-fabricated, myoelectric elbow-wrist-hand orthosis (MEWHO).

The Myopro® uses surface sensors - built into the orthosis and located over the bicep and tricep muscles - detect the user's electromyographic (EMG) signal once he/she initiates a muscle contraction. The EMG signal activates a motor to move the elbow in the desired direction, proportional to muscle output. An additional set of sensors are positioned over the wrist flexors and extensors. EMG output from these sensors power a motor to open and close the fingers in a 3 jaw-chuck grip pattern, upon user initiation.

METHOD

The participant is a 41 year old, right hand dominant woman diagnosed with left cavernous hemangioma in July 2009, with residual right hemiparesis. She received her MEWHO in 2014 and completed 21, 1 hour outpatient therapy sessions over 10 months, dedicated to training with her device. Outcomes included the UE component of the Fugl-Meyer (FM), the Wolf Motor Function Test Functional Ability Score (WMFT-FAS), the Box and Blocks (B&B) test and therapist observation of functional tasks. UE measurements of strength, range of motion (ROM) and spasticity (MAS) were also taken. Baseline assessments were taken without the orthosis. Subsequent testing was done with the participant wearing the orthosis (with the exception of the MAS). The participant also completed a log for 2 months every time she used her device at home.

RESULTS

The participant demonstrated statistically significant improvements across all measures. There was a 15 point increase in the FM scale, a 16 point increase in the WMFT-FAS and a 4 block increase in the B&B test between baseline (without orthosis) and discharge (with orthosis). The participant also demonstrated an improved ability to perform bilateral, gross motor tasks while wearing the MEWHO, such as carrying a laundry basket, taking out the trash and cutting food bilaterally. She was also able to return to work (with her orthosis) at a cosmetics retail store. Additionally, after 10 months of training, the participant began to exhibit a return of voluntary muscle activity in the wrist and finger extensors. Testing also showed a 1 point decrease in spasticity in the elbow, wrist and finger flexors, and increased ROM and strength both with and without the MEWHO on.

DISCUSSION

Over 10 months and under clinical supervision and training, the participant demonstrated improvements in the utilization of her affected extremity and subsequently, her level of function and independence. Consistent use of this orthosis also resulted in improvements in the ROM, strength and spasticity in her paretic arm including hand function both with and without the orthosis on. The improvements in scores relating to grasp/release and 3 jaw chuck pinch are particularly significant and translate into a better ability to complete tasks that previously required assistance from caregivers. Additional case studies and larger clinical trials are recommended to further investigate the benefits of the MyoPro® MEWHO.

CONCLUSION

The MyoPro® is a portable, custom fabricated MEWHO that was shown to provide the participant with paretic UE support and enhanced ROM that facilitated increased function and independence with ADLs, household management, family care and work tasks. This case report builds on the existing literature supporting MEWHOs as treatment options for paretic upper limbs (Page, 2013).

CLINICAL APPLICATIONS

The availability of custom fabricated myoelectric orthoses presents practitioners with a unique tool to offer patients with UE impairments, who have previously not had any options for improving their independence and upper limb function.

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Case Study: Upper Extremity Dynamic Orthoses in an Individual with Arthrogryposis

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INTRODUCTION
Arthrogryposis is a term used to describe congenital contractures that effect two or more parts of the body. Upper extremity involvement may include internal rotation of the shoulder, extension of the elbow, pronation of the forearm, and wrist/finger flexion (Bamshad,2009) Treatment for children with arthrogryposis may include passive stretching programs, serial casting, and surgical intervention (Smith, 2002). The goals of these treatments are to increase joint mobility and function (Smith 2002).

In this paper we will look at a single case study of two dynamic orthoses used in an individual with upper extremity involvement arthrogryposis.

METHOD
The patient is a male that was seen at The Rehabilitation institute of Chicago (RIC) both as an inpatient and outpatient from the ages of 1 to his current age of 4. Our orthotic goal for this patient was to improve range of motion and mobility in order to achieve more functional independence.

As the patient progressed in occupational therapy, a dynamic orthosis was introduced. The first orthosis was based on a prototype by his occupational therapist Katie Davis, OTR/L. From this, two orthotist from RIC developed a trunk orthosis with dynamic flexion assist, termed "the Batsuit." The Batsuit was used for approximately two years. This device consisted of a "vest style" TLSO and elastic bands traveling from the posterior vest, over the shoulder to attach to the wrist pieces to promote shoulder and elbow flexion assist. The vest was used over a TLSO for its ability to cross the shoulder joint and allow the individual continue to develop his own core strength and balance while minimizing trunk extension.

The second orthosis used is the Wilmington Robotic Exoskeleton (WREX). The WREX is produced by JAECO. It is a balanced forearm orthosis that is attached to a wheel chair. It uses rubber bands to partially unweight limb and enhance the individual's active movement. A lighter, 3-D printed, and slightly modified version that attached to a trunk orthosis developed by Tariq Rahman, PhD at DuPont (Rahman et al.2006). This system was ideal for the size and activity level of the patient.

RESULTS
In The Batsuit range of motion improvements were observed in both active elbow flexion and to a lesser extent shoulder flexion (Table 1). More importantly, for his goals, he was more independent. Prior to this orthosis he wasn't able to sit and play without outside assistance. In the orthosis he could clap, play, interact with his environment, and begin to work on self-feeding. As the patient grew a plateau effect was noted and increasing the tension no longer had an effect. It became clear that a more robust system was needed.

Patient's Active ROM (in Degrees)				
	Out of vest		In Vest	
	Elbow	Shoulder	Elbow	Shoulder
Right	About 0-20	80	55	85
Left	About 0-20	64	73	55

Table 1: Individuals active and passive range of motion in and out of orthosis

The WREX system was then put into use. It has only been in use for 3 months. A major material failure was observed at less than 1 month use due to excessive tension on a nut and bolt at the wrist. The device was repaired and now uses a bolt without nut. Patient and parent acceptance took time, but eventually he was able to utilize the device successfully. He is able to self-feed and groom, and overall is more functionally independent in the WREX.

DISCUSSION
The Batsuit was used early on in treatment. Eventually a point of diminishing return was observed due its inability of the materials to resist his tension as he grew. Stronger materials used in a similar fashion may have been successfully, but this was not explored. At this time, age also could have played a significant factor in results as he didn't always respond to directions.

The WREX also had positive results, however in the beginning we experienced material failure as well as tolerance issues. Once repaired no issues have been reported. The family thought the device was rather "bulky" in size and patient didn't like being in the WREX initially. The patient was eventually able to adjust to the orthosis and successfully use. The long term benefits of the device are yet to be seen as has only been using this device for 3 months.

CONCLUSION
The use of these two dynamic orthoses on this particular patient was effective, both were not without

Case Study: Upper Extremity Dynamic Orthoses in an Individual with Arthrogryposis

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their flaws. The uses of these devices is fairly new. There may be room for improvement on strength and size materials used. It is important to note that both devices were used in conjunction with occupational therapy, use without therapy was not determined.

CLINICAL APPLICATIONS

This case study on a single individual with a single diagnosis. These devices were effective on this particular patient with arthrogryposis, but wide scope and long term analysis of their uses was not evaluated, but maybe an area of future research.

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Giving Them a Hand:

Wearing a Myoelectric Elbow-Wrist-Hand Orthosis Reduces Upper Extremity Impairment in Chronic Stroke

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INTRODUCTION

Most stroke survivors exhibit upper extremity (UE) hemiparesis that undermines function and quality of life (Broeks et al., 1999). While a small proportion of these survivors exhibit active movement in the distal areas of their paretic UEs, the vast majority exhibit little to no active movement in their wrists and fingers (Wolf et al., 1983). These limitations severely diminish response to rehabilitative therapies and participation in daily activities. Thus, there remains a significant gap, centering on the need to develop devices that increase function in this rapidly-expanding group of moderately impaired stroke survivors.

Myoelectric wrist and hand orthoses (MEWHOs) bridge this gap by utilizing EMG sensors to provide powered assistance for elbow flexion and extension and gross grasp motions. While this technology has shown promising results, no study has directly investigated the effect of wearing a MEWHO on UE impairment, gross manual dexterity and functional task performance.

Accordingly, the purpose of this study was to determine the immediate impact of a MEWHO on paretic UE outcomes in chronic, stable, moderately impaired stroke survivors.

METHOD

Subjects: 18 chronic, moderately impaired stroke survivors were included (median age: 56 ± 11.8, 11 males, 28% Medicare Age, 16 right hand dominant, median Fugl-Meyer: 18.6±6.1)
Apparatus: The MyoPro Motion-G (Myomo Inc., Cambridge, MA, USA) is a MEWHO that provides powered assistance for elbow flexion and extension and gross grasp motions. Outcome measures included: (a) the Fugl-Meyer Scale (a measure of UE impairment), (b) The Box & Block Test (a measure of gross manual dexterity) and (c) a battery of functional tasks (to measure functional task performance).
Procedures: Subjects were administered the aforementioned measures with no orthosis. They then donned the MEWHO and were again tested on the same battery of measures.
Data Analysis: We used a paired t-test to test our primary hypothesis that there would be a significant difference in FM score when using the MEWHO as compared to not using the MEWHO. We utilized the Wilcoxon signed-ranks test to test our secondary hypotheses that there would be a significant difference in scores on the Box & Block Test and the Battery of Functional Tasks when wearing versus not wearing the MEWHO.

RESULTS

Subjects exhibited significantly reduced UE impairment while wearing the MEWHO (FM: t {17} = 8.56, p < .0001), and increased quality in performing functional tasks while wearing the MEWHO (Feeding {grasp}: Z=2.251, p=.024; Feeding {elbow}: Z=2.966, p=.003; Drinking {grasp}: Z= 3.187, p=.001). Additionally, subjects showed significant decreases in time taken to grasp a cup (Z=1.286, p=.016) and increased gross manual dexterity while wearing a MEWHO (BB: Z =3.42, p < .001).

DISCUSSION

While post-stroke ambulation and gait kinematics are increased when wearing an orthosis (Sheffer et al., 2013; Esquenazi et al. 2009), this is the first study to compare the effects of a myoelectric orthosis to no orthosis in the paretic UE. Results suggest that UE impairment is significantly reduced when donning a MEWHO. Further, utilization of a MEWHO significantly increased gross manual dexterity and performance of certain functional tasks. More MEWHO training is needed for subjects to be able to perform multi-joint functional movements in order to attain consistent functional changes, which will be incorporated into future work.

CONCLUSION

MEWHO use significantly reduces UE impairment and increases performance of certain functional tasks in chronic, moderately impaired stroke.

CLINICAL APPLICATIONS

With little to no training, subjects were able to utilize the MEWHO to perform daily tasks. As such, a MEWHO may constitute an additional device option for stroke survivors exhibiting moderate UE hemiparesis; a crucial finding, given the paucity of therapeutic options available to this group.

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CHANGES IN PRESSURE DISTRIBUTED WITH ALIGNMENT CHANGES

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INTRODUCTION
There is general consensus in the prosthetic community that prosthetic alignment is directly related to clinical outcomes. There is, however, not enough clinical outcomes data to adequately support and understand stresses experienced at the residual limb (Al-Fakih, 2016). Such studies can advance prosthetic socket design, and can further help meet the demand for evidence-based care and payment justification by health care payers.

Our hypothesis is that changes in the alignment of distal componentry relative to the socket will result in a significant difference in socket forces applied to the residual limb, functional outcomes measures, and Socket Comfort Score (SCS).

METHOD
Motion sensors and thin force sensors were integrated into an adjustable trans-tibial socket design. Force sensors were attached to the socket's distal end, along the long axis of the socket, and at the proximal aspect of the socket. Force sensors mapped the pressure distribution within the socket and motion sensors coupled to the socket were used to analyze socket movement. Data was recorded while the subjects performed subsequent functional tests.

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

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

Functional outcomes measures and SCS were best at the user and prosthetist perceived neutral alignment. Similarly, excessive varus/valgus and flexion/-extension movements were minimized at the neutral position.

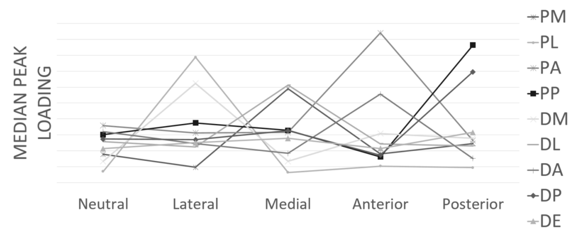

Figure 1: Mean peak pressures during functional outcomes measures for the given variables.

DISCUSSION
Altering the alignment of distal componentry relative to the socket caused a significant difference in subject outcomes. The regional location of increased and decreased peak pressures was correlated directly with the direction of offset from a neutral alignment. Motion sensors within the socket also showed significant differences among variable conditions. Compared to neutral alignment, relative motion was significantly higher for all other variables and the direction of increased motion was different for each condition.

Results suggest that measurements of regionally specific socket pressures applied to the residual limb can aid in determination of an optimal alignment. More specifically, regional profiling of socket pressures applied to the residual limb can help guide proper prosthetic alignment by giving specific recommendations on the direction and magnitude of alignment shift needed to reduce peak pressures and improve outcomes.

Functional outcome tests show reductions in both biomechanical control and functional capacity under all variables that deviated from neutral alignment. SCS results consistently reported less socket comfort with all variables that deviated from neutral alignment.

CONCLUSION
There are evident correlations among alignment, distribution of forces on the residual limb, functional outcomes, and patient perception. Future studies will be directed to increasing the number of subjects tested to further validate this correlation.

CLINICAL APPLICATIONS
Data that is collected from socket forces applied to the residual limb can be used to inform optimal prosthetic alignment. Results of this study and related future studies can be used to validate the need and billing for alignable prostheses and the need for appropriately aligned prostheses.

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THE RELATIONSHIP BETWEEN LIMB MOTION, LIMB VOLUME, SOCKET COMFORT, AND PROSTHETIC SUSPENSION

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INTRODUCTION

Elevated vacuum suspension (EVS) is one method to suspend a prosthetic limb onto the amputee user. Reviews of the existing literature highlight that EVS decreases pistoning, reduces internal socket pressures, and stabilizes limb volume (Gholizadeh, 2016).

What is not understood is the possible relationship between limb volume and limb motion inside the socket. Since the socket geometry is fixed, it is reasonable to surmise that a change in limb volume can affect the amount of limb motion inside the socket. Increases or decreases in limb volume alter the intimacy of socket fit which may be reflected by changes in socket motion. If a link between limb motion and volume were established, it could provide prosthetists with a clinically relevant tool to quantify limb volume and even the quality of socket fit. The purpose of this study is to understand the relationship between limb motion, limb volume, and socket comfort and how these outcomes are impacted by method of suspension.

METHOD

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

Apparatus: Limb motion during each visit and the amount of vacuum pump usage (for elevated vacuum users) between visits was collected using the LimbLogic Communicator (Gershutz 2010). Limb volume was collected using the Omega Scanner software. A study specific questionnaire was used to collect information regarding subject demographics as well as socket comfort scores at each visit.

Procedures: Each subject completed three study visits: initial, 1-week, and 8-week follow-up. Each visit started by collecting subjects' weight and socket comfort score. Subjects then doffed their prosthesis and the Omega Scanner was used to capture a digital image of their residual limb and liner. Tracking markers were placed at known landmarks to allow for systematic alignment and processing of the digital image for volume calculation. After the scanning was complete, subjects donned their prosthesis and completed a 15 minute intermittent walking task. Once complete, subjects re-doffed their prosthesis and another scan was taken to capture limb volume.

Data Analysis: Limb volume was calculated by the Omega software. Motion between the limb and socket was inferred from measured vacuum pressure variation (Gerschutz, 2015). The average vacuum pressure was calculated across each walking trial.

RESULTS

Limb motion inside the socket was found to correlate to limb volume and socket comfort. For suction suspension users, limb volume was significantly decreased after the walking tasks compared to before the walking. Alternatively, the limb volume of subjects using EVS was the same or even greater after the walking task compared to before. In addition, these users had a significant decrease in the amount of measured in-socket limb motion compared to suction suspension users. Distinct data trends suggest correlations between limb motion and volume. Among the vacuum users, socket comfort score was inversely related to limb motion inside the socket.

DISCUSSION

This study suggests that a relationship between limb motion and volume exists. The results of this work support claims of previous work completed by the authors (paper accepted in JRRD) investigating changes to limb health in response to prosthetic suspension. The claims state that beneficial changes in skin health and perfusion were a result of a more stable environment for the soft tissues, allowing the limb to adapt to the socket environment.

CONCLUSION

Changes in limb motion inside the socket appear to be related to limb volume changes, both of which are impacted by ones choice of prosthetic suspension methodology. Future studies should include real-time measurements of in-socket limb volume.

CLINICAL APPLICATIONS

Real-time monitoring of in-socket limb motion can provide clinicians valuable information regarding limb volume and even socket fit. Such data could be useful for defending clinical decisions in pursuit of reimbursement for socket changes.

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CLINICAL PRACTICES TO OPTIMIZE THE SOCKET FITTING PROCESS

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INTRODUCTION

Prosthetic sockets are custom made for each amputee in order to create an intimate fit for optimal comfort and performance. Prosthetists determine the appropriate socket geometry and which method of suspension will best serve an individual patient. Unfortunately, this process lacks quantitative methods to determine the quality of socket fit which could then provide clinicians with a tool to identify non-optimal fit. In addition the variability of a patient's residual limb has been well-documented (Sanders, 2011 & 2016) and can make the fitting procedures even more difficult.

Despite this reality, the authors are unaware of any studies investigating the effectiveness of limb volume management techniques that can be implemented during the socket fitting process so as to improve the fit of the resulting socket. Related to this observation, some studies conclude elevated vacuum suspension better manages limb volume compared to other methods of suspension.

The purposes of this study are to 1) investigate the effect of body position on residual limb volume while not wearing a prosthesis and 2) to determine the impact of prosthetic suspension on these volume changes.

METHOD

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

Apparatus: Limb volume was collected using the Omega Scanner software. A study specific questionnaire was used to collect information regarding subject demographics as well as individual weights and socket comfort scores at each visit.

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

Data Analysis: Limb volume was calculated by the Omega software. A repeated measures ANOVA was used for statistical comparisons.

RESULTS

Across all subjects, remaining in a seated position resulted in virtually no change in volume, while lying with the residual limb elevated resulted in the most limb volume loss during the 15-minute period. When the results are analyzed by suspension, the suction users gained volume when remaining seated, lost volume when lying supine, and lost the most volume when the limb was elevated. Limb volume measurements at the initial, 5-minute, and 15-minute collection points were highly influenced by body position. Vacuum users on the other hand were found to have a small loss of volume across all body positions. This loss was relatively consistent across the initial, 5 minute, and 15 minute measurement points.

DISCUSSION

The results suggest that elevated vacuum suspension buffers the residual limb from experiencing large swings in volume. Suction suspension users were more susceptible to volume loss, particularly in certain positions. The results of this study are consistent with reports that elevated vacuum suspension reduces pistoning and internal socket forces, suggesting that elevated vacuum suspension stabilizes the socket environment.

CONCLUSION

Limb volume changes were better managed with elevated vacuum suspension. Subject body position impacted limb volume.

CLINICAL APPLICATIONS

Prosthetist should consider the body position of their patients as they are waiting during the socket fitting process. Based on the findings, patients should vary body position to stabilize limb volume. Better managing the limb volume can result in better fitting sockets through obtaining a more representative limb shape, rather than trying to fit a swollen or shrunken limb shape.

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EFFECTIVE SUBJECT BLINDING IN P&O RESEARCH

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INTRODUCTION

Subject blinding, concealing the group assignment from research participants, is an important element of sound research design (Schulz, et al, 2002), yet it is not commonly used in Prosthetic and Orthotic (P&O) research. This is partly due to the nature of typical research interventions, which – unlike, i.e., the administering of a (placebo) pill in a drug study – are substantially more obvious to the study participant. Previously described methods used to blind subjects (Orendurff. 2013) have many limitations, including the unintentional alteration of essential device properties that are brought about by adding cover materials.

Biases can also be problematic in the clinic, when a P&O device is being optimized by trying out different settings or parts. Ideally, the patient, whose perception plays an important role in informing the eventual decision by the practitioner, would base his or her feedback solely on the relevant functional effects and be unaffected by the optical appearance or any other bias that may be present without blinding.

The purpose of this study was to investigate the effect that vision blinding has on how lower-limb prosthesis users assess alignment changes to their prosthetic ankle. It was hypothesized that obscuring their vision will reduce the accuracy and confidence with which patients recognize such alignment changes.

METHOD

Subjects: Persons with an endoskeletal lower limb prosthesis, who were able to walk without aid and whose vision was not severely impaired, were recruited for this IRB approved study. A sample size of 12 was determined by power analysis, assuming an effect size of 0.8 as vision accounts for 80% of all sensory input.

Apparatus: Subjects were blinded by opaque glasses, a cardboard shield, a combination of both, or not at all. After each trial, they were asked to report the perceived alignment change as well as how sure they were of their assessment.

Procedures: Five ankle alignment perturbations (changes by 1.5 degrees in plantar, dorsiflexion, supination, or pronation, as well as a pretend change) were combined with the four blinding conditions for a total of 5x4=20 trials. The sequence of trials was randomized for each subject, and a credentialed prosthetist performed all the changes. Subjects were asked to determine the occurred alignment change by any means possible, including standing or walking with the prosthesis or observing the process. Between perturbations, the initial alignment was reconstituted.

Data Analysis: A one-tailed paired t-test was conducted to determine the main effect of blinding on accuracy and surety of assessments. Secondary analyses included ANOVA with alignment direction and blinding method as independent variables. A critical alpha of 0.05 was determined prior to analysis.

RESULTS

The 12 participants were all male, on average 54 years old, prosthesis users for 10 years, and slightly above average in mobility with a 63% rating in the mobility score (PLUS-M).

The t-test indicated no significant effect of blinding on the accuracy of alignment assessment (p=0.233). However, subjects' confidence in their assessment (Figure 1) decreased significantly with blinding (p=0.009).

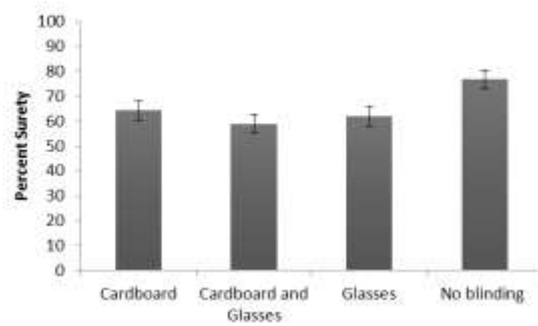

Figure 1: Average assessment confidence in the four different blinding conditions (n=12).

The direction of alignment change had a significant effect on a surety-weighted accuracy score (p=0.039).

DISCUSSION

Somewhat surprisingly, vision blinding seems to have no effect on patients' accuracy of detecting an intervention. Many of our subjects did not take advantage of the opportunity to observe alignment changes when not blinded or they misinterpreted their observations. Some tried to elicit the information by asking the investigators.

CONCLUSION

Vision blinding may be unnecessary in P&O research.

CLINICAL APPLICATIONS

P&O practitioners are conditioned to communicate any device alterations to their patients. This may introduce bias when patient feedback is solicited.

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SYSTEM GROUP DYNAMICS AND THEIR EFFECT ON INNOVATION IN O & P

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INTRODUCTION

This study represents a doctoral dissertation examining the effects of group dynamics and social interaction with innovation among a sample group of orthotists and prosthetists. Since any new innovation inherently comes with a higher degree of uncertainty and risk, the group or individual must deal with the anxiety created by this innovative behavior. Individuals who are less anxious and risk adverse may tend to adopt innovations more easily than others who regard change with greater uncertainty. Individuals can be classified into adopter categories based on their rate of adoption of new technologies and capacity for risk and anxiety. Individuals who are more susceptible to anxiety in general, may seek the emotional scaffolding of their organizational group to support innovative behavior. This may be especially true in healthcare where contextual stress is heightened.

METHOD

The intent of this study was to examine if there is any relationship between an individual's differentiation of self and level of technology readiness. The level of differentiation within the work context will be compared to innovation technology readiness. This study construct was a non-experimental, associational, design using an electronic survey comparing emotional differentiation, as measured by the Workplace Differentiation Inventory (WDI), and technology readiness as measured by the Technology Readiness Index 2.0 (TRI-2.0). The intent of the study was to examine the potential relationships between the WDI and TRI-2.0 as well as the subattributes of both instruments. The analysis was done to find if any relationships exist between the WDI and TRI-2.0 with respect to the demographic attributes of gender (G), years of experience (EXP), professional certification (CERT), technology self-assessment (TSA), number of high-tech patients per year (HTP), number of external linkages (EXLK), number of internal linkages (INLK), and professional affiliation (AFF).

RESULTS

The survey, which included the eight demographic questions as well as the WDI and TRI 2.0, was made available with a link and invitation on the OANDP-L list server. The survey was posted on Qualtrics from August 18, 2015 until August 31, 2015, and had n = 148 respondents. Examination of the relationships using two-tailed Person's correlations showed significance between Technology Optimism with all attributes of the WDI; Fusion with Others, Emotional Reactivity, and Emotional Cut-off. Technology Innovation also had significant relationships with Fusion with Others, Emotional Reactivity, and Emotional Cut-off. The regression analysis showed a moderately strong predictive relationship between the WDI and the TRI-2.0. A very strong predictive relationship was found between Technology Optimism with Emotional Cut-off and Emotional Reactivity. Technology Optimism and Emotional Reactivity alone shared a strong predictive relationship. Conversely, the WDI had very strong predictive relationship with Technology Optimism, Technology Innovativeness and Technology Insecurity with Technology Optimism contributing a majority of the effect. An extremely weak relationship between the WDI composite score and Years of Experience. width. Alternately, place them at the bottom of the page in a single column format.

DISCUSSION

This study has shown that Emotional Reactivity and Emotional Cut-off had a significant predictive relationship with Technology Optimism with Emotional Reactivity being the most substantial. This study has also shown that Technology Optimism, Technology Innovativeness, and Technology Insecurity had a very strong significant predictive relationship on Workplace Differentiation, specifically Emotional Reactivity, with Technology Optimism being the most substantial. The other key result was that Gender, Technology Self-Assessment, Certification Level, Years of Experience, and Office Affiliation had little or no effect on the measures of differentiation or technology readiness. The implication is that continual introduction of new concepts and technology would be a strong predictor of a less emotionally reactive and thoughtful group for change represented by technologic and reimbursement advancements.

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Online self-management program for people with limb loss: Initial evaluation of the PALS online program

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INTRODUCTION

The national and personal health care burden associated with disability related to limb loss is increasing. Economic pressures, and changes in health care delivery systems, place greater responsibility on persons with limb loss and their families for post-acute care. Further, payors are increasingly holding providers and patients responsible for health outcomes. Data indicates if we are to improve outcomes following limb loss we must attend to the psychosocial challenges patients face in addition to meeting their technical needs. Providing patient and family centered care that promotes peer support and self-management to empower patients to take charge of their own recovery is critical to meet this challenge.

Self-management programs have proven to be a successful intervention to improve outcomes for patients with a variety of chronic conditions and disability, including limb loss. In 2005, researchers from Johns Hopkins University and the University of Washington collaborated with the Amputee Coalition to develop Promoting Amputee Life Skills (PALS), a multi-week in-person self-management program for people with limb loss. Results from the study of this initial program demonstrated that self-management programs improve outcomes for individuals with limb loss.

Attempts to disseminate the PALS program throughout the limb loss care continuum revealed several key barriers to program participation – including the difficulties of attending a multi-week in person program. The current work builds on the existing PALS program by creating a self-directed online program that seeks to address these barriers and maintain the efficacy of the PALS program.

METHOD

This study uses a single-group pre-post design to gather initial information on program utilization and efficacy. Specific outcomes measures to assess program utilization include: user satisfaction, length of time to complete lessons, number of lessons completed, usefulness of the PALS online website and resources, likelihood of continuing to use the website, and likelihood of recommending the program to others. Specific outcome measures to program efficacy include: CESD, Positive Affect Schedule, Modified Self-efficacy scale, Musculoskeletal Function Assessment Scale, and Satisfaction with Life Scale.

Subjects: 25 individuals with major amputation (defined as greater than a thumb or big toe), over the age of 18, with internet access using a computer, tablet or mobile phone.

Apparatus: Pre-post questionnaires to assess depressive symptoms, positive mood, functional status, and satisfaction with life and satisfaction with program. PAL online utilization documented by program.

Procedures: Participants completed questionnaires assessing depressive symptoms, positive mood, functional status, and satisfaction with life. Participants then completed 8 online lessons on the PALS Online Website. After program completion patient reported outcomes questionnaires were repeated.

Data Analysis: Descriptive statistics are used to analyze program utilization measures. Inferential statistics were used to analyze pre-post questionnaire measures.

RESULTS

Results from previous work on the impact of an in-person PALS program indicated a reduced likelihood of experiencing depressive symptoms, reduced functional limitations, and improved self-efficacy(1). These results will be compared patient reported outcomes of the online program tested in this study.

DISCUSSION

Self-management programs have proven to be effective tools to improve patient outcomes. Expanding access to these programs, while maintaining their efficacy, represents a potential strategy to maximize their value within the US healthcare system.

CONCLUSION

The online Promoting Amputee Life Skills program is a potentially effective self-management program to improve outcomes for individuals with limb loss.

CLINICAL APPLICATIONS

Self-management programs have proven to be effective tools for improving outcomes for patients with chronic conditions and disabilities. The PALS program is an evidence-based program that has proven to reduce likelihood of experiencing depressive symptoms, reduce functional limitations, and improve self-efficacy for individuals with limb loss. The new online format for the PALS program provides a convenient resource prosthetists can refer their patients to in order to help them better cope with living with limb loss.

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Effectiveness of Augmented Reality Biofeedback in Balance and Gait Applications: A Pilot Study

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INTRODUCTION

Rehabilitation following surgery or musculoskeletal injury is crucial for recovery from surgery and successful ambulation (Salzman, 2010). An emerging technology for balance and gait rehabilitation is real-time biofeedback (RTBF). RTBF allows instantaneous feedback on the performance during tasks. Visual feedback allows patients to alter their walking patterns to obtain a more symmetric gait (Dingwell, 1996). A recent technological advance is the development of smart glasses. Smart glasses are similar to normal glasses that overlay a small translucent screen in the field of view. Smart glasses allow users to constantly view data and their environmental surroundings, as opposed to virtual reality where the real environment is removed. The goal of this project was to evaluate an augmented reality biofeedback system using smart glasses and inertial-based sensors. This system may enable patients to receive real-time biofeedback at home that is similar to the feedback received in a clinic.

METHOD

Subjects: Ten healthy participants (7 male, 3 female age: 22.1 ± 0.5 years, height: 175.1 ± 8.8 cm, mass: 77.5 ± 11.2 kg) with no balance or gait disorders participated in this IRB approved study.

Apparatus: Epson BT-200 smart glasses were worn by the participants and the control unit was placed in a waist belt. The waist belt was secured to the lumbar spine (L5) with an elastic strap. A compliant foam pad, locking knee brace, and shoe platform (2 cm) were used to alter balance and gait.

Procedures: Balance and gait tests were completed under three visual conditions (1) no smart glasses (NSG), (2) smart glasses with display off (DO), and (3) smart glasses with visual RTBF (BF). Balance tests consisted of 30 second trials of single leg, double leg, and tandem stances conducted on the ground and foam pad. Gait tests consisted of 2 minute walk tests around a 20 meter rectangular track. Three walking conditions were tested: normal gait, walking with locked knee brace on the dominant leg, and shoe platform on the dominant leg. Trunk flexion and lateral flexion were measured using the accelerometer embedded within the smart glasses control unit (14 Hz). RTBF was displayed on the smart glasses using an android application. As the participant's lumbar moved from vertical, an on-screen graphic moved to show magnitude, and direction of the angle (Figure 1).

Figure 1: Augmented Reality RTBF Interface

Data Analysis: Root mean square (RMS) values were calculated from trunk angles in each direction and averaged to determine trunk angle magnitude from vertical. Wilcox and Freidman tests used to determine differences between NSG/DO groups and DO/BF groups (α = .05).

RESULTS

Wearing smart glasses did not alter balance or gait performance (Figure 2). RTBF had no effect on balance conditions. RTBF significantly reduced trunk angles in sagittal and frontal planes (Figure 2).

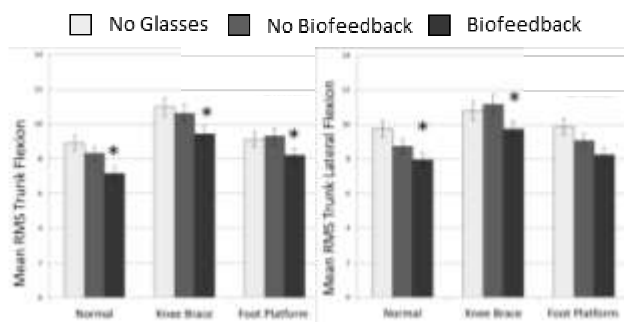

Figure 2: Mean RMS trunk flexion and lateral flexion for different conditions. * Significant difference due to biofeedback.

DISCUSSION

No significant difference between NSG and ND suggests that wearing smart glasses with no display does not affect balance or gait performance. Several variables may have prevented biofeedback from being effective in balance trials. Participants may have been distracted by visual feedback, causing balance errors. Future research will include a larger sample size of lower-limb prosthesis users.

CONCLUSION

Wearing smart glasses with the display off did not alter balance and gait. Augmented reality biofeedback may be an effective tool to reduce trunk movement during gait.

CLINICAL APPLICATIONS

Augmented reality biofeedback may be a technology to provide telerehabilitation services to patients that do not have access to traditional rehabilitation clinics.

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Predicting Fall Risk in People with Unilateral Lower Limb Loss Using a Component Timed-Up-and-Go (cTUG)

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INTRODUCTION

The Timed-Up-and-Go (TUG) test is a commonly used performance-based outcome measure to assess mobility in people with lower limb amputation (LLA) (Dite, 2007; Resnick, 2011; Schoppen, 1999; Wong, 2015), and the Centers for Disease Control (CDC) cites a 12 second performance threshold on the TUG as a prediction of elderly who may be at increased fall risk. The value of the TUG in providing information on strategies employed by prosthetic users is enhanced when it's component sub-tasks are assessed; sit to stand transitions, a 180° step turn, and linear walking. The purpose of this study was to identify variables that contribute to performance on a component TUG (cTUG) requiring greater than 12 seconds, which may indicate that a person with LLA could be at increased fall risk.

METHOD

Subjects: A convenience sample of 52 community ambulators with unilateral LLA with a mean age of 51 ± 13 years, were recruited at a national amputee conference.

Procedures: Subjects performed 4 trials of the cTUG; turning twice toward and away from their prosthetic limb. A total time to perform the test was recorded, as well as 5 cTUG interval times: 1) sit to stand, 2) walk entering the turn, 3) 180° turn, 4) walk exiting the turn, 5) turn to sit. A custom mobile software application was used to capture the interval times. Research personnel recorded demographics, anthropometrics, bilateral hip extensor strength, hip extension range of motion (ROM), and single limb balance.

Data analysis: SAS Version 9.4 statistical software was used to provide descriptive statistics of the sample. Mann Whitney U analysis was performed to compare group performance, and backward multiple linear regression analysis was utilized to obtain the contribution of each variable to mobility and fall risk.

RESULTS

Participants were categorized into low fall risk (LFR) and increased fall risk (IFR) based on the 12 second threshold. Sixty-nine percent of people with LLA were classified as LFR, and 31% categorized as IFR. Within the IFR cohort, 38% (n=6) were amputated at the transtibial level and 63% (n=10) were transfemoral. The IFR group were older (p<0.01), had greater comorbidities (p<.003), and a larger waist circumference (p<.04). Those classified as IFR also performed the cTUG significantly slower in total time (p<.001) and within each component (p<0.001), had poorer prosthetic single limb balance (p=.04), and had weaker residual limb hip extensors (p=.006) when compared to the LFR group. A backward regression model indicated a significant contribution of level of amputation (p=.009), waist circumference (p=.02), and residual limb hip extensor strength (p=.02) to performance on the cTUG. Cause of amputation was not a significant predictor of cTUG performance.

Table 1. Comparison of subject characteristics and cTUG performance

Variable	Increased Fall Risk (N=16) μ ± SD	Decreased Fall Risk (N=36) μ ± SD	p value
Age (yrs)	59 ± 9.1	47 ± 13.7	**.001**
Waist (cm)	109.2 ± 16.9	100.8 ± 13.5	**.04**
Comorbidity Score	2.7 ± 2.7	1.5 ± 1.9	**.03**
Hip Extension ROM			
Sound	6° ± 8.4°	7° ± 8.5°	.33
Residual	2° ± 8°	5° ± 8.2°	.08
Hip Extension Strength			
Sound	37.9 ± 4.8	36.1 ± 7.8	.23
Residual	34.9 ± 9.0	27.4 ± 11.3	**.006**
Single Limb Balance (sec)			
Sound	16.1 ± 13.1	20.3 ± 11.7	.17
Prosthetic	1.6 ± 1.1	2.23 ± 1.7	**.04**
TUG Test			
Interval time (sec)	μ ± SD	μ ± SD	p value
Total time	14.43 ± 3.2	9.74 ± 1.6	**≤.001**
Component 1	2.04 ± .54	1.34 ± .32	**≤.001**
Component 2	2.45 ± .47	1.72 ± .36	**≤.001**
Component 3	4.0 ± .98	2.9 ± .65	**≤.001**
Component 4	2.1 ± .37	1.6 ± .25	**≤.001**
Component 5	3.85 ± 1.36	2.18 ± .45	**≤.001**
Number of steps component 3	6.1 ± 1.12	5.3 ± .97	**.009**

**Bolded values indicate statistical significance

DISCUSSION

Using the 12s. performance threshold, individuals classified as IFR had a mean cTUG time of 14.43±3.2 s., and those at LFR had a mean time of 9.74±1.6 s. This is in contrast to the only previous study using TUG for fall risk assessment in amputees, where a TUG time of greater than 19s. was indicative of increased fall risk. (Dite, 2007)

CONCLUSION

Despite the fact that these subjects were community ambulating prosthetic users, almost 31% were at an increased risk for falling according to CDC standards. People classified as IFR presented a more proximal level of amputation, greater central adiposity, and weaker residual hip extensors.

CLINICAL APPLICATIONS

This study suggests that modifiable physical therapy intervention such as residual limb strength training, single limb balance and body weight education may improve basic mobility and reduce the risk of falls in lower limb prosthetic wearers.

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A Systematic Review to Determine Post-Amputation Functional Performance Level and Develop a Prosthetic Candidacy Treatment Algorithm

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INTRODUCTION

Criteria to determine prosthetic candidacy have not been standardized. This has lead to a large variation in prosthetic prescription and access to care for individuals with limb loss. AOPA has addressed this issue by commissioning a systematic literature review to serve as a basis for development of clinical practice recommendation and algorithm for determination of prosthetic candidacy. With implementation of the meaningful use criteria and evidence-based practice incentives of the Affordable Care Act looming, such a review should be congruent with this legislation. Further, with emphasis on MFCL K-Levels documentation by referring physicians for successful reimbursement in recent years, an ideal clinical practice recommendation for prosthetic candidacy would terminate with determination of functional level K0 or K1+. Therefore, the purpose of this systematic review was to evaluate existing literature and determine a clinical practice recommendation to equate factors commonly included in a routine evaluation by a physician to a baseline functional level for prescription of an initial prosthesis in adults with limb loss.

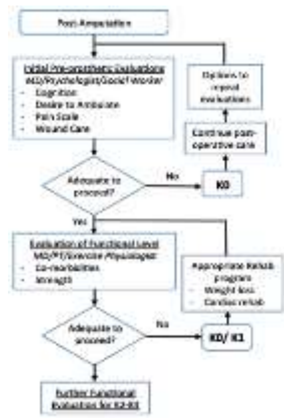
METHOD

A systematic review od multiple database were searched: PubMed, CINAHL, EMBASE, and Cochrane Library. Search terms included: prosthesis, amputee, limb loss, candidate, ambulate, walk, mobility, function, capacity, stability, mobility, meaningful use, and corresponding MeSH terms. Two prosthetic researchers reviewed resulting articles for relevance using filters, a title and abstract review, and full review when necessary. Relevant articles were then evaluated by a multi-disciplinary team to synthesize statements of predictive criteria for prosthetic use.

Data Analysis: Articles were assessed using an internationally recognized tool for critical appraisal of literature. This tool assigns a research grade for empirical evidence statements using applicability and quality of contributing literature. Evidence statements with research grade "A" were integrated into the clinical practice recommendation.

RESULTS

4616 articles were identified, of these, 57 were determined to be relevant after an exhaustive review. From these articles, 49 predictive factors were identified. Of these, 25 had sufficient evidence to be integrated into the candidacy treatment algorithm. Three were found to be exclusionary for prosthetic use. Two additional exclusionary criteria are dictated by Medicare policy. The remaining 20 were predictive of ambulatory ability, but did not preclude success in prosthetic use.



DISCUSSION

There are low barriers to prosthetic candidacy for people of all ages, amputation levels, body types, and physical capacities as determined by the results of this systematic review. Primary factors that would prevent prosthetic use include motivation to ambulate, functional level, pain, sores, and cognition. Remedies to mitigate these factors are commonly implemented and include psychiatric and physical therapies, pharmaceutical interventions, and wound care.

CONCLUSION

A clinical treatment pathway for determination of prosthetic candidacy was developed. A small number of modifiable factors for exclusion of prosthetic candidacy were identified.

CLINICAL APPLICATIONS

Implementation of this algorithm would increase and streamline access to prosthetic care for a majority of individuals experiencing limb loss in the United States.

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Gait Training Interventions for Lower Extremity Amputees
A Systematic Literature Review

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

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

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

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

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

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

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

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

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Matching Peak GRF by Utilizing Powered Prosthesis

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INTRODUCTION

Lower limb amputations have the greatest effect on gait and balance (e.g., gait asymmetries, abnormal gait, increased energy expenditure, and balance) (Herbet,1994; Martinez-Villalpando, 2011; Ku, 2014;). To attenuate these issues, many lower limb prostheses have been developed that can imitate the behavior of normal human walking and provide the possibility of recovering damaged walking functions. However, increased loading of the intact leg can lead to problems such as osteoporosis and scoliosis. Powered prostheses can potentially be used to minimize differences in peak forces. This study compares the amputee's Ground Reaction Force (GRF) while wearing the participant's own microprocessor-controlled transfemoral prosthesis and the newly developed powered transfemoral prosthesis: AMPRO II (Fig. 1). AMPRO II weighs 5kg and is 380mm tall. It utilizes a human inspired control at the knee and flat foot walking at the ankle.

Fig. 1 User wearing AMPRO II

METHOD

Subject: One 21 year old transfemoral amputee male was recruited. He was approximately 120lbs without a prosthesis and was 5'9" tall.

Apparatus: i) AMPRO II, ii) microprocessor knee, iii) low profile Triton foot, and iv) Bertec force plate.

Procedures: To compare the subject's microprocessor-type prosthesis (Genium, Ottobock, Germany) and AMPRO II, the subject's GRF was collected and Symmetry Index (SI) of GRF was computed. A force platform was used to capture the GRF during normal flat ground walking while the subject was wearing a prosthesis. This was completed 6 times total while using his microprocessor knee and AMPRO II; 3 times with the intact leg striking the ground and 3 times with the prosthetic leg striking the ground. Initially the subject used the Genium microprocessor followed by 13 practice sessions with AMPRO II with 1-3 days between each session. The process was repeated with GRF data collected while using AMPRO II.

Data Analysis: GRF information was used to compute SI between both limbs. SI was calculated as follows (Nigg, 2014): SI= $\frac{|x_I - x_P|}{0,5(x_I + x_P)}$, where x_I is the GRF for the intact leg and x_P is the GRF for the prosthetic leg. The closer the value is to zero, the more symmetric the gate.

RESULTS

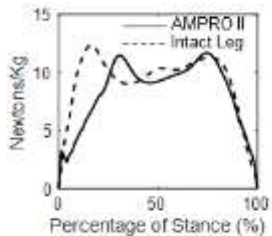

Fig. 2 GRF while using microprocessor knee

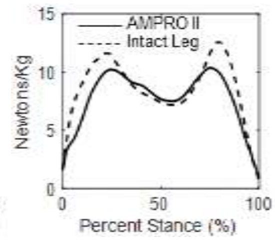

Fig. 3 GRF while using AMPRO II

Table 1: GRF SI and differences in maximum GRFs while using AMPRO II and participant's microprocessor knee

	MAX GRF (N/KG) DIFFERENCE	GRF SI
MICROPROCESSOR	1.91	11.51
AMPRO II	0.6	17.13

There were two peaks in GRF. The first peak is the loading response and the second is the push-off. Using AMPRO II caused a shift in the peak of the loading response. Peak forces, however, where closely matched while using AMPRO II. Using AMPRO II showed a reduced max GRF difference of 0.6 N/Kg and enhanced GRF SI of 17.13 compared to the difference of 1.91 N/Kg and SI of 11.51 using the Genium microprocessor knee and low profile triton foot.

DISCUSSION

A major problem of transfemoral amputees is the increased loading on their intact leg while walking. This study utilized a powered prosthetic to attempt to alleviate this problem. Even though the second GRF peak is slightly shifted, AMPRO II enhanced both the max GRF difference and GRF SI. Also, with AMPRO II, GRF matched the maximum load in the intact leg more closely to the normal healthy subject's data. This is important due to the many issues this overloading causes long term.

CONCLUSION

Powered prosthetics, such as AMPRO II, could help reduce the over loading of the intact leg and enhance GRF symmetry, potentially reducing some of the problems that unilateral transfemoral amputees face.

CLINICAL APPLICATIONS

One part of training amputees to use powered devices could be observing how they distribute weight while walking. This along with observing kinematics could lead to improved training for use of powered prosthetics.

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How Often Do People with Trans-Tibial Amputation Don and Doff Their Prosthesis?

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INTRODUCTION

Temporary doffing may be an effective means for facilitating limb volume recovery in prosthesis users who would otherwise lose volume over the course of a day (Sanders, 2016). However, it can be difficult for users to remember when and for how long they executed doffs each day. This lack of information may compromise proper execution of this strategy and challenge practitioners' ability to advise patients on how to stabilize their daily limb volumes. The purpose of this study was to develop and test a simple sensor for monitoring when people with trans-tibial amputation don and doff their prosthesis.

METHOD

Adults with trans-tibial amputation who were classified as K-level of 2 or higher participated in this study. Participants were required to use a prosthesis with an elastomeric liner.

A custom inductive sensor was developed to monitor limb presence within the socket. A low profile sensing antenna was mounted on the inside posterior surface of the socket, and the conductive target element was placed on the outside posterior aspect of the participant's elastomeric liner. An instrument box that powered the sensor and stored data was fastened to the lateral aspect of the prosthesis pylon (Fig. 1). The inductive sensor detected distance to the conductive element, allowing a donned socket to be differentiated from a doffed one. Participants wore the unit continuously for 10 to 14 days. Participants were instructed to recharge the unit nightly, but otherwise perform normal activities.

Figure 1. Prosthesis use monitor.

RESULTS

Results from nine participants demonstrated a range of don/doff patterns (Figures 2A-2C). For example, the participant in 2A showed more consistent daily prosthesis use than the participant in 2B. Three days before the end of the monitoring period, the user in 2A experienced skin breakdown and could not wear the prosthesis. Prolonged doffing in the days before suggest the user experienced gradual breakdown and attempted to mitigate the event by intermittently doffing her prosthesis.

Several times a day, the participant in Figure 2C executed short-term doffs to facilitate limb fluid volume recovery.

A.

B.

C.

Figure 2A-C. Don/doff data from three participants. Black lines indicate times the prosthesis was doffed.

DISCUSSION

The sensor developed in this study provided insight into participants' don/doff patterns, and helped to document consistencies and inconsistencies of prosthesis use. Data collected by the monitor may be useful to practitioners trying to diagnose patients' socket fit issues and monitor compliance with clinical recommendations. Knowledge of patients' prosthesis use may help practitioners probe users about unusual events or situations that may precede limb injury.

CLINICAL APPLICATIONS

A next step is to evaluate utility of sensor data towards improving clinical care. A smartphone app communicating with the sensor and providing reminders to the user as necessary may facilitate proper execution and recording of temporary doffing strategies.

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Diagnostic Assessment of Limb Fluid Volume Changes in People with Trans-Tibial Amputation: Testing a Clinical Monitoring Tool

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INTRODUCTION

Changes in limb volume over the day complicate prosthesis use for many people with limb loss. Volume fluctuations can adversely affect socket fit and induce gait instability. Understanding a patient's volume fluctuation patterns and factors that affect them is a formidable challenge faced by practitioners. The purpose of this research is to evaluate a clinical diagnostic tool for assessing a patient's limb fluid volume changes and establishing their fluid volume profile.

METHOD

A custom bioimpedance analyzer was developed to monitor extracellular fluid volume (ECF) changes in the anterior and posterior regions of a residual limb (Fig.1). The device is a portable version of a larger instrument used previously to evaluate limb fluid volume in a laboratory testing (Sanders, 2015). The device injects a small electric current between two electrodes, and monitors voltage from other pairs of electrodes on the residual limb. Current and voltage data are used to calculate impedance (DeLorenzo, 1997), which is converted to fluid volume using a limb segment model (Fenech, 2004).

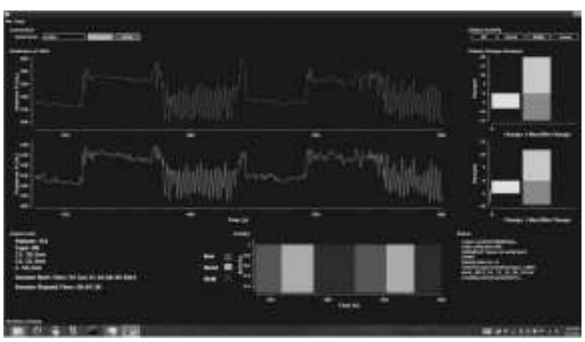

Figure 1. Data Presentation. Limb fluid volume (wave forms), patient activity (lower bar graph), and summary information (right bar graphs) are presented on a handheld tablet.

Fluid volume is monitored during 25-minute test sessions involving equal durations of standing, sitting, and walking. Results are presented on a tablet to the practitioner in real time (Fig. 1). For a two-week period before the fluid volume test session, participant activity (i.e., times and durations of sitting, standing, and active periods) is monitored using a custom sensor (Cagle, 2016). A fluid volume profile is created from the results and presented to the practitioner.

RESULTS

An example fluid volume profile for a trans-tibial prosthesis user is illustrated in Fig. 2. This individual's fluid volume loss during weight bearing (i.e., standing and active periods) is countered by gains experienced during sitting. However, he is weight-bearing often thus experiences an overall fluid volume loss during a typical day. An accommodation strategy that facilitates fluid volume gain during active periods (e.g., suction, elevated vacuum) may therefore benefit this individual.

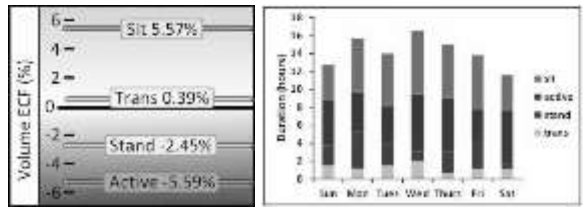

Figure 2. Example Fluid Volume Profile. Percentage fluid volume change for different activities are shown on the left. Activities by day of the week are shown on the right. Trans= transitions (e.g., sit-to-stand).

Results from clinical testing show that prosthesis users typically fall into 1 of 4 fluid volume profiles (A to D), depending upon how their limb volumes change during different activities (Table 1).

Table 1. Limb Fluid Volume Profile Categories

Category	Sit	Trans	Stand	Active
A	+	nc	-	-
B	nc	+	-	-
C	+	-	-	+
D	nc	nc	-	+

nc = no or minimal change

DISCUSSION

The developed instrument may provide insight relevant to prosthesis design and fitting. By knowing when and during what activities prosthesis users are prone to limb fluid volume loss or gain, practitioners can more effectively adjust socket design and educate users about strategies to accommodate volume changes.

CLINICAL APPLICATIONS

A next step is to determine if identifying a patient's limb fluid volume profile helps to predict effectiveness of different accommodation strategies such as sock addition/removal, elevated vacuum, size-adjustable sockets, or temporary (periodic) socket doffing. Large scale clinical testing will need to be conducted.

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CURRENT PRACTICE IN ORTHOTIC TREATMENT OF ADOLESCENT IDIOPATHIC SCOLIOSIS

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INTRODUCTION

Best practice guidelines regarding the biomechanical principles employed during orthotic treatment of adolescent idiopathic scoliosis (AIS) are not clearly defined. Ongoing efforts to clarify and define biomechanical principles of adolescent idiopathic scoliosis have begun to lay the groundwork for what could eventually become best practice guidelines. In 2002 the American Academy of Orthotics and Prosthetics convened a State of the Science Conference, which outlined basic understandings as well as identified shortcomings in current research regarding orthotic interventions. While this served a great need and remains a gold standard, several years have passed and many advances have been made in the treatment of AIS[1]. The SOSORT group has been a leader in the international community of the conservative treatment of scoliosis, and has published several articles in the SOSORT journal that convey "expert" agreement in areas that cannot be defined by research yet[2]. Creating a consensus statement on orthotic treatment of AIS is necessary for better treatment for AIS. By definition, consensus statements are an agreed upon current best practice based on scientific outcomes based evidence. Medicine in general does not always have the necessary scientific evidence to confirm a consensus, and when such a situation arises, a poll of so-called "experts" that agree on a statement may be used until a true consensus may be reached. The objective of this study is to use a survey tool that polls expert opinions of experienced spinal orthotists to determine where areas of agreement or disagreement arise regarding the biomechanical correction theory used for orthotic treatment for AIS. When areas of disagreement are identified, literatures are reviewed to identify existing evidences and advance understanding on these areas.

METHOD

Apparatus: Online-based survey method and literature review method.

Survey Procedures: Twenty-one questions (including three questions for defining qualification for data) with multiple-choice style were developed for this study focused on general concepts and typical case examples (PA and lateral view x-rays were provided for case examples) to target orthotic biomechanical concepts including some of the more controversial topics within the spinal orthotic community. The subjects were invited to participate by sending a link for the online survey to the Spinal Orthotic Society (SOS) members of the American Academy of Orthotists and Prosthethists (AAOP) through a mass emailing system, and spinal orthotists in the spinal orthotic field who are not in the SOS via each individual email address and by posting the link on other O & P community websites

Participant inclusion: Certified orthotist / certified orthotist and prosthetist, with scoliosis orthotic treatment experience of at least 2 years.

Literature Review Procedures: A review of the literature was conducted on each of the areas identified as a topic of disagreement from the survey. The following criteria was used to select studies: Studies related to AIS are included; Studies related to aetiology, operative treatment, or physical therapy are excluded; Studies looking at a specific orthotic system are excluded; Studies designed using a non-descriptive method are included; All literature reviews and education materials, including books, are included. However, oral presentations are excluded; Studies published before the year 1960 are excluded; Studies designed for any correction in-orthosis by radiography are included.

Data Analysis: The data was analyzed by measuring the answers of multiple choices for each survey question. During the analysis of literature, the level of evidence was marked for each article.

RESULTS

Fifty people surveyed and 46 people qualified for inclusion. 3 people were not certified orthotists and one had less than 2 years experience in orthotic treatment of scoliosis and were excluded.

Participants agreed with ten topics. Eight topics were defined for which participants failed to find a clear agreement (less than 50% of participants): Biomechanical correction goal of AIS treatment; The level of a thoracic pad for right thoracic curve case; The placement(s) of a primary corrective force(s) in the sagittal plane to address the thoracic hypo-kyphosis case; The necessity of abdominal compression for non-lumbar hyper-lordosis case; The necessity of reducing lumbar lordosis for non-lumbar hyper-lordosis case; Orthotic recommendation for a single primary curve case (more than 35 degree Cobb angle), where the apex is located at or below T12/L1; Orthotic recommendation for an upper thoracic curve (with an apex T2-T6) / cervico-thoracic curve (with an apex C7-T1) case; the treatment necessity for pelvic obliquity case, secondary to scoliosis.

DISCUSSION and CONCLUSION

Experts agreed with 10 biomechanical orthotic correction topics and found some evidences for 8 topics, which participants failed to find an agreement. However, more quantitative investigations are still needed to understand biomechanical correction concepts while treating AIS with an orthosis.

CLINICAL APPLICATIONS

A long-term goal associated with this project is to contribute toward the ongoing efforts to work toward reaching a consensus for better orthotic treatment of AIS.

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BIOMECHANICAL EFFECTS OF ADDING A FLAT REGION TO CONSTANT RADIUS ROCKER BOTTOM SHOES

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INTRODUCTION

The physiologic ankle has been shown to adapt to changes in footwear to maintain a consistent roll-over shape (Wang and Hansen, 2010). Our group used this finding to develop a constant radius rocker bottom shoe (CR-RBS) that “naturally immobilizes” the ankle during single limb support (SLS). This CR-RBS was found to reduce chronic ankle pain during walking in a person with talar dome lesions (Koehler-McNicholas et al., in press). However, the CR-RBS was found to be unstable for standing balance. An approach to enhancing the stability of patients using RBS may be to add flat regions in the rocker. However, addition of flat regions may eliminate the “natural immobilization” of the ankle and potential for ankle pain relief. Thus the purpose of this study was to determine whether or not flat regions built into the CR-RBS would have an effect on ankle kinematics.

METHOD

Subjects: Single healthy 42 year old male, height: 178 cm, weight: 90 kg

Apparatus: CR-RBS (stiff rocker with 10mm layer of crepe) with flat regions of 0 cm, 3 cm, and 7 cm centered at 40% shoe length from the heel. A shoe without a rocker (flat) was also used for comparison.

Procedures: Kinematic data of the ankle were collected using an 8-camera Oqus 100 motion capture system (Qualisys, Gothenburg, Sweden) at a frequency of 120 Hz while the subject walked using each of the four footwear conditions.

Data Analysis: Marker data were used to create anatomical coordinate systems on the foot and shank. Ankle flexion was measured as the sagittal plane rotation between these coordinate systems. Average ankle ROM during SLS was calculated as the difference between the maximum and minimum ankle flexion during SLS. To visualize the data, ensemble average curves were also generated using a cubic-spline function in which ankle ROM data were normalized to 100 samples over the gait cycle and then averaged across all strides for each condition.

RESULTS

A reduction in peak-to-peak mean ankle ROM was observed across all RBS conditions when compared to the flat condition (Fig. 1). The subject’s average ankle motion during SLS decreased from 13.4 degrees in the flat condition to 4.9 degrees in the 0 cm condition, to 6.7 degrees in the 3 cm condition, and to 7.1 degrees in the 7 cm condition.

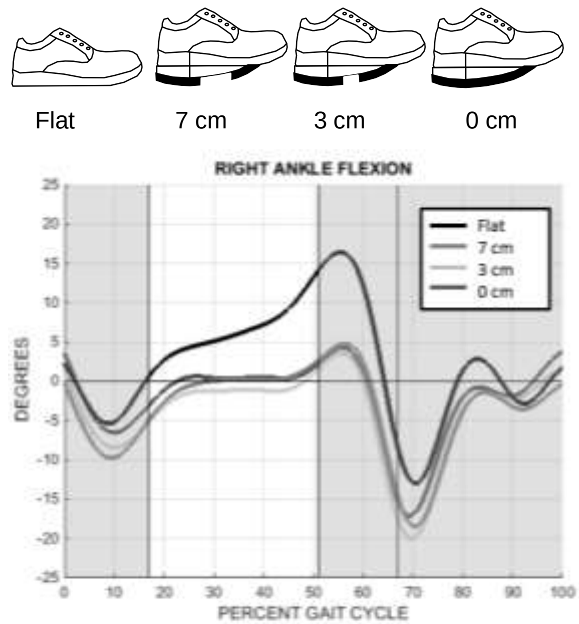

Fig. 1. Sagittal plane kinematic data of the right ankle. Each line represents the mean ankle ROM measured in degrees versus the percentage of the gait cycle.

DISCUSSION

Although there was an increase in movement with the addition of a flat region to the CR-RBS, there was still an appreciable reduction in movement (47%) with the largest flat region (7 cm condition) when compared to the unmodified shoe. This reduction in movement may be significant enough to reduce pain in persons with chronic ankle pain while also providing stability for standing. Future research and development is needed to examine these relationships.

CONCLUSION

The addition of a flat region to our CR-RBS design had minimal effects on sagittal plane ankle ROM during SLS of the gait cycle.

CLINICAL APPLICATIONS

Ankle pain, ankle immobilization, orthotics, rocker bottom shoes.

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Study funded by the Department of Veterans Affairs (VA RR&D-A9224-P).

"Mechanical Properties and Isolated Effects of Ankle-Foot Orthosis Plantarflexion Resistance, Dorsiflexion Resistance and Alignment on Hemiparetic Gait in Stroke"

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INTRODUCTION

The importance of adjusting mechanical properties of an articulated ankle-foot orthosis (AFO) to optimize gait in individuals with stroke has been gradually recognized by researchers and clinicians.[1-3] This paper presents the mechanical properties of a novel articulated AFO with independently adjustable plantarflexion resistance, dorsiflexion resistance and alignment, and their effect on ankle and knee joint angles, moments and power for a chronic stroke subject.

METHOD

Subject: The subject for this study was a 50-year-old female, 5.5 years post stroke with left hemiparesis. The subject presented with neuromuscular tone and +5° range of motion in dorsiflexion. The subject was unable to actively dorsiflex past 10° plantarflexion and walked in equinus in swing phase with excessive knee flexion in stance phase.

Apparatus: A custom polypropylene AFO was fabricated for the subject using Triple Action™ ankle joints. The sagittal resistance and alignment of the AFO were quantified under 12 different ankle joint adjustment settings using a motorized torque-angle tester comprised of an optical encoder and inline uniaxial torque sensor. Gait analysis was performed using a Vicon motion analysis system and Cleveland Clinic marker set with the subject walking on a Bertec split belt, instrumented treadmill at self-selected speed.

Procedures: The subject was fit with the AFO and the ankle joints were kinematically optimized using observational gait analysis. During motion trials, two of the three component settings were held at their optimum values while the ankle joint setting of interest was changed.

Data Analysis: Data were recorded and post-processed using Vicon Nexus and Visual3D software. Ankle and knee joint angles, moments and power were averaged and normalized to the gait cycle under each setting.

RESULTS

These results showed some systematic effects of ankle joint plantarflexion resistance settings on ankle angle at initial contact and moment from initial contact to loading response. The effects of changing AFO dorsiflexion resistance on ankle and knee joint kinematics and kinetics showed systematic effects on ankle angle at mid-stance and power at terminal stance. Changes in AFO alignment showed some systematic effects on ankle angle at initial contact and mid-stance and joint moments from initial contact to loading response.

DISCUSSION

The aim of this study was to investigate the mechanical properties and influence of a novel articulated AFO on ankle and knee joint angles, moments and power on stroke hemiparetic gait. The AFO showed systematic changes in mechanical characteristics with adjustment of the ankle joints. The subject's ankle and knee joint kinematics and kinetics showed some systematic changes in response to changes in AFO mechanical properties during gait.

Improvement in heel rocker was demonstrated with a more normal dorsiflexor moment pattern when plantarflexion resistance was increased and ankle alignment was changed toward dorsiflexion. This study suggested that optimization of heel rocker during gait requires adjustment of both plantarflexion resistance and alignment.

Both knee and ankle moments were systematically responsive to dorsiflexion resistance and alignment changes of the AFO in mid to late stance.

CONCLUSION

This study suggests the advantages of using kinematic and kinetic data in addition to observational gait analysis for AFO optimization in stroke. It was also suggested however that patient preference and comfort need to be considered during the optimization process.

CLINICAL APPLICATIONS

The treatment of lower extremity biomechanical deficits resulting from stroke is an important area of orthotic practice. A better understanding of the factors that influence the process of AFO optimization has important implications for the quality of care of stroke patients.

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EFFECTS OF HEEL WEDGE PROPERTIES ON GAIT WITH THE INTREPID DYNAMIC EXOSKELETAL ORTHOSIS (IDEO)

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INTRODUCTION

Severe lower limb injuries can limit physical function and affect many aspects of an individual's life (Doukas, 2013; MacKenzie, 2006). The Intrepid Dynamic Exoskeletal Orthosis (IDEO) is a custom-made dynamic response carbon fiber device, designed to restore function. The heel wedge is an integral part of the IDEO-heel wedge-shoe system (Figure 1). The purpose of this study was to determine the influence of heel wedge properties on the walking gait of individuals using an IDEO.

Figure 1: The IDEO-heel wedge-shoe system. Compression of the heel wedge under the IDEO simulates plantarflexion during loading response and allows smooth forward progression.

METHOD

Subjects: 12 unilateral IDEO users (11 male, 1 female), age 32.1±7.5 yrs, height 1.84±0.10 m, mass 96.7±23.3 kg, injuries: fracture, tendon rupture, arthritis, fusion, volumetric muscle loss

Procedures: Biomechanical gait data were collected as participants walked over level ground at a controlled speed using their IDEO with 6 different heel wedges (2 durometers X 3 heights).

Data Analysis: Outcome measures included: center of pressure (COP) velocity, ankle moment, and roll-over shape (ROS). Self-reported pain, IDEO comfort, and smoothness of gait were combined to determine wedge preference. Repeated measures ANOVA and Friedman tests were utilized with α=0.05.

RESULTS

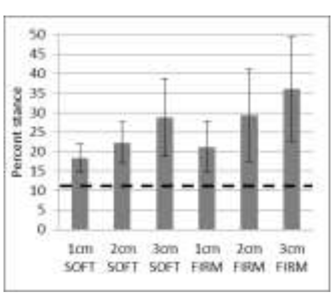

Figure 2: Time to peak COP velocity (as a percent of stance) was significantly earlier for 1 cm wedges compared to 2 cm wedges, 1 cm wedges compared to 3 cm wedges, 2 cm wedges compared to 3 cm wedges, and soft wedges compared to firm wedges. Dashed line is able-bodied.

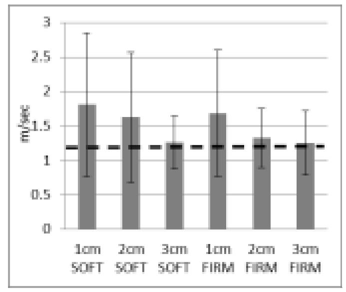

Figure 3: Peak COP velocity (m/sec) was significantly greater for 1 cm wedges than 3 cm wedges. There was also a non-significant trend for greater peak COP velocity for shorter wedges. Dashed line is able-bodied.

Time to peak internal dorsiflexion moment and time of ankle moment zero crossing (moment changed from dorsiflexion to plantarflexion) were significantly earlier for shorter and softer wedges. ROS radius of curvature was significantly less for shorter wedges, and ROS center of curvature was significantly further anterior for shorter and softer wedges.

DISCUSSION

In general, shorter and softer heel wedges stopped compressing earlier. This led to an earlier and greater peak in COP velocity as the foot pivoted on the heel and abruptly transitioned to the forefoot. COP position predictably influenced ankle moment zero crossing time. Taller and firmer wedges had a more posterior ROS center of curvature, which is similar to a dorsiflexed prosthetic foot (Hansen, 2008).

CONCLUSION

Changes in heel wedge height and durometer systematically affected loading of the foot. Participants preferred wedges which produced ankle moment zero crossing timing and ROS center of curvature position which were close to that of able-bodied individuals.

CLINICAL APPLICATIONS

Adjusting the heel wedge is a simple, straight-forward way to adjust the IDEO-heel wedge-shoe system. Selecting the most appropriate wedge height and durometer has great potential to improve an individual's gait.

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Clinical Impact of a Tunable Ankle Foot Orthosis on Hemiparetic Gait in Stroke: A Case Study

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INTRODUCTION

Clinicians have increasingly recognized the importance of optimizing mechanical characteristics of orthoses specific to each patient's needs. Research has demonstrated that the optimization of AFO stiffness and alignment can impact the clinical outcome in the treatment of some neuromuscular conditions including stroke (Jagadamma, 2010; Kobayashi, 2015; Singer, 2014). This case study presents the clinical approach and outcome of the orthotic treatment of a chronic stroke subject using a novel ankle joint that facilitates the independent adjustment of various mechanical characteristics.

METHOD

Subject: The subject is a 76 year old male, 16 years post stroke presenting with left hemiparesis. There is profound involvement of the upper extremity, hypertonicity and spastic co-contraction of the left ankle and knee. The subject has a 5° knee flexion contracture, and his dorsiflexion range of motion is limited to -5° with the knee extended. The subject's gait pattern is equinovarus with a pathologic extensor synergy. Gait deviations include foot drop, circumduction, forefoot first contact, limited tibial progression, and shortened contralateral step length.

Apparatus: A custom composite AFO was fabricated using Triple Action™ ankle joints and intrinsic support to resist equinovarus. The orthotic ankle joints allow for independent adjustment of ankle alignment, plantarflexion resistance, and dorsiflexion resistance. A Vicon motion capture system was used for data collection with the subject walking on a level treadmill at self-selected speed.

Procedures: The subject's clinical presentation was fully qualified by manual muscle testing, range of motion, observational gait analysis, and other functional measures. The subject was fit with the AFO using customary orthotic practice. The AFO was kinematically optimized in the clinical setting using a standard adjustment procedure that defines specific events to be observed during gait. Ankle joint settings and postural support of the AFO were changed systematically during motion capture to determine the kinematic effects of each adjustable feature.

Data Analysis: Mean joint angle graphs over the entire gait cycle were generated to compare the effects of incrementally adjusting each setting.

RESULTS

Observational gait analysis, supported by kinematic data, revealed systematic changes in biomechanical variables with AFO mechanical characteristics. Lateral supramalleolar support was effective resisting varus at the ankle. The ankle alignment setting had arguably the greatest effect of all the controlled variables. While the alignment had a more measureable impact at the ankle, an indirect influence of the knee was also observed. In addition to closed chain effects during stance phase, ankle alignment also influenced knee flexion angle during terminal swing. This may have been due to biomechanical coupling secondary to the subject's shortened gastrocnemius. The increase toward a dorsiflexed alignment coincided with a decrease in terminal swing knee extension.

The plantarflexion resistance was tuned to soften knee flexion during loading response as well as maintain clearance during swing. Also, when plantarflexion resistance was decreased, this allowed greater plantarflexion range of motion during preswing, and an increase in knee flexion during preswing and inital swing was observed. Overall the influence of the plantarflexion resistance was seen throughout gait, except during terminal stance, whereas the dorsiflexion resistance appeared to influence only terminal stance.

DISCUSSION

The purpose of this case study was to determine if a tunable ankle foot orthosis could be an effective means of orthotic treatment for a chronic stroke subject exhibiting lower extremity gait deficits secondary to weakness and spasticity. Each of the adjusted mechanical characteristics of the AFO impacted the subject's gait in a particular way that was useful for optimizing his gait. By isolating these adjustments, the effects of each variable were observed more clearly during observational gait analysis. The ability to tune the custom AFO specific to this subject's needs proved beneficial in improving his functional outcome.

CONCLUSION

The tunable AFO was effective in influencing lower extremity kinematics for this particular chronic stroke subject. Overall his clinical outcome was enhanced due to the ability of the orthosis to be optimized to compensate for his biomechanical deficits.

CLINICAL APPLICATIONS

This case study has demonstrated the importance of tuning custom AFOs specific to each patient. Understanding the effects of varying different mechanical properties of AFOs and having the ability to independently adjust these properties can improve patient outcomes.

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The Osseointegration Group of Australia Accelerated Protocol (OGAAP- 1) for Two- Stage Osseointegrated Reconstruction of Amputees

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INTRODUCTION

Amputation of a lower extremity results in major changes in a person's function, body image, and quality of life (Hagberg et al, 2001). It is estimated that less than half of those who require amputations return to work, and the average time to return to work exceeds one year. One-third of all amputees encounter socket-interface problems, leading to reduced prosthetic use and a markedly diminished quality of life. Over the last two decades, a new concept called osseointegration (OI) has emerged; connecting the artificial limb prosthesis to the residual bone. The primary objective of this study was to describe a protocol in detail (OGAAP-1) as a comprehensive strategy for a two-stage OI reconstruction and rehabilitation of lower extremity amputated limbs. The secondary objective was to assess the clinical outcomes in a case series of 50 unilateral transfemoral amputees as a preliminary report on the efficacy of the OGAAP-1 program

METHOD

Subjects: Prospective data from March 2011 to June 2014, a total of 53 unilateral trans-femoral (TFA) amputees were treated using the OGAAP-1. Males (34) and females (16) aged 24-73 (mean 49.4±12) years. Selection criteria: age >18 years, unilateral, TFAs who had socket related problems, or wheelchair bound with non-reconstructable limb pathology. Exclusion criteria included smokers, non-compliance, pregnancy, irradiated affected bone, diabetes, and vasculopathy.

Apparatus: The main outcome measures included the Questionnaire for persons with a TFA (Q-TFA), the Short Form Health Survey 36 (SF-36), K levels, and the Six Minute Walk Test (6MWT) and Timed Up and Go (TUG) tests, pre- and post-operatively.

Procedures: OI reconstruction was performed using either the Integral Leg Prosthesis (ILP) or the Osseointegrated Prosthetic Limb (OPL); titanium press-fit implants, allow bony ingrowth.

RESULTS

Three patients died of unrelated causes, and the remaining 50 treated under this protocol, none were lost to follow-up. Both the post-operative Q-TFA global score (47.82±2.69 to 83.52±2.66, p<0.0001, and the SF-36 physical component summary (37.09±1.41 to 47.29±1.33, p<0.0001, were markedly superior to those of the preoperative values. Both the 6MWT (281±19 to 419±20, p<0.0001) and the TUG (14.59±1.19 to 8.74±0.40, p<0.0001), were significantly improved. 23 out of 50 (46%) participants had no adverse events; the other 27 had one or more complications (54%). There were episodes of infection in 21 patients (42%): 13 responded to oral antibiotics alone; 5 responded to IV antibiotics; and surgical soft tissue debridement was required on 3 occasions. Four patients had a post-operative fracture as a result of a fall related to their increased activity levels. Revision of the implant was required in 2 patients; one as a result of an undersized device, and the other as the result of an implant fatigue failure at 3.5 years (96% implant survival).

DISCUSSION

These findings are comparable to, or better than, those reported previously by other groups using alternative implants and rehabilitation protocols. Under the OGAAP-1 protocol the time interval between the initial procedure and fully independent ambulation was approximately 4.5 months. This contrasts markedly with the protracted interval between the initial procedure and independent ambulation previously reported for screw-type osseointegration implants, typically requiring as long as 9 to 12 months. The more rapid completion of reconstruction is likely due to a combination of factors, including the decreased interval between stages and the accelerated progression of weight bearing exercises and rehabilitation.

CONCLUSION

The main objective of this study was to describe in detail the OGAAP-1 clinical protocol and accelerated rehabilitation program for the OI reconstruction of amputees. In this series of 50 unilateral trans-femoral patients with a minimum of one-year follow-up, significant improvements were achieved in all of the outcome measures of QOL, ambulation ability, and functional level: QTFA (global score), SF-36 (PCS), K-levels, TUG, and 6MWT.

CLINICAL APPLICATIONS

Osseointegration is a realistic option for primary and secondary reconstruction of non-dysvascular amputees. Observationally, in this study outcomes are improved compared to socket users.

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Post Limb Reconstruction Strategy for Post Traumatic Amputees (OGAAP-2)

Al Muderis, M[1,2,3], Bosley, B[3], and Kahle, JT[4]

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INTRODUCTION

Osseointegration was developed to attempt to overcome persistent issues associated with socket-mounted prosthetics, by direct attachment of the prosthetic limb to the skeletal residuum. Until recently this has almost always been performed in two stages; however, since March 2014 this has been routinely performed as a single-stage under the Osseointegration Group of Australia Accelerated Protocol-2 (OGAAP-2). Our group is currently the only centre in the world routinely performing osseointegration as a single-stage procedure. The primary objective here is to describe this single-stage reconstruction strategy for post- traumatic amputees. The secondary objective is to report on our early experience, including preliminary assessment of the safety and efficacy of the protocol in this particular group of potentially challenging patients.

METHOD

Subjects: A prospective pilot study of 20 patients, compared to 32 similar two-stage cases; all amputations were related to prior trauma. The study groups comprised 39 males, 13 females; aged 20-71 (mean 46.8) years; minimum one-year follow-up. Selection criteria included age >18 years, amputees who had socket-related problems, as well as wheelchair bound patients with short stumps and non-reconstructable limb pathology.

Apparatus: Principle outcome measures included: Questionnaire for persons with a Trans-Femoral Amputation (Q-TFA); Short Form Health Survey 36 (SF-36); K Levels; Six Minute Walk Test (6MWT); and Timed Up and Go (TUG).

Procedures: Adverse events were recorded including infection, revision surgery, fractures, and implant failures.

Data Analysis: Outcomes were obtained pre- and post-operatively, at a minimum follow-up of one year. Comparisons were made between these two protocols using the difference from the mean pre-operative values and the mean post-operative values in each group; the improvements observed for all four outcomes were comparable.

RESULTS

The post-operative Q-TFA global score in the single-stage cohort (44.95±21.66 to 71.30±18.22) was not significantly different from the two-stage cohort (52.50±28.88 to 87.04±16.72) (mean diff 11.43, p=0.1204). The post-operative SF-36 physical component summary in the single-stage cohort (39.30±12.42 to 46.37±9.90) was not significantly different fom the two-stage cohort (38.47±13.88 to 49.58±4.37) (mean diff 1.3, p=0.7216). The 6MWT in the single-stage cohort (164.8±178.4 to 392.2±148.1) was not significantly different from the two-stage cohort (224.8±154.8 to 405.5±83.1) (mean diff 42.7, p=0.3659). The TUG in the single-stage cohort (10.48±8.67 to 6.21±6.84) was not significantly different from the two-stage cohort (11.94±9.28 to 8.63±2.13) (mean diff 2.05, p=0.3823). A total of 13 participants of 20 were adverse event-free; 7 patients had superficial infections that resolved with antibiotics, 2 of whom also underwent debridement of their stoma. Refashioning of soft tissue was performed on 3 patients; there were no periprosthetic fractures; no cases of implant fatigue failure; and no cases of aseptic loosening

DISCUSSION

The main objective of this study was to provide preliminary results of the comparison between the OGAAP-1 two-stage protocol and the OGAAP-2 single-stage protocol for the osseointegrated reconstruction of amputees. In this series of 52 post-traumatic amputees with a minimum of one-year follow-up, significant improvements were achieved in all of the outcome measures of health-related quality of life and functional levels.

CONCLUSION

These preliminary results suggest single-stage osseointegration surgery following the OGAAP- 2 is a comparably safe and effective alternative protocol for amputees experiencing socket- related discomfort.

CLINICAL APPLICATIONS

This protocol has the potential to dramatically reduce recovery time to only 3 months, compared with previously employed two-stage protocols which required anywhere from 4.5 to 12 months. Osseointegration represents a realistic paradigm shift fro the non-dysvascular amputee.

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Safety of osseointegrated implants for transfemoral amputees: A multicentre prospective cohort study

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INTRODUCTION

The etiology, incidence, and types of infections associated with osseointegrated (OI) prostheses are not well described for lower-limb amputees (Tabanella G, et al., 2009). Two previously published studies involved the OPRA System, and reported a very low (<3%) risk of deep infection leading to implant removal. The first study was a 5-year prospective of 39 patients, and reported only one patient with an infection leading to implant removal after 3 years.[2] A subsequent prospective study of 51 patients reported a 55% cumulative incidence of superficial infections at 24 months, with implant removal due to infection in only one patient. In Australia and the Netherlands a macro-porous press-fit type of implant allows a novel protocol of OI surgery and accelerated rehabilitation. Data regarding the infectious and non-infectious adverse events associated using this particular implant has not previously been reported. The main goal of this study was to develop a classification system specifically for OI related infections that includes both clinical and radiological signs enabling prospective reporting of the true incidence of these events, as well as a means to assess their severity.

METHOD

Subjects: A total of 86 patients aged 25-81 (47) years were included. Selection criteria: age >18 years, unilateral, trans-femoral amputees who had socket related problems including wheel-chair bound patients with short stump non reconstructable limb pathology. Exclusion criteria included smokers, psychological instability, non-compliance, diabetes, and vasculopathy.

Procedures: OI reconstruction was performed using either the Integral Leg Prosthesis or the OI Prosthetic Limb (OPL) titanium implants specifically designed for press-fit fixation, allowing bony in growth.

Data Analysis: Odds ratios were calculated to assess the association between patient gender, smoking status, and the presence of complications. An independent two-sample t-test was performed to test for a difference inpatient and surgical characteristics measured as continuous variables between patients with and without complications. A p-value <0.05 was significant.

RESULTS

Patients were followed up for a median of 34 (24-71) months, during which 31 patients had an uneventful course without any complications. Of the remaining 55 patients, 25 had minor complications but no infections. A total of 24 patients developed infections,

but all of these were either grade 1 or grade 2 and did not necessitate surgery. During the period of the study, no patients developed grade 3 or grade 4 infections. Other adverse events requiring intervention were observed in 26 patients, including: inadequate OI with replacement of implant (1); stoma hyper-granulation (17); implant breakage (2); breakage of the dual cone component safety pins (3); and proximal femur fractures (3). There was a significant association between gender and risk of severe infection with women having more than a 6-fold increase in risk (OR 6.5, 95% CI 1.1-38.15). A BMI > 25, was associated with a significant 3-fold higher risk of a mild infection (OR 3.47, 95% CI 1.16-10.39). Smokers had a 7-fold higher risk of a recurrent infection (OR 7.5, 95% CI 1.32-42.35).

DISCUSSION

This study represents the largest prospective cohort evaluation of transfemoral amputees treated with press-fit OI implants reported to date. A comprehensive classification for infection related to OI systems including treatment criteria was introduced and used to assess the safety of these press-fit type OI. Mild infection and irritation of the soft tissue in the skin penetration area are common, but successfully managed with simple measures. This multicenter study indicates that severe infections resulting in septic implant loosening are rare, and were not observed in this cohort. These findings suggest careful soft tissue handling and appropriate intervention as indicated can successfully limit the potential risk of deep infection that might otherwise be associated with OI.

CONCLUSION

Mild infection and irritation of the soft tissue in the skin penetration area are common and successfully managed with simple measures. Severe infections resulting in septic implant loosening are rare. These findings indicate careful surgical soft tissue handling is essential.

CLINICAL APPLICATIONS

Osseointegration is a safe procedure for the primary and secondary reconstruction for all non-dysvascular amputees. Adverse effects are similar to those associated with other implant procedures, such as hip and knee replacement.

REFERENCES

Safety of osseointegrated implants for transfemoral amputees: A multicentre prospective cohort study

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Improved Function and QoL Following Osseointegrated Reconstruction of Post-Traumatic Amputees

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INTRODUCTION

One of the major causes of lower limb amputation is severe trauma resulting in a mangled extremity or failed attempt at limb salvage. Unfortunately, at least one-third of all amputees still encounter symptomatic socket-residuum interface problems, leading to reduced prosthetic use and a markedly diminished quality of life. Over the last two decades, a new concept called osseointegration has emerged in an attempt to overcome the many issues associated with traditional socket-mounted prosthetics. By intimately connecting the artificial limb prosthesis to the residual bone, the socket interface can now be potentially eliminated. This study introduces the Osseointegration Group of Australia Accelerated Protocol (OGAAP-1) using press-fit fixation for transcutaneous prostheses. The primary objective was to describe in detail this two-stage strategy (OGAAP-1) for the osseointegrated (OI) reconstruction of amputated limbs, specifically unilateral transfemoral amputees (TFA).

METHOD

Subjects: Prospective case series of 32 post-traumatic unilateral TFAs treated at a single center. The study included 25 males and 7 females, aged 24-67 (mean 46.8) years, with a minimum one-year follow-up.

Apparatus: The main outcome measures included the Questionnaire for persons with a TFA (Q-TFA), the Short Form Health Survey 36 (SF-36), K levels, and the Six Minute Walk Test (6MWT) and Timed Up and Go (TUG) tests, pre- and post-operatively.

Procedures: Adverse events were recorded including infection, revision surgery, fractures, and implant failures.

RESULTS

Clinical outcomes were obtained pre- and post-operatively from 12 to 46 months, with a mean follow-up of 22 months. Compared to the mean preoperative values with socket prostheses, the mean post-operative values for all five validated outcome measures were significantly improved. Both the post-operative Q-TFA global score (46.88±3.51 to 83.62±3.47, $p<0.0001$) and the SF-36 physical component summary(36.89±1.81 to 48.49±1,69, $p<0.0001$) were markedly superior to those of the pre-operative values. K levels improved in 16 patients, and remained unchanged in 16 patients; no patient had a reduction in their K level. Both the 6MWT (193±31.67 to 434±23.78, $p<0.0001$) and the TUG (11.17±1.77 to 7.40±0.4, $p=0.04$) were also significantly improved. 8 participants were wheelchair bound pre-operatively, and could not perform the TUG and 6MWT; however, all 8 were able to do so after OI reconstruction, and their post operative values were comparable to those of the prosthetic users who were ambulatory preoperatively. A total of 20 participants were adverse event-free, three of whom required elective soft tissue refashioning 12 month after the second stage procedure to avoid redundant tissue impingement, skin irritation and infection. There were episodes of infection in 10 patients: 7 responded to oral antibiotics and 3 required surgical soft tissue debridement, one patient also required IV antibiotics. Refashioning of the soft tissue residuum was performed on 4 patients; 1 periprosthetic fracture occurred due to increased activity 1 implant failed due to fatigue, which was revised successfully.

DISCUSSION

These findings are comparable to, or better than, those reported previously by other groups using alternative implants and rehabilitation protocols. Under the OGAAP-1 protocol the time interval between the initial procedure and fully independent ambulation was approximately 4.5 months. This contrasts markedly with the protracted interval between the initial procedure and independent ambulation previously reported for screw-type osseointegration implants, typically requiring as long as 9 to 12 months. The more rapid completion of reconstruction is likely due to a combination of factors, including the decreased interval between stages and the accelerated progression of weight-bearing exercises and rehabilitation.

CONCLUSION

In these 32 post-traumatic unilateral TFAs, significant improvements were achieved in all of the outcome measures of health-related quality of life, ambulation ability, and functional levels. These results confirm the OGAAP-1 is a suitable alternative for post-traumatic unilateral TFAs experiencing socket-related discomfort, with the potential to reduce recovery time compared to other staged treatment protocols.

CLINICAL APPLICATIONS

Osseointegration is a realistic primary and secondary reconstruction option for all non-dysvascular amputees. Observationally, in this study functional and QOL outcomes are improved compared to socket users.

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A Comparison of Prosthetic Mobility in Amputees with Osseointegration versus Traditional Amputation and Socket

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INTRODUCTION

The Osseointegration (OI) limb reconstruction surgical procedure for people with lower limb amputations (LLA) has been performed in Sweden since the 1990's and is performed in Germany, England, Australia and most recently the United States. Presently, there are variations with the two-stage surgical procedure. Published outcomes for people who have had osseointegration reconstruction report improvements within subjects when comparing pre to post-surgical mobility or quality of life.[1,2,3] To date no studies have compared prosthetic mobility in people with LLAs who use an osseointegration prosthesis (OIP) to a traditional socket prosthesis (TSP).

METHOD

Subjects: A convenience sample of 28 community ambulators with unilateral LLA, 14 who had an OIP and 14 age and level of amputation matched LLA with TSP with a mean age of 46 ±13 and 48 ±15 years respectively, were recruited at the Amputee Coalition conference. All OIP subjects had the same surgeon, Munjed Al Muderis, MD, with their surgery performed in Sydney, Australia.

Procedures: Subjects competed Prosthetic Limb Users Survey of Mobility™ (PLUS-M) short form, 12 questions. In addition, subjects performed 2 trials of the 10 meter walk test (10MWT), component Timed Up and Go (cTUG) test at self selected and fast walking speeds. A custom mobile software application was used to capture all data.

Data analysis: SAS Version 9.4 statistical software was used to provide descriptive statistics of the sample. Paired t-tests was performed to compare differences in group performance.

RESULTS

The OIP transfemoral (TFA) group was found to have significantly better mobility as measured by the PLUS-M (p<0.02). However, differences were not found with the PLUS-M with the transtibial (TTA) group. No other differences in mobility were detected in mobility as measured by the 10 MWT, TUG and TUG-fast.

Measures (N=28)	OIP (n=14)	TSP (n=14)	p
Age (years)	45.7 ± 13.5	48.3 ± 15.1	.64
Time amp (mths)	94.3 ± 97.8	142.1 ± 175.5	.38
PLUS-M12 (t-score)	60.3 ± 6.1	54.1 ± 7.6	.02
10 MWT (m/sec)	.87 ± .16	.90 ± .18	.64
TUG (sec)	11.5 ± 2.8	11.6 ± 2.1	.92
TUG –Fast (sec)	9.1 ± 2.0	9.5 ± 2.2	.59

Measures (N=28)	TTA OIP (n=5)	TTA TSP (n=5)	p
PLUS-M12(t-score)	61.7 ± 7.1	58.1 ± 9.1	.5
10MWT (m/sec)	.98 ± .14	.82 ± .22	.2
TUG (sec)	9.9 ± 2.4	12.2 ± 2.7	.2
TUG -fast (sec)	7.99 ± 2.3	9.7 ± 2.9	.35
	TFA OIP (n=9)	**TFA TSP (n=9)**	**p**
PLUS-M12(t-score)	59.6 ± 5.8	51.9 ± 6.1	.02
10MWT (m/sec)	.81 ± .15	.95 ± .17	.09
TUG (sec)	12.4 ± 2.8	11.3 ± 1.8	.35
TUG -fast (sec)	9.6 ± 1.8	9.4 ± 1.8	.76

DISCUSSION

Osseointegration surgical procedures are currently indicated for LLAs who have difficulty or cannot wear a traditional socket and are relatively healthy. Prior published research has reported significant differences between TSP versus OIP when using within subject designs comparing their mobility prior to OI surgery in their existing prosthesis to their post-surgical capabilities.[1,2,3] This small study found that the LLA with OIP were able to demonstrate mobility similar to LLA with TSP and were similar to previous reports post-OI surgery.[1,3] Moreover, OIP TFAs self-report significantly better mobility. Further research with a larger sample and other measures of mobility would provide greater insights to similarities and differences between the two groups.

CONCLUSION

This study suggests that osseointegration surgical procedure enables people with LLA to have mobility equal to those LLAs who are comfortably fit in a traditional socket.

CLINICAL APPLICATIONS

The osseointegration surgical procedure enables LLAs to benefit from a prosthesis and enjoy the level of mobility that LLAs a comfortable socket fit demonstrate.

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Comparison of Balance Outcomes in Amputees with an Osseointegrated versus Traditional Socket Prostheses

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INTRODUCTION

Osseointegration (OI) for bone-anchorage of an external lower limb prosthesis has become an alternative for traditional socket suspension. People with an osseointegrated prostheses (OIP) have reported a phenomenon called osseoperception, which is an improved ability to identify various sensations through their artificial limb.[1] Research has quantified that amputees with OIP have improved ability to detect vibrations through the prosthesis[2] with potential applications for improved ability to balance. The purpose of this study is to compare balance confidence and balance performance in people with lower limb amputation who use an OIP to a traditional socket prosthesis (TSP).

METHOD

Subjects: A convenience sample of 15 community ambulators with unilateral OIP participated at the 2016 Amputee Coalition National Conference. All OIP subjects had surgical procedure performed in Sydney, Australia by Dr. Munjed Al Muderis. Another 15 participants with TSP were identified as case-control matches for the OIP cohort based on age (range 25-67), gender (7 male, 8 female), amputation level (4 TTA, 11 TFA), and K-Level of the OIP cohort.

Procedures: Subjects completed the Activities Specific Balance Confidence Scale (ABC), single limb stance, and conditions 1-3 of the Modified Test for Sensory Integration and Balance (mCTSIB). An inertial measurement unit (IMU), was attached to the sacrum with an elastic belt to measure postural sway during the mCTSIB activities.

Data analysis: SPSS Statistical Software was used to describe the study sample, paired t-tests were used to compare differences in the two groups.

RESULTS

There was no significant difference in single limb balance duration between groups, but there was a trend of the OIP group to have better sound limb balance (p=.09)(Table 1). The OIP group had significantly higher ABC scores, with an average increase of 7% balance confidence over the TSP group.

All subjects (n=30) were able to maintain bipedal balance for 30 seconds in the mCTSIB conditions. There was no difference in the postural sway in the AP or ML directions between the groups for mCTSIB conditions 1-3.

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	OIP (n=15)	**TSP (n=15)**	**p**
Balance Confidence			
ABC (%)	94.7 ± 5.68	86.97 ± 12.18	.04*
Single Limb			
Prosthetic (sec)	0.98 ± 0.47	1.14 ± 0.58	.44
Sound (sec)	23.13 ± 11.0	17.93 ± 13.86	.09
mCTSIB conditions:			
1.Firm, Eyes Open			
AP (cm)	1.29 ± 0.55	1.26 ± 0.45	0.86
ML (cm)	0.88 ± 0.46	0.87 ± 0.42	0.84
2.Firm, Eyes Closed			
AP (cm)	1.94 ± 0.99	1.63 ± 0.51	0.29
ML (cm)	0.89 ± 0.46	0.90 ± 0.36	0.26
3.Foam, Eyes Open			
AP (cm)	1.37 ± 0.46	1.39 ± 0.39	0.88
ML (cm)	1.63 ± 0.79	1.57 ± 0.83	0.84

Table 1. Comparison of Balance Outcomes for OIP and TSP; results show the mean maximal sacral excursion in AP and ML directions for mCTSIB conditions 1-3, mean single limb balance durations, and mean percentage of balance confidence. *Significant at p<.05 level.

DISCUSSION

Balance performance measures selected for this small study did not show any differences between subjects with OIP and TSP. Both groups demonstrated minimal sway excursion during bipedal mCTSIB conditions 1-3, whereas single limb balance performance was more variable and challenging. Subjects with OIP had higher balance confidence.

CONCLUSION

Individuals with unilateral transtibial and transfemoral amputation with an OIP demonstrated similar balance performance compared to a matched-case control TSP group. However, the OIP group reported higher balance confidence. Because of the small sample in this study future work should determine where differences in posture during single-limb and bipedal balance activities might exist.

CLINICAL APPLICATIONS

The osseointegration surgical procedure allows an alternative to traditional socket suspension with similar balance outcomes in bipedal and single limb stance. Moreover, there is a self-reported increased confidence by the OIP group that may be related to osseoperception or other factors related to balance not yet determined.

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SOCKET FIT COMFORT HELPS TO PREDICT PHYSICAL ACTIVITY LEVEL AMONG ADULTS WITH A UNILATERAL TRANSTIBIAL AMPUTATION

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INTRODUCTION

Physical activity, e.g. daily step counts and time spent at various levels of physical activity, has been objectively assessed using accelerometers in multiple patient populations. To reduce the risk of chronic health conditions, recommendations are for adults to take ≥10,000 steps per day *and* participate in ≥150 minutes per week of moderate-intensity (~50 steps per side/minute) physical activity or ≥75 minutes per week of vigorous-intensity (~65 steps/side/minute) physical activity (Abel, 2011; Liu, 2016). In patients utilizing a lower extremity prosthetic device, socket fit discomfort may result in reduced physical activity. The objective of this study was to determine if socket fit comfort helps to predict physical activity level as obtained with accelerometers among amputees. We hypothesized that greater socket fit discomfort would predict lower step counts and less minutes spent in higher-intensity physical activity.

METHODS

Participants: 50 prosthetic users, aged 18-85 years, with a unilateral transtibial amputation were included in this study funded by the OPERF. Individuals with bilateral amputations or with weight-bearing restrictions of the residual limb were excluded. The project was approved by the University of Delaware Institutional Review Board for Human Subjects; all individuals signed an informed consent.

Procedures: Participants provided demographics information, including medical history and medications, and filled out the Socket Fit Comfort Score (Hanspal, 2003). The Cumulative Illness Rating Scale (CIRS; Hudon, 2005), which is a measure of comorbidity burden, was completed. Participants wore a StepWatch 3 activity monitor around the prosthetic pylon for 7 days following the examination; average daily step count, as well as percentage of time in low (1-30 steps/minute), medium (30-60 steps/minute), and high (≥60 steps/minute) intensity activity, was extracted from the monitor. Individuals with at least 5 days of activity monitor data were included (n=47).

Data Analysis: Linear regression modeling was used to explore relationships between SFCS *and* average daily step count and minutes per week spent in various intensities of physical activity, while controlling for sex, age, time since initial amputation, and comorbidity burden (p<.050).

RESULTS

Sixty-six percent of the sample was male (n=31). Mean age was 58.5±12 years, mean time elapsed since the initial amputation was 12.7±14.5 years, and the mean CIRS was 11.0±6.7 points. Participants walked on average 5491±4043 steps/day; they spent an average of 1170±577 minutes/week performing low-intensity activities and 341±265 and 111±134 minutes participating in medium- and high-intensity activities, respectively (based on StepWatch categorization using steps/minute of the prosthetic limb). Covariates explained 35.2% (p=.001) of the variance in average daily step count, while SFCS explained an additional 8.3% of the variance in step count (p=.018). SFCS explained 7.8% (p=.037) of the variance in number of minutes spent in high-intensity activity, but did not explain any of the variance in number of minutes spent performing low- or moderate-intensity activity (p>.050). Our hypothesis was supported as lower SFCS predicted decreased daily step counts *and* reduced high-intensity activity.

DISCUSSION

Previous research has evaluated the impact of various socket designs on clinically important outcomes (Safari and Meier, 2015), but there has been less research on patient-perception of socket fit and its relationship to outcomes. Given that amputees are at higher risk for chronic health conditions, and based on these data are not meeting physical activity daily step count recommendations (i.e. 55% of recommendation), practitioners need to identify modifiable factors that if addressed, may promote movement. It appears that SFCS may be an important modifiable factor for increasing physical activity, particularly time spent in high-level activity.

CONCLUSION

Socket fit comfort is independently associated with physical activity, as assessed via accelerometers.

CLINICAL APPLICATIONS

Future longitudinal work may determine if improved socket fit comfort through prosthetic adjustments increases the number of steps taken per day and/or the number of minutes spent in high-intensity activity.

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SELF-REPORT MEASURES HELP PREDICT DAILY STEP COUNTS AMONG INDIVIDUALS WITH A UNILATERAL TRANSTIBIAL AMPUTATION

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INTRODUCTION

One construct of interest in determining prosthetic componentry is the patient's physical activity level. Accelerometers, which provide daily step counts, have been used to assess physical activity level, in multiple populations. Since the cost of research-grade accelerometers precludes their use in routine clinical practice, practitioners rely on clinical measures to make inferences as to a patient's physical activity level in their home and community. However, research evaluating relationships between clinical measures and daily step counts among individuals with lower limb loss is limited. Thus, the purpose of this study was to determine if commonly used self-report measures are predictive of physical activity, as assessed via accelerometer data, i.e. daily step counts, among adults with a lower limb amputation.

METHODS

Participants: 50 prosthetic users, aged 18-85 years, with a unilateral transtibial amputation were included in this study that was funded by the Orthotics and Prosthetics Education and Research Foundation, Inc. Individuals with bilateral amputations or with weight-bearing restrictions of the residual limb were excluded. The project was approved by the University of Delaware Institutional Review Board for Human Subjects; all individuals signed an informed consent.

Procedures: Participants provided demographics information and completed the Prosthetic Evaluation Questionnaire-mobility section (PEQ-m; Franchignoni, 2007), the Activities Specific Balance-Confidence Scale (ABC; Miller, 2003), and the Houghton Scale of Prosthetic Use (HOU; Wong, 2016). Medical history and medications were reviewed with a licensed practitioner and the Cumulative Illness Rating Scale (CIRS; Hudon, 2005), which is a measure of comorbidity burden, was completed. Participants wore a StepWatch 3 activity monitor for 7 days following the examination; average daily step count was extracted from each monitor. Individuals with at least 5 days of activity monitor data were included (n=47).

Data Analysis: Linear regression modeling was used to explore relationships among self-reported outcome measures and average daily step count, while controlling for sex, age, time elapsed since the initial amputation, and comorbidities per the CIRS ($p<.050$). Assumptions for regression modeling were met.

RESULTS

Sixty-six percent of the sample was male (n=31). Mean age was 58.5±12 years, mean time elapsed since the initial amputation was 12.7±14.5 years, and the mean CIRS was 11.0±6.7 points. Participants walked on average 5491±4043 steps/day. Covariates explained 31.4% ($p=.004$) of the variance in average daily step count, while PEQ-m explained an additional 13.0% of the variance ($p=.004$). Covariates explained 32.7% of the variance in the ABC and HOU ($p=.002$); the ABC and the HOU explained an additional 13.3% ($p=.003$) and 11.3% ($p=.007$) of the variance in average daily step count, respectively. For all self-report measures, higher scores helped predict greater average daily step counts in the days that followed.

DISCUSSION

Routine use of research-grade accelerometers to determine physical activity level is not feasible. Thus, it is important to identify clinical measures that provide insight into daily physical activity, which is a major consideration when determining a patient's prosthetic componentry. The PEQ-m, ABC, and HOU predict physical activity level among individuals with a unilateral transtibial amputation who are using a prosthetic device, regardless of age, sex, time elapsed since the individual's initial amputation, and comorbidities. Our work adds to the research of Lin et al. (2014) who found that mean daily step counts as assessed via pedometers were correlated to various physical performance measures. Our future work will seek to determine a cluster of clinical measures, i.e. self-report and performance-based, that predict physical activity level among patients with lower limb amputations over a longer time period.

CONCLUSION

The PEQ-m, the ABC, and the HOU may assist practitioners with predicting daily physical activity among individuals with a unilateral transtibial amputation.

CLINICAL APPLICATIONS

This work is the first step in determining a cluster of clinical measures that may serve as a surrogate for physical activity data obtained from accelerometers.

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STEP COUNT ACCURACY OF THE STEPWATCH AND FITBIT® ONE™ AMONG INDIVIDUALS WITH A UNILATERAL TRANSTIBIAL AMPUTATION

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INTRODUCTION

Daily step counts, as obtained via activity monitors, provide insight into real-world activity level (Albert, 2013). For persons with lower-limb amputations, the StepWatch (Modus Health LLC) has historically been the most widely used monitor. The StepWatch is costly, though, making its use prohibitive for many clinicians (Albert, 2013; Fulk, 2014). The FitBit® One™ (Fitbit Inc.) is a lower cost option. However, accuracy assessments of both monitors are limited among individuals with lower-limb amputations. This study's purpose was to (1) evaluate the step count accuracy of both monitors during forward, linear walking and more complex walking and (2) compare monitor step counts during real-world walking.

METHOD

Participants: 50 prosthetic users, aged 18-85 years, with a unilateral transtibial amputation were included in this IRB-approved study. Participants were excluded if they had any current issues with overall health or their residual limb that limited their walking ability or if they had an amputation of the sound limb.

Procedures: Participants were equipped with a StepWatch and FitBit® One™ secured about the distal prosthetic pylon. Participants completed a clinical evaluation that included the 6 Minute Walk Test (6MWT) to evaluate forward, linear walking accuracy, and the Figure of 8 Walk Test (F8WT) and 4 Square Step Test (FSST) to evaluate complex walking accuracy of the two monitors. An investigator, blinded to the activity monitor counts, manually counted steps taken during the 6MWT and F8WT/FSST. After each test, step counts recorded by each monitor were extracted, and monitors were reset. Following this evaluation, participants were sent home with the monitors and told to perform their regular activities, wearing the monitors at all times. Monitors were mailed back after a 7-day period.

Data Analysis: Percent errors and intraclass correlation coefficients (ICC[2,1]) with 95% confidence intervals (CIs) were used to evaluate the accuracy of the StepWatch and FitBit as compared to a manual step count for the 6MWT (forward, linear walking) and F8WT/FSST (complex walking). The absolute percent error was calculated as ((abs(Monitor – Manual)/Manual)* 100). Once monitors were returned after the 7-day data collection, the total step count recorded by each monitor was extracted, and the absolute percent difference was calculated (abs((SW-FB)/((SW+FB)/2))*100). Finally, a linear regression was used to evaluate associations between the monitors' total real-world steps counts.

RESULTS

Of the 50 participants, a subset participated in part 1 of the study. For part 2, participants were excluded if they did not wear one or both monitors for at least five days or there was device failure, resulting in n=42.

Table 1: Step Count Accuracy Data.

	6MWT Manual	*6MWT SW*	*6MWT FB*	*Complex Manual*	*Complex SW*	*Complex FB*
n	31	31	27	17	17	16
Avg. Step Count	361.6 ±137.8	358.8 ±137.1	346.9 ±150.9	56.7 ± 23.0	56.8 ± 25.9	57.7 ± 28.3
Avg. % Error		4.3 ± 9.2%	4.3 ± 9.2%		13.0 ± 12.2%	15.5 ± 26.5%
ICC (LB, UB)		0.99 (0.98, 0.99)	0.97 (0.93, 0.99)		0.90 (0.75, 0.96)	0.88 (0.69, 0.96)

Both monitors showed excellent accuracy based on percent errors and ICCs during forward, linear walking (Table 1). During complex walking, percent errors were higher; ICCs were excellent but CIs were large. During real-world walking, the absolute percent difference was 25.4±28.6%, but monitor step counts had a nearly perfect linear relationship, with the StepWatch consistently counting an almost fixed number of additional steps over the FitBit (SW= 0.985FB + 4588.6, R^2=0.972).

DISCUSSION

Both monitors accurately counted steps during forward, linear walking, with high ICCs and average percent errors well below the 10% threshold considered acceptable (Lee, 2014). The StepWatch appeared to outperform the FitBit during complex walking, but percent errors exceeded the acceptable threshold and large CIs suggest a larger sample is needed. Real-world step count discrepancies were high, yet these step counts were highly associated.

CONCLUSION

The StepWatch and FitBit are accurate in for forward, linear walking. The StepWatch appears more accurate during complex walking, but more research is needed. The FitBit consistently counted fewer steps than the StepWatch during real-world walking.

CLINICAL APPLICATIONS

The StepWatch appears to be an acceptable tool for assessing real-world activity level among individuals with transtibial amputations. The FitBit, which under-counts steps but is less costly, may be used to estimate real-world activity level.

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NMES Use in Transtibial Amputations

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Introduction: Individuals with amputations experience an invasive surgery compromising the residual limb resulting in detriments such as a decrease in muscle strength, muscle atrophy, gait impairments and pain. To alleviate these problems there are current solutions to provide temporary relief but none are cost effective or readily available to all individuals; nor do they help all individuals with amputation. Neuromuscular Electrical Stimulation (NMES) has been shown to improve the strength and volume of the quadriceps muscles in individuals who have experienced a total knee arthroplasty, osteoarthritis of the knee, anterior cruciate ligament repair and in individuals who suffer from a chronic illness. NMES has also been shown to decrease pain in conditions such as knee osteoarthritis, chronic back pain, and total knee arthroplasty. We are proposing a novel idea to apply NMES to individuals with amputation to see if we can achieve the same results.

Objective: The purpose of this study is to demonstrate the efficacy of NMES for individuals with a transtibial amputation. We aim to demonstrate that when compared to a control group individuals who receive three months of NMES intervention will show greater knee extension strength, increased volume of the residual limb, decreased chronic and phantom pain and improved gait relative to the baseline measures. We will also evaluate the feasibility of this intervention and determine effect sizes to power a larger study.

Methods: Up to twenty-five unilateral transtibial participants who are greater than one year post amputation will be recruited and randomized into two groups. One group will receive the NMES intervention and the other group will continue with their activities of daily living. The study consists of a baseline visit and four follow up visits. Outcome measures will be assessed by isometric and isokinetic knee extension strength tests, residual limb volume measurements, a pain questionnaire, the Prosthetic Evaluation Questionnaire (PEQ) and gait analysis with the GAITRite® System. A mixed model repeated measures ANOVA will be used to compare the outcome measures between groups and over time. If successful, this study may lead to a new low cost treatment for maintaining residual limb strength, volume and managing pain after an amputation.

PRELIMINARY EVALUATION OF A MICROPROCESSOR CONTROLLED KNEE ANKLE PROSTHESIS (MKAP) FOR ABOVE KNEE AMPUTEES

"Dauriac, B.1,2, Bonnet, X. 2, Djian, F.2, and Pillet, H. 1"

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INTRODUCTION

Microprocessor-controlled prosthetic knees (MPK) have improved the safety and the functional outcomes of above knee amputees (Sawers & Hafner 2013). Knee flexion control during stance improved the walking ability both during stair (Schmalz et al. 2007) and slope descent (Burnfield et al. 2012). In spite of this knee control, patients continue to report some difficulties during outdoor activities (Samuelsson et al. 2012). Some of these difficulties could be attributed to the ankle lack of adaptations to different terrain (Vickers et al. 2008; Schmalz et al. 2007). The objective of the study was to evaluate a Microprocessor-controlled Knee Ankle Prosthesis (MKAP) able to mimic various adaptations quantified for asymptomatic people in slopes and stairs (Bonnet et al. 2014)

METHOD

Six above-knee amputees were fitted with the MKAP prototype. Motion was captured with a 54 marker set placed on the patient according to the protocol described by Pillet (Pillet et al. 2014). Acquisitions were made in 3 daily living situations simulated using instrumented devices: level ground, 12% (7°) inclined ramp and a 4-step staircase. From the marker set, kinetic and kinematic of 18 body segments were computed. A control group was formed with ten above knee amputees fitted with a conventional Microprocessor-controlled Prosthetic Knee and an Energy Storing And Return Foot. To evaluate the benefit of ankle joint control, several parameters were computed to compare MPK users and MKAP users such as the foot flat motion time (Dauriac et al. 2015)

RESULTS

Fig. 1 presents the sagittal kinematic of the hip, knee and ankle of the prosthetic limb during slope ascent and descent and stair descent for the ten MPK users (shaded area) and for the six MKAP users (solid lines). Compared to MPK, MKAP allows a wider range of motion of both the prosthetic knee (especially during stair descent) and prosthetic ankle both during stance and swing phase. MKAP users showed longer foot flat period compared to MPK users

	Slope descent	Level	Slope ascent
MKAP group	20	19	14
MPK group	11	15	16

Table 1 - Slope and level walking foot-flat period in % of the gait cycle for the two presented groups

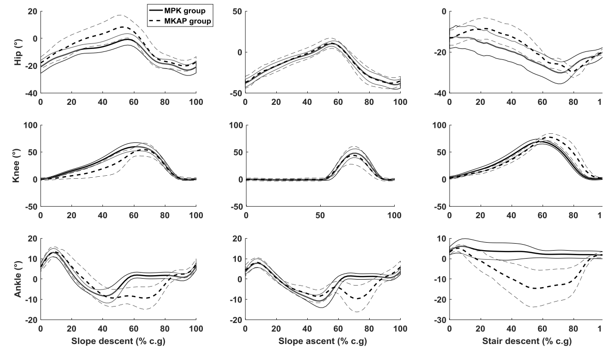

Figure 1. Mean +/- standard deviation for Ankle, knee and hip sagittal angles on prosthetic side during slope ascent and slope and stairs descent

DISCUSSION

The limited range of ankle motion in conventional prosthetic feet does not allow amputees to keep the foot flat on the floor during ramp descent. Using the prototype, the reduction of "equivalent" stiffness allows restoring a large foot flat period during the unipodal stance phase on the prosthesis, securing this critical phase of gait. During slope ascent, the ankle dorsiflexion during swing helps the user to increase toe clearance reducing falling risk. During stair descent, the ankle range of motion during stance allows avoiding the placement of the prosthetic foot on the edge of the step conventionally used to perform the tibial forward movement. All these adaptations were felt by the user as a gain in comfort and stability in these situations.

CONCLUSION

This prototype allows several adaptations in different daily living situations by allowing a greater ankle range of motion and adaptation and by restoring the ankle-knee synergy. These adaptations have been quantified and demonstrate strategies closer to asymptomatic people than the MKP users.

CLINICAL APPLICATIONS

This prototype permits to adapt both ankle and knee behavior during gait cycle. Compared to MKP, it should enable users to walk with more comfort and stability during slopes or stairs locomotion

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PRELIMINARY EVALUATION OF A MICROPROCESSOR CONTROLLED KNEE ANKLE PROSTHESIS (MKAP) FOR ABOVE KNEE AMPUTEES

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Comparative effectiveness of MPK and NMPK knees in K2 transfemoral amputees

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INTRODUCTION

The benefits of a microprocessor-controlled knee (MPK) have been well documented in Medicare Functional Classification Level (MFCL) K3 transfemoral amputees (TFA). There have been suggestions that a K2 level TFA will also benefit from this advanced technology by increasing their ambulatory functional level to an unlimited community ambulator (K3) when receiving a MPK (Kahle, 2008; Hafner, 2009; Theeven, 2011; Burnfield, 2012; Eberly 2013). Current medical policy restricts MPKs to K3 or K4 amputees and, thereby, potentially limits functional capabilities. Therefore, the purpose of this study was to assess if K2 amputees would benefit from a MPK.

METHOD

Study Design: A reversal A-B-A design was used whereby only the prosthetic knee was changed. Each subject was tested using their current NMPK, fit and tested with a MPK, and then retested with their NMPK. The subjects received a randomly assigned MPK prosthesis from one of four manufacturers (Otto Bock Compact, Ossur Rheo, Endolite Orion, Freedom Innovations Plie). All prosthesis fittings were performed by the subject's own certified prosthetist according to the manufacturer's fitting guidelines with oversight provided by the manufacturer's representative.

Subjects: 49 unilateral transfemoral amputees over age 55 (mean age 69±9 years with 4 years' experience using a prosthesis) who were MFCL K2 (with 12 K3 exceptions) were studied. Subjects were excluded if they had neuromuscular problems, a partial amputation of the contralateral limb, were on dialysis, had poor prosthetic socket fit or had residual limb breakdown. The majority of the subjects were using a Medi knee (53%) or an Otto Bock (3R60, 3R80, 3R90, 3R92, 3R93) knee (27%).

Outcome measures: Outcomes were assessed at baseline, 10 weeks after conversion to the MPK, and 4 weeks after reversion to their NPMK. Patient function was assessed in the free-living environment using activity monitors worn on the waist, thigh, and bilateral ankles for a period of four consecutive days. Patient satisfaction and safety was measured using the Prosthesis Evaluation Questionnaire (PEQ) and PEQ addendum (PEQ-A).

Data Analysis: A one-factor repeated measures ANOVA was used to determine if there was a difference in outcomes between the MPK and NPMK. Statistical significance was attained when the p-value was <0.05.

RESULTS

The subjects demonstrated improved outcomes when using a MPK. Patients reported a significant reduction in falls when receiving a MPK (Figure 1). The subjects spent significantly less time sitting when using a MPK. The mean time/day sitting was 58% at baseline, 49% on the MPK, and 63% when returning to the NPMK. In addition, there was a trend ($p=0.09$) toward increased loadbearing and improved gait entropy (i.e. more complex movements) when using the MPK. The subjects reported significantly improved ambulation, greater appearance, less frustration and greater utility when using a MPK, as measured by the PEQ.

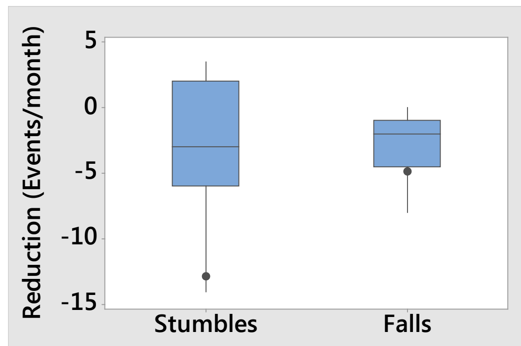

Figure 1. Box plot illustrating a reduction in stumbles and falls when using a MPK. The central line represents the median, the dot represents the mean, and the edges of the box are the 25th and 75th percentiles. The whiskers extend to ± 1.5 of the interquartile range.

DISCUSSION

This clinical trial demonstrated that K2 TFAs using a MPK improved their safety and activity, which resulted in increased subject satisfaction. Notably, a reduction in stumbles and falls occurred while the subjects engaged in more physical activity. The increase in activity resulted in a greater exposure to fall risk, but that risk was diminished by the advanced technology.

CONCLUSION

The study provides evidence that individuals with a TFA and K2 mobility clearly benefit from a MPK.

CLINICAL APPLICATIONS

MPK use in a K2 TFA will allow the patient to adopt a more independent lifestyle and an increase in general ambulation activity with a reduced risk of falls.

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INITIAL FINDINGS OF USER FEEDBACK OF POWERED KNEE-ANKLE INTENT REGONITION ERRORS

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INTRODUCTION

Recently developed powered lower limb prostheses may provide individuals with a high level lower amputation improved ability to perform activities of daily living. With an increased number of configurable ambulation modes comes the challenge to seamlessly and reliably switch between desired modes. Intent recognition using mechanical sensors and residual limb muscle activity data has been suggested and shows encouraging results[1]. Despite high accuracy rates, errors do occur and, depending on the specific error, user stability is affected to varying degrees. The goal of this study was to use a previously developed questionnaire[3] to quantify the effect of real-time classification errors when transfemoral amputees were ambulating on a powered knee-ankle prosthesis.

METHOD

Four subjects with a unilateral transfemoral amputation participated and had previously received training on the use of a powered knee-ankle prosthesis designed by Vanderbilt University. All subjects were able to use the device independently and safely for standing, level-ground walking, ramp ascent/descent and stair ascent/descent.

All subjects participated in an initial session where they completed a series of activity circuits where the prosthesis was controlled using a key fob. Data recorded, including 22 mechanical sensors and 8 channels of residual limb muscle activity, were used to create a intent recognition system specific to each subject. On a separate day, subjects came back into the laboratory to participate in a similar set of activity circuits where the prosthesis was controlled using the intent recognition system[1]. Subjects were asked to rate each trial using the Subject Evaluation of Gait Stability (SEGS) scale[3] where 0 indicated the subject did not perceive the error, 1 indicated the subject perceived the error but still felt stable, 2 indicated the subject felt unstable but could recover, and 3 indicated the subject felt unstable and would fall.

Subjects only reported one value per trial; if multiple errors occurred within one trial the value reported was in response to the first error. Questionnaire results were compiled and score results of 1-3 were categorized by steady state error (i.e., the subject intended to remain in an ambulation mode) and transitional state error (i.e., the subject intended to switch to a new ambulation mode).

RESULTS

There was an average of 14.75 trials with real-time intent recognition errors. Eighteen trials had the scored error occur during steady-state ambulation and 28 trials had the scored error occur during transitions between activities. Fig.1 indicates that majority of ranking '3' happened during transitions.

Figure 1: Number of trials reported for scores 1-3 separated by steady state and transition error.

DISCUSSION

Subjects did not rate all errors the same; different types of errors affected each person's stability differently. For example, an error in which the subject wanted to continue climbing stairs but the prosthesis transitioned to walking too early was rated a '2' by some subjects and a '3' by others. Steady-state walking errors (i.e., the intent recognition system switches prosthesis modes when the subject intended to continue walking) were rated a '1', '2', and '3' A limitation of this study is the low number of participating subjects. Additionally, the subject's response is based on activities experienced within the lab environment. The perception of these errors in their home and community environment may vary.

CONCLUSION

We successfully were able to implement the SEGS scale to rate users response to lower limb intent recognition errors. The majority of errors in which the user felt the most unstable (i.e., rated a '3') occurred during activity transitions.

CLINICAL APPLICATIONS

Not all real-time intent recognition errors have the same effect on users. Further development in intent recognition systems should focus on reducing or elimination errors that cause the user to become unstable or not allow them to safely recover.

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INITIAL FINDINGS OF USER FEEDBACK OF POWERED KNEE-ANKLE INTENT REGONITION ERRORS

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

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

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

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

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

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

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

RESULTS

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

Table 1. Outcome Measures:

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

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

DISCUSSION

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

CONCLUSION

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

CLINICAL APPLICATIONS

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

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ROBUST INCLUSION OF EMG SIGNALS INTO THE CONTROL OF LOWER LIMB POWERED PROSTHESES

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INTRODUCTION

Electromyographic (EMG) signals have been used to control powered upper-extremity prostheses for decades. However, they have not been used clinically to control microprocessor-controlled passive or powered lower-limb prostheses though research has shown EMG provides important control information[1]. This is primarily attributed to the difficulty in robustly capturing EMG signals from the lower extremity within a socket during locomotion. Changes in signal quality caused by volume fluctuation, perspiration, electrode liftoff, or excessive movement artifact must be accommodated to prevent deterioration of control. Here we present a control system that automatically accommodates EMG signal changes and learns to reincorporate information provided by EMG signals when they change over time. The entire system was embedded onto a microcontroller and used for online control a powered knee-ankle prosthesis.

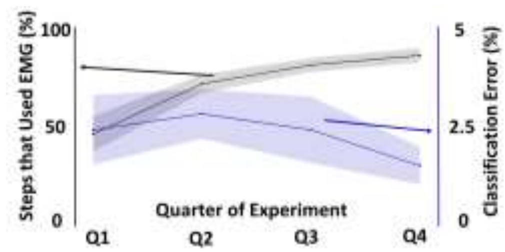
METHODS

Six individuals with a unilateral above-knee amputation were fit to a third generation powered knee-ankle prosthesis designed by Vanderbilt University[2]. The prosthesis was controlled with an impedance-based model of the knee and ankle joints. All subjects had prior experience walking on this prosthesis. The prosthesis was configured for six activities including standing, level-ground walking, ramp ascent/descent, and stair ascent/descent. Eight channels of residual limb EMG and 22 channels of mechanical sensor data embedded on the knee-ankle prosthesis were recorded[2]. The experiment required two visits. In visit one, each participant performed a sequence of ambulation circuits that included all activities while the prosthesis was controlled by an experimenter using a key-fob. These data were used to train a pattern recognition system resistant to EMG signal changes[3], capable of predicting the desired mode. They were also used to create a gait model for each ambulation mode[4]. In session two, participants ambulated while the online pattern recognition system controlled the leg. The parameters of this system were adapted in real-time using semi-supervised covariance shift adaptation[5].

Outcome metrics included the percentage of decisions that used EMG signals and classification error. We used an analysis of variance to check for significant differences in metrics between each quarter of the online session.

RESULTS

Subjects on average took 2090 steps during the second session. The control system gradually learned to incorporate EMG signals over the duration of the session with a statistically significant increased EMG usage by the end of the experiment ($p<0.01$). The online experiment had an overall classification error rate of 2.3% percentage (Fig. 1)



Fig

Fig. 1: Percent of patterns where EMG was incorporated into predictions, and performance of the online system. The total amount of patterns was divided into quarters (Q1 – Q4) to the show the progression of EMG use/system performance throughout the experiment. Data are averages of six subjects (+/- 1 SEM).

DISCUSSION

Components of this adaptive system have previously been described and tested in offline experiments[3,4], but this is the first time we have demonstrated a fully adaptive system in online experiments. This is an important distinction because offline experiments may not capture user responses to any misclassifications. The error rates found in this experiment are much lower than previously reported values[1]. While this could partially be attributed to the adaptation, it could be caused by other factors such as using more mechanical sensors or having more experienced individuals walking on the prosthesis.

CONCLUSION

The pattern recognition system automatically accommodated to changes in EMG signals during session two and by the end of the session used EMG data for ~90% of decisions. The system operated within real-time constraints and users were able to seamlessly ambulate across the activities tested.

CLINICAL APPLICATIONS

In this work we have addressed a major limitation in clinical application of EMG signals to improve control of microprocessor lower-limb prostheses.

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ROBUST INCLUSION OF EMG SIGNALS INTO THE CONTROL OF LOWER LIMB POWERED PROSTHESES

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In-vivo performance of a Fiberglass Dynamic Elastic Response Feet

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INTRODUCTION

Dynamic elastic response (DER) feet are designed to store and release energy during gait. However, there is little scientific evidence to guide the clinical prescription of DER feet (Hofstad, 2004). Prosthetic guidelines are currently based on clinical consensus among experts (van der Linde, 2004). Comprehensive studies are needed to form a solid basis for prosthetic prescription.

Recently, a new type of DER foot appeared on the market, which is composed of a fiberglass composite material. Therefore, the purpose of this study was to compare the functional performance of individuals with transtibial amputation using two types of prosthetic foot designs: carbon fiber vs. fiberglass.

METHOD

Study Design: The study used a cross-over design. Half of the subjects started on the fiberglass foot (FF) while the others starting on a carbon fiber foot (CF).

Subjects: 10 male subjects with a unilateral transtibial amputation (age: 49+9 years, BMI: 29+7 kg/m^2, 10.4+9.8 years of prosthesis use, K-Level III) were studied after giving informed consent.

Prosthetic Feet: The FF was an Ability Dynamics Rush foot. The CF studied were Otto Bock Triton, Ossur Variflex, Ossur Variflex EVO, Ossur Reflex Shock, Freedom Renegade, Freedom Pacifica, Freedom Thrive with Vertical Shock, Freedom Highlander, and Freedom Agilix.

Procedures: Gait analysis was performed using a 10 camera system (Motion Analysis, Santa Rosa, CA) and 6 force plates (Kistler, AMTI, Bertec). Data was collected over level ground at self-selected and normalized speed controlling for leg length (Froude=0.25) as well as ascending and descending a 10 degree ramp. Patient satisfaction was assessed with the Prosthesis Evaluation Questionnaire (PEQ), a reliable and valid tool (Legro, 1998).

Data Analysis: A multivariate approach was used to compare all conditions (gait data) or subscales (PEQ) simultaneously using a single factor repeated measures ANOVA. Statistical significance was set at p=0.05.

RESULTS

The subjects exhibited increased ankle dorsiflexion ($p<0.01$), similar ankle moments ($p=0.07$) and increased ankle power generation ($p=0.01$) when using the fiberglass composite foot (Fig 1). The increased power generation did not affect peak knee flexion ($p>0.19$). The subjects expressed greater satisfaction with the fiberglass composite foot ($p=0.02$).

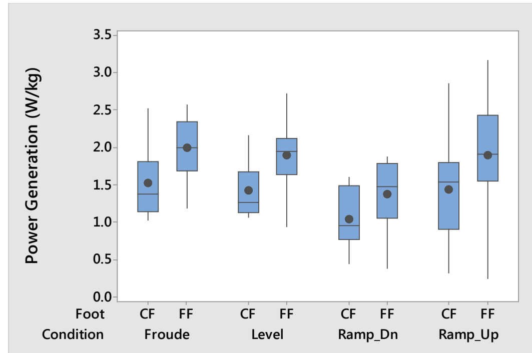

Figure 1. Box plot of ankle power generation during gait for four ground conditions. CF=carbon fiber foot. FF=fiberglass foot. The central line represents the median, the dot represent the mean, the edges of the box are the 25th and 75th percentiles, and the whiskers extend to ±1.5 of the interquartile range. The fiberglass foot (FF) generated significantly more power than the carbon fiber foot (CF) for all walking conditions.

DISCUSSION

Ankle muscles generate and absorb mechanical energy necessary to create movement. The single variable that summarizes that role of the ankle plantarflexors is mechanical power, which is the product of the joint moment of force and joint angular velocity. This study showed that walking with a fiberglass composite foot resulted in a 31% increase in power production (1.79 W/kg with FF vs 1.36 W/kg for CF). However, the power is still 50% lower than that produced by an intact limb (3.4 W/kg) (Winter, 1983). Nonetheless, the subjects reported greater satisfaction when using the fiberglass composite foot as measured by the PEQ. The PEQ is composed of nine validated scales. All scales were improved when using the fiberglass foot, with significant increases reported for appearance and utility.

CONCLUSION

The prosthetic foot made from the fiberglass composite material returned more energy while walking. As a result, the subjects reported they were more satisfied with this foot.

CLINICAL APPLICATIONS

The fiberglass composite foot makes it easier to walk. This will mean that the patient can walk further on a daily basis without fatigue.

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Crossover and energy storing prosthetic feet in adults with transtibial amputation: a comparative effectiveness study

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INTRODUCTION

People with transtibial amputation (TTA) demonstrate increased energy expenditure, reduced walking speed, compromised balance, and decreased endurance compared to people without amputation (Waters, 1999; Genin, 2008). Contemporary energy storing feet (ESF) promote users' mobility, but do not fully restore their functional capabilities (Hsu 2006). Crossover feet (XF) combine features of ESF (carbon fiber heel, split keel, foot shell) and running-specific prostheses (extended keel, posterior attachment) to facilitate greater energy return and performance across a wide range of functional activities.

The goal of this study was to determine if use of an XF could decrease users' energy required for walking, increase endurance, enhance walking performance, or improve self-report health, relative to using an ESF.

METHOD

Participants: People with TTA due to non-dysvascular causes were recruited from local prosthetics clinics.

Interventions: Participants were tested in a prosthesis with an XF (Össur Cheetah Xplore) and an equivalent prosthesis (duplicate socket and suspension) with an ESF (Össur Vari-flex with EVO foot).

Procedures: A randomized crossover study was conducted to assess changes in energy expenditure, walking performance, endurance and reported health. Participants wore an activity monitor (Orthocare Innovations Stepwatch 3) for 1 month before testing. Energy expenditure was measured with a portable metabolic analyzer (Cosmed K4b2) while participants walked at 3 speeds (self-selected slow, comfortable and fast) on a treadmill (Landice L7). Endurance was measured with the 6-min walk test (6MWT). Walking performance was measured with an electronic walkway (CIR Systems GAITRite) while participants performed the 6MWT. Self-reported mobility, fatigue, balance confidence, activity restrictions, and satisfaction were measured with standardized surveys (PLUS-M, PROMIS-Fatigue, ABC, and TAPES).

Analysis: Mean mass-adjusted metabolic rates were calculated from the last 3 minutes of each 6-minute treadmill trial (slow, comfortable, and fast). Overall 6MWT distance was measured; mean speed, cadence, and step length, width, time were computed using the GAITRite software; mean daily steps were calculated. Surveys were scored according to developers' instructions. All outcomes were compared across conditions using a Wilcoxon Signed-Rank test and a threshold of $\alpha<.05$.

RESULTS

Participants: 14 participants have completed the study to-date; 2 people were dropped due to extrinsic factors that affected data integrity. 12 participants (83% male, age = 41±10 years, time since amputation = 12±12 years) were included in this analysis.

Metabolic energy: Participants showed significantly reduced mean mass-adjusted metabolic rates at comfortable (p=0.0499) and fast (p=0.0499) walking speeds in the XF compared to the ESF (Fig. 1). No significant differences in metabolic rates were seen at slow speed (p=.638).

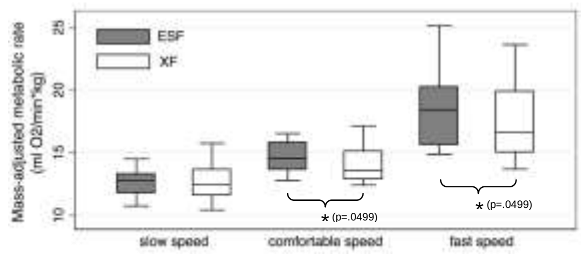

Figure 1. Mean mass-adjusted metabolic rate during walking

Walking performance: No significant differences in walking distance (p=0.730), speed (p=.875), cadence (p=.239), step length (p=.099), step width (p=.0504), or step time (p=.857) were observed between the XF and ESF conditions. Similarly, no significant differences in step activity were seen between conditions (p=.182).

Self-report: Participants reported improved mobility (p=.004), balance confidence (p=.005), and functional satisfaction (p=.007); lower fatigue (p=.008); and fewer activity restrictions (p=.021) in the XF, relative to the ESF. No differences in aesthetic satisfaction were reported (p=.673).

DISCUSSION

Results indicate that XF may reduce users' metabolic energy at comfortable and fast walking speeds. Indoor walking performance and endurance may not reflect performance under real-world conditions, as users perceived significant benefits and were highly satisfied with the XF's function. However, not all participants experienced the same outcomes. Thus, future work is needed to refine prescription criteria.

CONCLUSION

XF are a promising alternative to traditional ESF, as they may reduce energy expenditure during walking and improve users' perceived functional outcomes.

CLINICAL APPLICATIONS

Crossover feet may be an effective solution for people with TTA who wish to engage in a range of activities, particularly those that require walking at fast speeds.

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Comparing Prosthetic Feet Using Stiffness Profiles

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INTRODUCTION

The stiffness of a prosthetic foot can significantly influence the gait mechanics of lower-limb amputees (e.g., Fey et al., 2012). Currently, prosthetists rely heavily on experience and patient feedback when prescribing specific stiffness levels for an individual. Previous studies quantifying prosthetic foot stiffness (e.g., Major et al., 2012) have often focused on quantifying stiffness during isolated conditions (e.g., at heel strike or toe-off) in a single plane of motion. Understanding how prosthetic foot stiffness varies over the gait cycle in both the sagittal and coronal planes would allow prosthetists to more accurately compare specific feet and improve prescription outcomes for individuals who walk on a variety of terrains. The purpose of this study was to identify the sagittal and coronal plane stiffness profiles for a number of commercially available prosthetic feet during walking conditions and assess how these profiles vary across feet.

METHOD

Twenty-eight feet with a range of stiffness categories across 9 different foot styles were evaluated using quasi-static linear compression tests over a range of forces and displacements experimentally measured during gait. The force and displacement data applied to each foot were measured with a 9281CA Kistler force plate affixed to an R-2000 Rotopod robot.

The stiffness was calculated at each orientation by applying a linear regression to the force-displacement data over a force range of ±1 standard deviation from the expected load at each sagittal (-15,-10,-7.5,-5,-2,-1,0,1,2,5,10,15,20,25,30°) and coronal (-10,-5,0,5,10°) orientation. Several stiffness ratios were then calculated to compare relative changes in the stiffness profiles across feet (Table 1).

RESULTS

The maximum stiffness of the category (cat) 6 feet ranged greatly from 208 N/mm for the Sierra foot to 474 N/mm for the Catalyst. However, the range of stiffness measured at midstance was much less, ranging from 72 N/mm to 87 N/mm (Table 1).

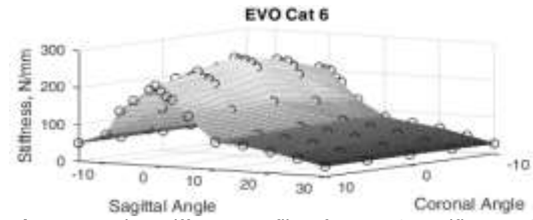

Figure 1. The stiffness profile of a cat 6 Variflex EVO. The circles indicate the orientations tested.

Most cat 6 feet had a greater stiffness at foot flat (0°) than inversion (10°) or eversion (-10°), with the Seattle Lightfoot inversion being the exception. All cat 6 feet had a toe off stiffness of at least 48% less than during midstance. While most cat 6 feet had a heel stiffness greater than the midstance value, the EVO foot had a heel stiffness 15% lower than its midstance value.

DISCUSSION

Most feet showed decreasing stiffness as the inversion or eversion angle increased. Most feet also displayed increasing stiffness through heel strike and the transition to midstance, followed by decreasing stiffness in terminal stance and toe off. Despite having similar profile shapes, the feet differed in how stiff specific orientations were relative to the overall profile. The relative stiffness ratios highlight how the coronal and sagittal stiffness characteristics can vary widely across feet.

CONCLUSION

While the general shape of the stiffness profiles were similar across feet, the magnitude of the stiffness varied despite being considered in the same category.

CLINICAL APPLICATIONS

Quantifying the stiffness profiles of prosthetic feet will allow for more informed prescription decisions.

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	Catalyst	EVO	Sierra with Heel Wedge	Sierra	Seattle Lightfoot	SureFlex
Stiffness @ 30% GC (N/mm).	77	87	81	77	72	73
Inversion (10° / 0°)	0.86	0.94	0.89	0.91	1.04	0.83
Eversion (-10° / 0°)	0.84	0.87	0.92	0.93	0.97	0.86
Heel (5% GC/ 30% GC)	1.69	0.85	1.06	1.06	1.62	1.40
Toe (50% GC/ 30% GC)	0.43	0.34	0.50	0.52	0.51	0.44

Table 1. Stiffness metrics for the category 6 feet tested. The stiffness value reported is for a 0° coronal orientation at midstance (30% of the gait cycle (GC)). The inversion and eversion ratios are normalized metrics comparing the stiffness value at 0° coronal angle with ±10° coronal stiffness values, respectively. The heel and toe ratios are normalized metrics comparing the stiffness value at 30% GC with the stiffness values at 5% GC (loading) and 50% GC (late stance), respectively.

EFFECT OF SHOES ON THE MECHANICAL PROPERTIES OF PROSTHETIC FEET UTILIZED IN TROPICAL COUNTRIES

Principal Investigator: Corin Shirley   *Investigator: Alex Ashoff*

Introduction: Previous studies have shown that low cost prosthetic feet have had a short lifespan in tropical nations (Jensen, 2006). This has been known to be linked to the lack of practitioners in these nations, and the low funds available to continue to replace damaged feet (Jensen, 2006). Clinicians have observed that shoes tend to protect the prosthetic foot from wear, but it is unclear the magnitude of protection (Pye, 2015). This study investigated the effect of shoes on the preservation of the material properties of prosthetic feet when exposed to harsh UV and humid conditions. It is hypothesized that the mechanical properties of the feet would be maintained in both the forefoot and heel regions if shoes were worn over the prosthetic feet, and significantly deviate if no shoes were worn.

Materials and Methods: ISO 10328 static testing was performed on six samples of the ICRC feet. Three samples were tested with shoes (S group), while the other three were tested without (NS group). Following this testing, the samples were put in an environmental chamber where they were exposed to UV light at 38°C and 98% humidity for 400 hours. After this exposure, the samples were put through ISO 10328 static testing again along with the cyclic test. The cyclic test involves sinusoidally loading the heel and forefoot alternately between 50 and 1330N at a frequency 1Hz. Lastly, after 2,000,000 cycles, the ISO 10328 standard prescribes a final static proof test identical to the initial static proof test unless failure is observed during the cyclic test. Additionally, the feet were checked for visible damage before and after testing. This was done using a systematic Qualitative Assessment form where the observer ranked the condition of each foot from 0 (Failure) to 3 (Excellent)

Results:

Quantitative Results

Changes in stiffness, creep and max deformation for each group can be seen in **TABLE 1**. The foot was analyzed at the forefoot and heel individually due to inherent differences in mechanical properties.

TABLE 1: **Differences in mechanical factors in forefoot (FF) and heel (H) before and after testing.**

	FF		***H***	
	NS Group	**S Group**	**NS Group**	**S Group**
Δ Stiffness (N/mm)	125.7± 28.1*	79.9± 44.7*	70.1 ± 9.56*	30.9 ± 15.1
Δ Creep (mm)	2.46 ± 0.17*	2.52 ± 0.19*	2.15 ± 0.06**	0.37 ± 0.08*
Δ Displacement (mm)	4.6 ± 2.94**	-9.96 ± 7.76*	10.19 ± 2.39*	-5.73 ± 3.14

*indicates a significant difference (p value <0.05)

**indicates a very significant difference (p value <0.01)

Qualitative Results

Due to the small sample size, a Paired-Samples Wilcoxon Signed Ranks test was then used to assess whether or not qualitative changes in both categories were significant (α=0.05). JMP Pro 12 software was used to aid in performing the statistical analysis.

Discussion:

The hypothesis stated that the shoe group would show no significant differences after testing. When analyzing the FF region, it was found that the shoe group and the no shoe group both saw significant changes in maximum stiffness, creep, and maximum deformation from the baseline tests (TABLE 1) disproving this prediction. Interestingly, while creep and stiffness in the FF region increased significantly, max deformation saw a different trend. In the S group, the max displacement actually *decreased significantly*, while the NS group saw a *significant increase*. Creep in this region is also thought to be affected due to the flexibility of the forefoot during loading, not just the deformation of the foot upon compression.

In the H region, it was found that the shoe played a significant role in protecting the foot from changes in increases in maximum stiffness and maximum displacement. While the creep was still found to increase significantly with the application of a shoe, it was also significantly less than the change seen in the NS group. This could mean that the sole of the shoe works to adequately protect the H from changes in stiffness while ambulating in harsh environments.

Limitations:

Issues with the environmental chamber had to be fixed several times which resulted in inconsistent exposure during the 400 hrs. Foot 4 was also overloaded to failure during final static testing due to a machine malfunction and left out of data processing due to the significant effect the outlier had on the small sample size. Small sample size was the result of time and foot donation limitations. Collected data values however, were consistent among groups and data trends are believed to be similar in a large sample size.

Conclusions:

Changes in mechanical properties of the heel region of the ICRC foot were significantly reduced by the application of a shoe in harsh environmental conditions. Further testing is needed with a larger sample size to confirm the preliminary results of this study.

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

Andreas Kannenberg
Otto Bock HealthCare LP, Austin, TX

INTRODUCTION

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

METHOD

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

RESULTS

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

DISCUSSION

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

CONCLUSION

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

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DISCLOSURE

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

"TRANSFEMORAL AQUATIC REHABILITATION"

Cutler, TJ
Limbitless LLC

INTRODUCTION

Aquatic rehabilitation in transfemoral amputee populations is very limited. Little to no literature related to this is available. Whether arising from concerns about compromising componentry or general concerns about the aquatic environment, little is known about the outcomes that can be gained from focusing on a reduced-gravity environment for amputees. Drawing from a case study currently under review by the JPO and additional patients, lessons gained from 2 years of aquatic transfemoral rehabilitation will be presented for consideration.

METHOD

Subjects will include geriatric unilateral transfemoral amputee, mature female adult bilateral transfemoral traumatic amputee and young K4 unilateral transfemoral amputee. Video of patients will be available (media releases have been obtained). All results are corroborated by collaborating physician and/or therapist. Lessons from initial case study method have been incorporated into subsequent cases since there is no current protocol for this intervention. Configurations both with and without prosthetic knees were used.

RESULTS

The benefits of aquatic rehabilitation for transfemoral amputees in a reduced gravity environment have been significant. Ambulation time during therapy sessions increased 900% from 5 minutes to 45 minutes. After 30 days, ambulation range increased from 100 feet to 400 feet and 3-year-old hip flexion contractures reduced from 45 degrees to 20 degrees. Use of a motorized underwater treadmill would reduce time until patient fatigue by 50%. Bilateral transfemoral amputation increased 4000% from 100 feet to 30 minutes at 1.5 mph on a motorized treadmill. K4 military candidates were able to increase gains without compromising contralateral comorbidities. Patients reduced disability ratings from 78% to 48% in 4 months starting aquatic rehabilitation 3 years after amputation. Additional results will be discussed.

DISCUSSION

The results of aquatic ambulation transformed the lives of the patients. The patience of the initial patient made it possible to learn many valuable lessons for both the amputee as well as for broader applications in orthopedics.

There was significant carryover from the aquatic environment to land-based ambulation. The exponential increase in walking time without fear of falling had a tremendous impact on balance and confidence.

Advancing from open walking to motorized treadmill walking allowed greater distance and walking speed since the subjects' bodies were no longer subjected to water resistance. The motorized element created a trunk extension reaction for a more upright posture and a longer stride. Water is known to reduce the sympathetic nervous system response, allowing patients to relax, which improved the stretch on the hip flexors. Additionally, eliminating the fear of falls allowed patients to better gain proficiency in walking, both in water and on land.

CONCLUSION

With the increase of available waterproof componentry and the results from these patients, we can conclude that further study into the benefits of aquatic ambulation for transfemoral amputees is worthy of exploration.

CLINICAL APPLICATIONS

Aquatic ambulation is an effective way to assess potential issues for patients. It can rehabilitate patients who may be a greater fall risk or may put a compromised sound limb at risk before the affected limb can support the burden of ambulation. Surgeons were willing to reduce post revision NWB periods by 75% when patients were walking at 25% body weight.

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CAN STILETTO HIGH-HEELS IMPROVE THE GAIT SYMMETRY OF A TRANSTIBIAL PROSTHESIS USER?

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INTRODUCTION

Walking in high-heeled shoes can be challenging [1], and biomechanical gait analysis suggests that high-heels should be avoided altogether [2]. However, high-heels are part of many people's attire and having the choice to wear shoes that are perceived as appropriate for a given occasion is important. This choice can be particularly difficult for prosthesis users, who are limited by the footwear that can accommodate their prosthesis [3]. Several adjustable heel height prosthetic feet recently were introduced to accommodate a 5 cm heel rise, however, 62% of women wear heels over 5 cm [4]. We report here the gait results of a 29 year old female service member who successfully returned to wearing high heeled shoes after a traumatic unilateral transtibial amputation.

METHOD

The subject's goal was to walk in 10 cm stiletto high-heels (see photo). Her prosthetist modified a pediatric running foot (Flex Run, Össur) to meet this goal. She anecdotally reported walking more symmetrically in high-heels than in flat shoes. In order to determine the source of this perceived improvement, a biomechanical analysis was performed comparing gait in two footwear conditions: 10 cm stiletto high-heels and flat athletic shoes. She used an energy-storing-and-returning foot (Talux, Össur) with her athletic shoes. Kinematic data were collected on a straight, flat surface at a self-selected and controlled speed (1.1 m/s) and eight trials were analyzed in each shoe condition. Sagittal plane ankle, knee, hip, pelvis and trunk kinematics were incorporated into a Global Gait Asymmetry (GGA) score [5] at the controlled speed. Symmetry indices [6] were calculated for temporal-spatial measures. Greater GGA and symmetry index values indicate a more asymmetrical gait.

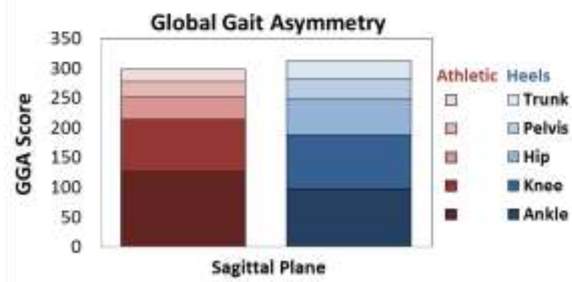
RESULTS

Self-selected speed was 27% slower in heels than athletic shoes (0.84 vs. 1.15 m/s). Step lengths were more asymmetric in heels (longer on prosthetic side) but stance and swing times were more symmetric than athletic shoes.

Symmetry Index

	Step length	Step time	Stance time	Swing time
Athletic	0.6%	0.2%	5.1%	8.7%
Heels	6.2%	1.4%	2.0%	2.3%

Cumulative GGA scores were only 2% different between shoe conditions. Prosthetic and intact limb ankle angles, in particular, were more symmetrical in the high-heels than in athletic shoes. Across all the other joints there were subtle increases in gait asymmetry in the heels condition



DISCUSSION

The use of high-heels with a pediatric running foot improved the symmetry of ankle kinematics and some temporal-spatial measures compared to flat, athletic shoes. Improvements in symmetry are not always synonymous with improvements in gait quality, as high-heels are known to adversely affect some components walking mechanics [1,2].

CONCLUSION

Stiletto high-heels did not negatively affect overall gait symmetry when walking on a flat, level surface. The greater gait symmetry at the ankle in heels may be the result of constrained motion imposed by the footwear. Thus, increases or decreases in gait symmetry may not necessarily relate to gait quality.

CLINICAL APPLICATIONS

A return to pre-injury activities can include walking in high-heeled footwear and requests for high heels (including 10 cm stilettos) should not be discounted. Accommodations can be made using creativity in prosthetic foot selection, but attention to gait mechanics may be important for safe use.

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Clinical algorithm for gel liner selection

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INTRODUCTION

The relationship of the residual limb to the prosthetic socket is a critical variable in determining both function and acceptance of a prosthesis (Michael, 1997). Selecting the appropriate gel liner for a patient can be a complicated decision due to the numerous types of gel materials, gel profiles, manufacturers and most importantly the individual needs of the patient. Combine these variables with the limited amount of published research on gel liners, and their performance when used on a patient and it is easy to see how selection of the appropriate liner can be a confusing hit-or-miss process. Prosthetic prescription for individuals with lower-limb amputation is chiefly based on empirical knowledge (Tucker et. al. 2012). A new clinician deciding on a gel liner for a patient is dependent on the experience of a senior clinician's recommendations, and preferences. Many prosthetic companies provide gel liners to their patients based on company preference, discounts, and reimbursement. This study can be related to the works done by Cagle et. al., as well as the clinical considerations by J. W. Michael. Cagle concluded that silicone and urethane exhibit the highest compressive resistance, which in this study is related to durometer and that thermoplastic elastomer (TPE) has the lowest durometer. Michael believed that" the single most critical aspect of any prosthesis is the quality of the interface between the residual limb and the prosthesis. This project's purpose is to evaluate durometers of different gel liners and develop a clinical algorithm to use when selecting appropriate gel liner options for a prosthetic patient.

METHOD

Six manufacturers of gel liners with varying materials and thicknesses were examined at the Surgical Clinic of Nashville, Tennessee.

The sample material consisted of a 2" x 2" proximal square of each liner. The samples were tested using the durometer scale (Shore 00 scale) by following the testing procedure using CHECK-LINE: Analog Duromenter Model: AD-100, purchased from Electromatic Equipment Company, Inc. as intended by the manufacturer.

The instrument was placed level and perpendicular to the sample, the foot of the instrument was placed firmly against the sample, but not so firmly as to imbed the foot of the instrument into the surface of the material. Pressure was maintained for 2-3 seconds and the dial hand gave the reading in durometer points.

This procedure was repeated 3 times and the average of 3 trials for each sample was recorded to be the durometer of that specific material.

RESULTS

The manufacturers of the materials tested, the gel types, and thickness were all recorded and notated in Table 1. The table consists of three different gel types which include urethane, silicone, and TPE. The thicknesses tested were 3mm and 6mm. It was observed that urethane and silicone had the highest durometers and TPE was observed to have lower durometers. Additionally, the majority of 6mm samples had a softer durometer than that of 3mm samples.

DISCUSSION

This study was conducted in order to determine an appropriate liner for a patient based on durometer as a starting point for gel liner selection. By utilizing experience together with quantitative information, this strategy could potentially lead to increased successful patient outcomes. The durometer chart indicates a shore 00 value for each liner tested and can be used to improve liner selection for the needs of individual patients.

CONCLUSION

This study validates the need for a clinical algorithm using the variables body weight, K-level, % time standing, limb length, and assistive device type (Table 2). From this algorithm, a durometer value is determined and then potential liners can be gathered and test fit to the patient to determine optimal fit and function. When fitting a liner after an appropriate durometer is determined, the characteristics such as radial tension, knee flexion range of motion, patient's ease of donning, and matching liner shape to patients limb shape are considered in treatment.

(K level + Body weight + % time standing) – limb length (inches) – assistive device)= durometer of gel material optimal for the patient	
Body Weight **(add points)**	For every 50 lbs add 5 points in the formula up to a maximum of 30 points for 300 + lbs
k level **(add points)**	K1 = 10, K2 = 15, K3 = 20, K4 = 25
%Time Standing up **(add points)**	25%= 5, 50%=10, 75%=15, >75%=20
Limb Length **(minus points)**	3in=5, 5in=10, 7in=15, 9in=20
Assistive Device **(minus points)**	Walker= -15 2 forearm crutches or 2 canes= -10 1 forearm crutch or 1 cane= -5

(Table 2)

CLINICAL APPLICATIONS

Utilizing the quantitative objective durometer information provided and the clinical algorithm when prescribing a gel liner for a patient will potentially provide improved outcomes for the prosthetic patient. Further research of the algorithm and durometer chart method using patients with gel liners is necessary in order to validate these improved outcomes

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Electromatic Equipment Company, Inc, CHECK-LINE: Analog Durometer Model: AD- 100

American Academy of Orthotists & Prosthetists
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Clinical algorithm for gel liner selection

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Table 1

Manufacturer	Gel Material/Name Brand		3mm (Shore 00 Durometer)	6mm (Shore 00 Durometer)	Flow
OttoBock	**Urethane**				
		Uncovered	40	50	x
		Covered		35	x
	Silicone				
		6Y70	46		
		Skeo 6Y75	51		
		6Y80	58		
		Skeo 6Y85	64		
OWW	**TPE/Classic**		35	29	
	Hybrid		35	26	
	Express/Silicone		40	30	
	Silicone		40		
	SmartTemp		46		
Ossur	**Silicone/Comfort**		40	30	
	Silicone/Dermo		36	24	x
	Silicone/Synergy		38		x
	Silicone/Seal-in TF		48		
	Silicone/Seal-in-X-TT		33	30	x
	Silicone/Seal-in-X-TF		43		
	Silicone/Seal-in V		30		
ALPS	**TPE/Grip gel**		32	18	
	TPE/Easy gel				
		Covered	21		
		Uncovered		23	
	TPE/HD gel			22	
Medi	**Silicone/4 seal**		66		
	Silicone/silver		52		
	Silicone/protect		31		x
Evolution	**Silicone/Uncovered**		55	48	x

Oww= Ohio Willow Wood
TPE= Thermoplastic Elastomer

CHECK-LINE: Analog Durometer Model: AD-100
ELECTROMATIC Equipment Company, Inc

Clinical effects of an innovative spinal orthosis on low back pain and pain-free walking distance

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Introduction

Lower back pain (LBP) is a common problem with a mean prevalence of 31% in general population [1]. In many cases LBP, especially in patients with radiculopathy, deteriorates with increasing walking distance, forcing people to stop after a certain distance limiting their mobility in a severe way. Treatment options include physical therapy, orthoses, surgery and/or pain medication. Physical therapy should always be a key element to strengthen back muscles in their basic function to support the bony spine structure. An innovative spinal orthosis was developed to reduce LBP and to increase pain-free walking distance (PFWD) by using a dynamic spring construction that straightens the lumbar spine. An observational study was conducted to collect data from the first clinical experience.

Methods

The 'Dyneva' spinal orthosis consists of an open metal frame construction where the upper and lower parts of the back frame are connected with a dynamic realignment spring (Figure 1). The torque of this spring is exposed to the lumbar spine during dynamic locomotion, resulting in a straightening with consequential decompression and relief of the lumbar spine.

Figure 1: 'Dyneva' orthosis (frontal/dorsal view)

31 subjects (age 65.0±11.5) with LBP were treated over a period of 4 weeks with a baseline assessment prior to the fitting of the 'Dyneva' and after 4 weeks of use. The assessment included changes in pain level and the change in PFWD.

Results

The trial period with the Dyneva over 4 weeks showed an increase in the reported PFWD in 61% of all patients. 39% reported no change, and none of the patients reported a reduction. Average waking distance was increased by 602 meters (50%) (Figure 2). 26 patients rated their pain levels at baseline and after 4 weeks of Dyneva treatment. 14 of them stated a reduction of their pain level at the end of the intervention period; in 1 patient the pain level was increased.

Figure 2: average change of PFWD

Overall there was a mean decrease of pain on the VAS scale of 1.27 points; the difference was highly statistical significant ($p<0.001$).

85% of the patients reported that they wanted to continue wearing the 'Dyneva' orthosis, since they benefitted either from reduced pain level and/or increased PFWD.

Discussion

The 4-week intervention with the 'Dyneva' spinal orthosis showed clinically and statistically significant effects regarding the reduction in LBP and the improvement of PFWD. Over 60% of the patients improved their walking distance during the intervention period, enabling them to achieve a higher grade of mobility in their daily life.

The orthosis may significantly contribute to patients' remobilization; significant clinical improvements are present for all tested indications. The subjects' high preference (85%) is a compelling first result showing the immediate effects of the 'Dyneva' orthosis.

Clinical effects of an innovative spinal orthosis on low back pain and pain-free walking distance

Ingo Rembitzki [1]

[1] Otto Bock Healthcare GmbH, Duderstadt, Germany

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Disclosure

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"Collaborative Patient Assessments in Prosthetic Education"

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INTRODUCTION

Interprofessional education (IPE) has increasingly gained momentum to promote successful teamwork, which leads to better care, improved patient outcomes, and decreased costs (Arvedson, 2008). There have been broad-based goals established for IPE, including reducing bias between professions and improving teamwork and collaboration, but less is understood in what format to teach interprofessional skills.

Because collaboration between professions is crucial to improving quality, safety, and access to care, providing IPE opportunities can help prepare future professionals for a team approach to providing care (Hackett, 2015). Students who interact with other health professions, learn to value diverse perspective, respect the knowledge and expertise of other professions, collaborate when problem-solving, and communicate as a team to ensure patient safety (Olenick, 2010).

This study highlights a joint learning experience between Masters of Science Orthotics and Prosthetics (MSOP) and Masters in Social Work (MSW) students aimed to promote interprofessional communication and a better understanding of professional roles and responsibilities of the students own discipline and other disciplines, specifically in the role of assessment. This IPE experience focused on enhancing interprofessional practice by offering a collaborative, shared expertise, delivery of patient care over three sessions. First, the students completed an initial assessment of a patient model seeking a transfemoral prosthesis. During the second session, students collaborated in identifying treatment goals and identifying appropriate community resources. The final session culminated with the students debriefing about their experiences from the interprofessional experience.

METHOD

The sample (N=20) consisted of 13 men and 7 women with an average age of 31.5 years. Participants were enrolled in the MSW aging concentration (n=11) and MSOP program (n=9). Demographics were collected and a pre-post test design was used to address IPE values and promotion of collaborative assessment on an interprofessional team. Evaluation measures included the Interprofessional Assessment Scale to assess attitudes that relate to core competencies for Interprofessional Collaborative Practice (Norris, 2015), and additional questions were used from the four sub-scales of the UWE Interprofessional Questionnaire. A paired T-test was used to compare the student responses on the pre-post tests. Independent T-tests were used to evaluate responses based on major or gender.

A semi-structured interview guide was used during the debriefing session. Questions explored the participant's experience of the IPE exercise and working with another health care professional. The group interview was recorded, transcribed, and analyzed. Coding procedure included the use of axial coding to incorporate an a priori of 5 codes based on the IPE core competencies, followed by open coding.

RESULTS

Participants demonstrated increased value and appreciation for collaborative learning, including obtaining a better understanding of the other discipline's professional function, the patient assessment process, the challenges of working within health care systems to deliver high quality patient care, and reported high value of the educational experience.

	Pre v Post	Major	Gender
Roles and Responsibilities	**0.007**	0.332	0.771
Patient Centeredness	0.409	0.075	0.772
Interprofessional Biases	0.177	0.797	0.678
Communication	**0.049**	0.479	0.606
Interprofessional Learning	**0.011**	0.872	0.555
Interprofessional Relationships	0.067	0.44	0.836

DISCUSSION

This study provided graduate students an opportunity for real world experiences in collaborative health care delivery. Shared IPE among students in the allied health professions can lead to improved understandings of role and responsibilities, communication and lead to interprofessional learning. This study will be repeated in the winter 2017 semester.

CONCLUSION

Interprofessional education can improve communication and understanding between prosthetic and social work students.

CLINICAL APPLICATIONS

Providing students with IPE opportunities demonstrates the benefits and need for multidisciplinary patient care in the clinical setting.

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

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INTRODUCTION

Advancements in microprocessor prosthetic ankle-feet (MPA) allow additional functionality for lower limb amputees. Evidence on MPA includes 3D kinematic and kinetic data (Struchkov 2016), gait symmetry (Agrawal 2013), energy expenditure (Darter 2014), and socket pressure (Wolf 2009). Further comparative effectiveness research is needed in larger samples. This pilot study compares differences in perceived balance and mobility, functional capabilities, socket comfort and ramp ambulation between energy storing and returning (ESAR) and MPA components.

METHOD

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

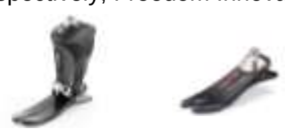

Figure 1. Kinnex Microprocessor Prosthetic Ankle and Pacifica LP Energy Storing and Returning Foot

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

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

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

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

RESULTS

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

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

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

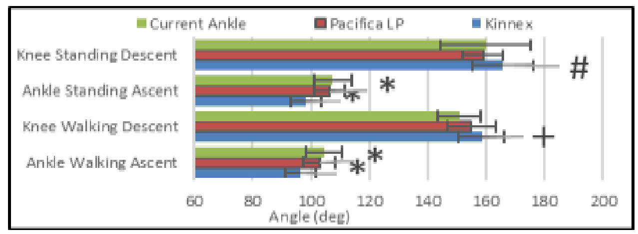

Figure 2. Ankle and Knee angles on the prosthesis side when using different ankle-foot configurations. (*) denotes Kinnex and Pacifica LP significantly different than Current Ankle, (+) denotes Kinnex significantly different than Current Ankle, (#) denotes Kinnex significantly different than Pacifica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

DISCUSSION

HAI on ramp descent showed improved function with Kinnex, and a significant difference between Kinnex and Current Ankle. Angle measurements showed a trend of the Kinnex providing more accommodation at the ankle during slope ascent and a more stable knee position at mid-stance in slope descent. Several differences in knee and ankle angle between ankle-foot configurations reached statistical significance.

CONCLUSION

The pilot study showed statistically significant benefits with the Kinnex on ramp ascent and descent, while other measures showed positive trends of improved balance, mobility, and socket comfort with the Kinnex. The significant benefits demonstrated on ramps, and strong trends toward improved balance, mobility and socket comfort, motivate a comparative effectiveness study of MPA with a larger sample size.

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Design Considerations for a Direct Muscle Actuated Prosthesis

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INTRODUCTION

Advancements in the field of osseointegrated prosthesis could provide improvements in prosthetic care beyond sole replacement of the soft tissue interface or socket. A unique advantage provided by osseointegrated prostheses over the traditional socket interface is access to the wearer's internal control systems. For instance, it may be possible for the prosthesis to make direct connections to residual muscles and/or nerves resulting in a more biointegrated prosthesis. This is particularly relevant in the development of upper extremity prostheses especially for the hand and fingers, as the fine movements cannot be easily reproduced with advanced prostheses even though much of the musculature used to control these movements remains. Therefore, the overall goal of this study was to design and implement a novel muscle actuated prosthesis utilizing a bone anchored prosthesis with direct connections to the residual musculature in a rat trans-tibial amputation model.

METHOD

Design: Design of the implants and prostheses (Fig 1) used in this study consisted of three major areas of interest: 1) the implant interface with the skin and bone, 2) the direct connections to the residual musculature for actuation and 3) the external prosthesis of foot.

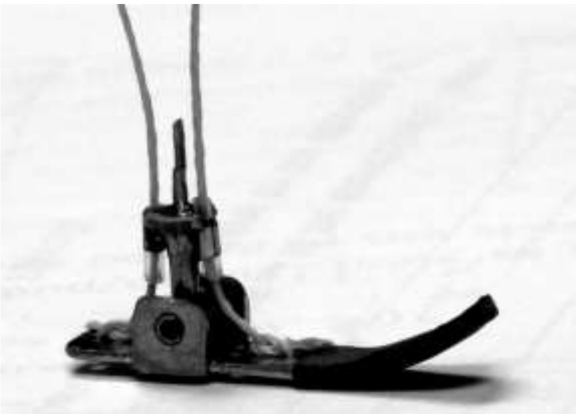

Figure 1: Implant and Prosthesis

Subjects: Four female rats (275-350 g) underwent a trans-tibial amputation and implantation procedure.

Procedures: All experimental procedures were approved by the Institutional Animal Care and Use Committee. While the animal was anesthetized, the tibia was transected and the stainless steel implant was cemented into the reamed marrow canal. A coated stainless steel wire or Kevlar thread was connected to the residual muscle/tendon of gastrocnemius and tibialis anterior just proximal to the level of amputation and was routed through the implant for connection to the external prosthesis. The percutaneous portion of the implant was then directed through a hole in the skin and the skin was closed with a posterior skin flap. After closing, the percutaneous portion of the implant and cabling was attached to the external prosthesis to allow for ankle dorsi- and plantar-flexion with muscle contraction. The foot and ankle prosthesis was designed to function as a single degree of freedom joint replicating the ankle. After the procedure the animals were allowed to recover for 5-14 days before undergoing gait analysis.

RESULTS

From a design perspective, the implant and prosthesis combination underwent 3 iterations of design during the course of the present study. The major changes associated with each generation included: implant stem modifications to prevent rotation along the tibia longitudinal axis, material additions to lower friction for a smoother muscle actuation, and changes in muscle cable attachment procedures for better tensioning.

The animal model results were successful in three out of four animals. One animal was removed from the study due to post-op complications while the three remaining animals and implants survived until the terminal procedure 1-month post implantation. In two of those three animals, the muscle/cable interface ruptured prematurely preventing direct muscle actuation of the prosthesis. This was due in part by choice of cabling material and early loading before proper muscle integration could occur. However, all three of these animals utilized the prostheses for standing and walking though some to a limited degree and none had signs of infection around the implant.

DISCUSSION

These results provide preliminary evidence that our novel implant and prosthetic design can potentially provide residual muscle actuation of a bone anchored prostheses. Future research is needed to finalize device design for translating it to a larger animal and eventually human studies.

CONCLUSION

In conclusion, the novel implant and prosthesis design and implantation procedure have shown promise for future direct muscle actuated prostheses.

CLINICAL APPLICATIONS

While currently this prosthetic design cannot be directly translated to humans, this study provides promising results that the residual musculature can be utilized to directly actuate an attached prosthesis.

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

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INTRODUCTION

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

METHOD

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

RESULTS

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

DISCUSSION

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

CONCLUSION

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

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DISCLOSURE

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

EFFECT OF SHOES ON THE MECHANICAL PROPERTIES OF PROSTHETIC FEET UTILIZED IN TROPICAL COUNTRIES

Principal Investigator: Corin Shirley *Investigator: Alex Ashoff*

Introduction: Previous studies have shown that low cost prosthetic feet have had a short lifespan in tropical nations (Jensen, 2006). This has been known to be linked to the lack of practitioners in these nations, and the low funds available to continue to replace damaged feet (Jensen, 2006). Clinicians have observed that shoes tend to protect the prosthetic foot from wear, but it is unclear the magnitude of protection (Pye, 2015). This study investigated the effect of shoes on the preservation of the material properties of prosthetic feet when exposed to harsh UV and humid conditions. It is hypothesized that the mechanical properties of the feet would be maintained in both the forefoot and heel regions if shoes were worn over the prosthetic feet, and significantly deviate if no shoes were worn.

Materials and Methods: ISO 10328 static testing was performed on six samples of the ICRC feet. Three samples were tested with shoes (S group), while the other three were tested without (NS group). Following this testing, the samples were put in an environmental chamber where they were exposed to UV light at 38°C and 98% humidity for 400 hours. After this exposure, the samples were put through ISO 10328 static testing again along with the cyclic test. The cyclic test involves sinusoidally loading the heel and forefoot alternately between 50 and 1330N at a frequency 1Hz. Lastly, after 2,000,000 cycles, the ISO 10328 standard prescribes a final static proof test identical to the initial static proof test unless failure is observed during the cyclic test. Additionally, the feet were checked for visible damage before and after testing. This was done using a systematic Qualitative Assessment form where the observer ranked the condition of each foot from 0 (Failure) to 3 (Excellent)

Results:

Quantitative Results

Changes in stiffness, creep and max deformation for each group can be seen in **TABLE 1**. The foot was analyzed at the forefoot and heel individually due to inherent differences in mechanical properties.

TABLE 1: Differences in mechanical factors in forefoot (FF) and heel (H) before and after testing.

	FF		***H***	
	NS Group	**S Group**	**NS Group**	**S Group**
Δ Stiffness (N/mm)	125.7± 28.1*	79.9± 44.7*	70.1 ± 9.56*	30.9 ± 15.1
Δ Creep (mm)	2.46 ± 0.17*	2.52 ± 0.19*	2.15 ± 0.06**	0.37 ± 0.08*
Δ Displacement (mm)	4.6 ± 2.94**	-9.96 ± 7.76*	10.19 ± 2.39*	-5.73 ± 3.14

**indicates a significant difference (p value <0.05)*
***indicates a very significant difference (p value <0.01)*

Qualitative Results

Due to the small sample size, a Paired-Samples Wilcoxon Signed Ranks test was then used to assess whether or not qualitative changes in both categories were significant (α=0.05). JMP Pro 12 software was used to aid in performing the statistical analysis.

Discussion:

The hypothesis stated that the shoe group would show no significant differences after testing. When analyzing the FF region, it was found that the shoe group and the no shoe group both saw significant changes in maximum stiffness, creep, and maximum deformation from the baseline tests (TABLE 1) disproving this prediction. Interestingly, while creep and stiffness in the FF region increased significantly, max deformation saw a different trend. In the S group, the max displacement actually *decreased significantly*, while the NS group saw a *significant increase*. Creep in this region is also thought to be affected due to the flexibility of the forefoot during loading, not just the deformation of the foot upon compression.

In the H region, it was found that the shoe played a significant role in protecting the foot from changes in increases in maximum stiffness and maximum displacement. While the creep was still found to increase significantly with the application of a shoe, it was also significantly less than the change seen in the NS group. This could mean that the sole of the shoe works to adequately protect the H from changes in stiffness while ambulating in harsh environments.

Limitations:

Issues with the environmental chamber had to be fixed several times which resulted in inconsistent exposure during the 400 hrs. Foot 4 was also overloaded to failure during final static testing due to a machine malfunction and left out of data processing due to the significant effect the outlier had on the small sample size. Small sample size was the result of time and foot donation limitations. Collected data values however, were consistent among groups and data trends are believed to be similar in a large sample size.

Conclusions:

Changes in mechanical properties of the heel region of the ICRC foot were significantly reduced by the application of a shoe in harsh environmental conditions. Further testing is needed with a larger sample size to confirm the preliminary results of this study.

Effects of Gait Training with Reciprocating Gait Orthosis on Quality of Life for the SCI Patients and Caregivers

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INTRODUCTION

It is well known that quality of life (QOL) in the caregivers as well as spinal cord injury (SCI) patients is worsened (Unalan et al. 2001). Gait training with reciprocating gait orthosis (RGO) is one of effective rehabilitation programs for the SCI patients. There were few studies on the effects of RGO gait training for QOL in the SCI patients and caregivers. The aim of this study was to evaluate the QOL for the caregivers as well as the SCI patients after RGO gait training for 1 year.

METHOD

In this study, 5 complete SCI patients (Height:, Weight: Age:, injury level: ~~~) and their caregivers were enrolled. RGOs for SCI patients were fabricated. SCI patients administered RGO gait training for 1 hour, 5 days/week, and 1 year. Before and 1 year after RGO gait training, QOL in SCI patients and their caregivers were evaluated by using SF-36 form.

RESULTS

All scores in SF-36 were tended to be increased in SCI patients (Fig. 1). However, there were no significant differences following 1 year of RGO gait training. For caregivers, PF, VT, SF, RE and MH were significantly improved ($p < 0.05$). Furthermore, other scores were also increased.

DISCUSSION

In this study, we found significant improvement of QOL in caregivers, particularly mental aspects. There results indicated that RGO gait training in SCI patients might positively affect caregiver. However, less improvement of QOL in SCI patients were shown. These paradoxical results might imply that other factors regardless of SF 36 might affect QOL in caregivers, such as less labor burdens or efforts for caring SCI patients. In this study, only a few subjects were enrolled. Further studies with more subjects were needed. Additionally, we did not evaluate physical health in the SCI patients.

ACKNOWELDGEMENT

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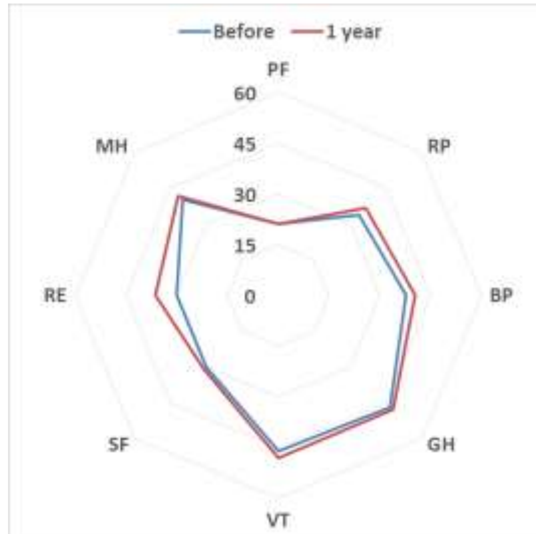
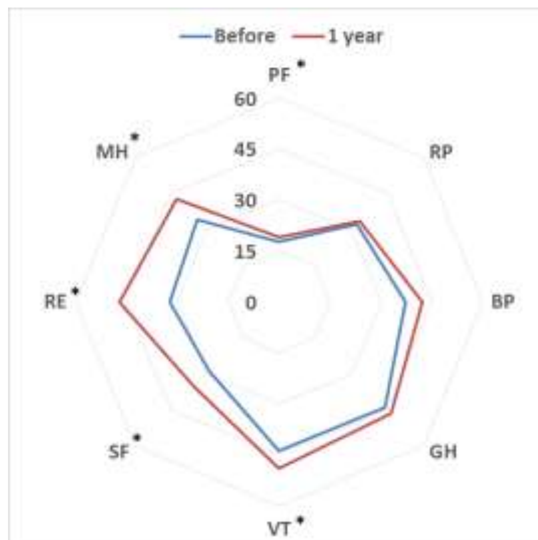


(a)



(b)

Figure 1. Alterations of SF 36 (a) SCI patients (b) caregivers, *: before vs. after 1 year ($p < 0.05$)

EFFECTS OF PROSTHETIC SOCKET SUSPENSION ON GAIT IN UNILATERAL TRANSTIBIAL AMPUTEES

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INTRODUCTION

Socket suspension is essential in prosthetics and plays an important role in the control of artificial limb. A wide range of suspension systems exist including but not limited to suction, locking-pin and elevated vacuum (VASS). Each type of suspension has its own pros and cons. For example, locking-pin suspension is reported to significantly reduce the pistioning movement between the stump and the socket. However, during swing phase the locking-pin suspension could cause significantly larger negative pressure at the distal end of the limb than suction, which likely leads to skin problems. When compared to suction, VASS applies a significantly higher yet more uniform negative pressure on the residual limb, which helps reduce volume fluctuation and promote wood healing in residual limb. In addition, VASS is reported to improve gait symmetry.

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

METHOD

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

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

Procedures: test sockets with a built-in expulsion valve were fabricated for each individual participant. With suspension sleeve and/or vacuum pump, we were able to obtain two other types of suspension: suction and VASS. Participants visited the lab three times. We used modified Helen-Hays marker set (including 19 reflective markers) and applied the markers on anatomical landmarks. The camera system and the force plate were carefully calibrated and synchronized. Signals were collected at 100 Hz. Before the test, participants were asked to walk for around 3-5 min. Adjustment was made if needed. The patients were instructed to walk at self-paced speed and target the force plate with either side. Walking trial was repeated three times with at least 1-min break in between for each side.

Data Analysis: gait parameters including spatiotemporal characteristics and kinematics/kinetics of the joints of both sides in the sagittal plane were obtained using Visual3D. We did not conduct statistics for this small sample.

RESULTS

The self-selected walking speeds were 0.94 (0.18), 0.85 (0.26) and 0.96 (0.22) m/s when using locking-pin, suction and vacuum respectively. Temporospatial data was summarized in table 1.

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

		Amputated side		Sound side	
	Double Support Time (s)	Stance %	Step Length (m)	Stance %	Step Length (m)
LP	0.23 (0.02)	67 (2)	0.57 (0.12)	70 (2)	0.54 (0.12)
Suction	0.24 (0.03)	70 (3)	0.56 (0.14)	69 (2)	0.59 (0.13)
Vacuum	0.23 (0.03)	70 (2)	0.59 (0.11)	70 (3)	0.54 (0.1)

The peak ankle dorsiflexion angles were 8.89 (2.34), 13.25 (7.19) and 9.31 (6.14) degrees, and the peak knee angles during stance phase in the sagittal plane were 5.63 (7.87), 15.8 (11.85) and 12.45 (7.49) when using locking-pin, suction and vacuum respectively. When using suction the ankle torque was 1.32 (0.26) Nm/kg on the amputated side while the sound side generated a torque of 0.92 (0.31) Nm/kg.

CONCLUSION

This pilot study indicates that the overall performance of suction is poorer than the other two suspension types. Suction or vacuum not only influence the ankle/knee kinematics but also lead to distinct characteristics of gait kinetics. Particularly, participants generated more ankle torque on the amputated side than the sound side.

CLINICAL APPLICATIONS

The outcomes of this pilot study could help practitioners in selecting the appropriate type of socket suspension and likely improve the functional performance of the patients.

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Knowledge Translation of Dilatancy Socket Fabrication

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INTRODUCTION

In general, new technology makes computers better and cheaper. By contrast, in health care new technology may improve quality but it is often associated with higher costs. Continuous rising of health care cost in the U.S., from 4% of national GDP in 1950 to 17.8% in 2013, is not a sustainable trend. In addition, global warming and disposal of waste are issues of concern to everyone involved with health care services. Dilatancy prosthetic technology was originally developed to improve healthcare utilizing low-maintenance low-cost equipment and eliminating the use of Plaster-of-Paris for fabricating sockets.

Like vacuum-packaged coffee beans sold by millions in supermarkets, granules that are enclosed in a flexible container (Spandex bag) can form and retain any shape as long as the air inside is evacuated. This phenomenon, called dilatancy, was first investigated 68 years ago (Mead, 1949), reported to use for fabricating experimental sockets in 1970s (Wilson, 1980) and recently developed into two clinical procedures (Wu, 2003; Wu 2009).

By placing a bag of micro polystyrene (PS) beads around the residual limb, upon application of vacuum, the granule-filled bag can instantly become a solid negative mold of the body segment. The negative mold can be filled with sand, sealed, and the air inside evacuated to create a positive sand model for forming prosthetic sockets in as little as 30 minutes. (Figure 1)

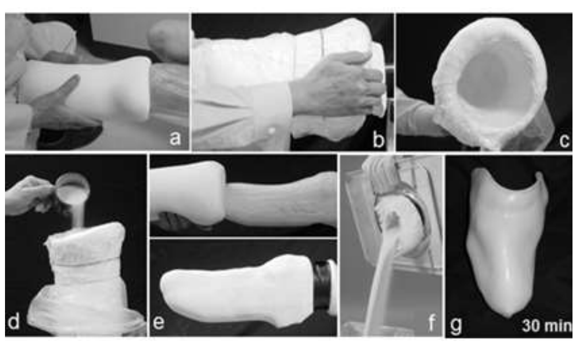

Figure 1, Dilatancy (PS) Casting System (or CIR Casting System) enables the clinician to fabricate transtibial prosthesis during a single clinic visit.

METHOD

Dilatancy socket fabrication systems underwent initial clinical testing in the lab and independent field evaluation in Vietnam by the International Society for Prosthetics and Orthotics (ISPO) (Jensen, 2005; Thanh, 2009). The results confirmed, as compared to bench data from standard plaster-based approach, an improvement of socket fitting from 65% to more than 80% with comfort fit. It also confirmed the possibility of speedy service provision in one hour.

With the proven technology, a global knowledge translation strategy and plan of this innovation were developed. (Figure 2)

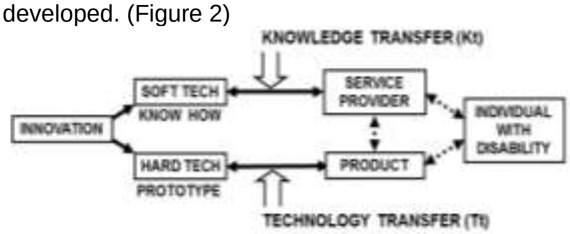

Figure 2, Knowledge translation strategy

RESULTS

With the support from NIDILRR, WHO, Rotary Clubs and BMVVS JaipurFoot, the Dilatancy (PS) Casting System has been translated to several low-income countries. Since 2005, more than 10,000 prostheses have been fabricated for individuals with amputations in India & Thailand. (Jivacate, 2011) The Prostheses Foundation in Thailand has been translating the technology to other countries. It also provided nine prostheses for two landmine-injured elephants.

Currently, we are assisting three local P&O clinics to implement dilatancy systems as the first step of our "reverse innovation" effort in the U.S.

DISCUSSION

Dilatancy system allows rapid formation of a high quality prosthetic socket using low-cost equipment. A future study is needed to compare the dilatancy technology with plaster-based and CAD-CAM-based approaches to determine its value in clinical settings.

CONCLUSION

Dilatancy socket technology is a potential alternative to current plaster or CAD-CAM-based approaches.

CLINICAL APPLICATIONS

Dilatancy socket technology is an emerging prosthetic procedure for clinicians who want to improve socket quality, cost-time efficiency, save energy and reduce waste production.

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LOW-COST PATTERN RECOGNITION BASED MULTI-DIGIT MYOELECTRIC HAND PROSTHESIS

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INTRODUCTION

Upper extremity prosthetics devices range from high-cost thought controlled dexterous prosthetic limbs [Hotson 2016] to low-cost 3d printed devices with limited dexterity. This effort addresses the gap between these two extremes by incorporating low-cost and open-source components with advanced concepts in prosthetic control to create a low-cost pattern recognition based multi-digit myoelectric hand prosthesis. This study represents not only prototype devices, but also provides resources, documentation, and tools for the community to replicate, customize, and improve prosthetic devices for upper extremities.

METHOD

Advanced prosthetic devices incorporate high fidelity sensor technologies for Electromyography (EMG), sophisticated signal processing using machine learning, and multi-degree of freedom (DOF) actuation. However, each technology domain has vibrant open-source options thanks to the "maker" community. We developed a custom-interface for the Thalmic Labs Myo armband (Myo) for signal acquisition, developed a pattern recognition controller using the Raspberry Pi system-on-a-chip, and incorporated multi-digit actuation using up to 6 independent servos adapted to the eNABLE Raptor Reloaded 3d printed hand (Raptor).

Integration for all these components was achieved using an open-source version of the Johns Hopkins University Applied Physics Lab's Virtual Integration Environment (VIE) [Armiger 2011], written in MATLAB and Python (https://bitbucket.org/rarmiger/minivie).

Pattern recognition based control was achieved using Linear Discriminant Analysis of EMG signals characterized using four features: mean average value, slope sign change, zero crossing, and signal length. A custom Myo driver was developed to detect and stream up to 16 raw EMG channels (8 channels per Myo) simultaneously at a rate up to 300Hz wirelessly over a Bluetooth low-energy connection.

The Raptor hand was retrofit with universal servo mount interfaces to accommodate a variety of servo motors allowing either individual finger control, or four unique grasps: cylindrical grasp, point grasp, lateral pinch, and open hand. The device was evaluated by one individual with intact limbs and one individual with congenital limb deficiency (right hand with only a partial palm and thumb).

RESULTS

The advanced prosthesis cost on the order of $300 with 1 Myo or $500 with 2 Myos. An initial design concept offers a 6-DOF prosthesis using 8 EMG signals from 1 Myo streaming at 200Hz in a partially-embedded system. A custom design offers a 4-DOF prosthesis which will control four independent phalanges based on 16 EMG signals from 2 Myos streaming at 300Hz in a fully embedded system. Leveraging rapid prototyping from extruded polylactic acid (PLA) material, design improvement and customization was possible from multiple part reprints within hours of functional evaluation.

DISCUSSION

This development effort sought to act as a proof of concept for bringing advanced concepts in upper extremity prostheses such as pattern recognition, wireless control, machine learning and multi-digit actuation to the open-source community at low cost. Clinical EMG systems can cost several thousands of dollars and prosthetic hands can cost tens of thousands with only basic mode-switching control. The results represent a lower-bound for cost while incorporating advanced prosthetic capabilities. Improvements to this proof of concept effort are endless including substituting extruded plastic for sintered metal parts.

A significant gain from this effort is the ability to obtain 16 discrete EMG signals from non-invasive, intuitive, and comfortable sensor devices. The custom system allowed one user to experience independent finger articulation in his right hand for the first time in his life. The open source architecture presented is being leveraged by other researchers for development of additional modular prosthesis sensors.

CONCLUSION

A low-cost open source advanced intent-based prosthesis design is possible for ~$300. The open source modularity concept presented expands the trade space between device cost and prosthesis performance. All aspects of this design effort have been documented as an open-source reference for others to utilize and extend as necessary.

CLINICAL APPLICATIONS

This effort offers users access to an intuitive prosthesis that has increased functionality with access to increased activities of daily living.

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MATERIALS ENGINEERING FOR COMFORT: ELASTIC MODULUS AND VISCOELASTICITY

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INTRODUCTION

A prosthetic socket interfaces the human limb with distal componentry and functions to transfer biomechanical forces resulting from gait and other movements as well as weight bearing forces. Limbs are soft while distal componentry is hard. Thus, the socket must transition from hard distal componentry to soft tissue in a way that is effective at counteracting biomechanical and weight-bearing forces, avoids skin breakdown, and is comfortable. The ability for a socket to function in this way is dependent on how the socket is configured or shaped to engage with the limb and the materials that comprise the socket. Outside of geometry, we believe that elastic modulus and viscoelasticity (also referred to as cold flow, pack-out, and creep) are the most important factors affecting socket comfort; elastic modulus for the instantaneous fit and viscoelasticity for the long term fit.

METHOD

Materials within three types of conventional laminated sockets (CLS), two types of patented sockets, and two types of adjustable sockets were investigated for tensile and flexural elastic moduli. Tests were performed on a mechanical testing system. The tensile elastic modulus was determined using the tensile test (ASTM D638), and the flexural modulus was tested using the 3-point bend test methods (ASTM D790). Tested materials included various carbon fibers, thermoplastics, textiles, foams, and gels. The viscoelastic response to a tensile load was measured as per ASTM D2990.

RESULTS

The tensile and flexural moduli were determined for most materials. The flexural moduli of the textiles were immeasurable, since there was no inherent rigidity.

The carbon fiber composites of each socket had the highest elastic moduli. Of the sockets tested, the patented socket type had the highest stiffness. The foams and textiles had the lowest moduli, while the thermoplastics varied in between the two.

The patented socket type without flexible inner liner and the CLS without flexible inner liner had the fewest materials, and thus the fewest discrete values of elastic moduli, sockets with a flexible inner liner and adjustable socket #2 had several more discrete values of elastic moduli, and socket type #1 had the most discrete values of elastic moduli as well as the widest range of elastic moduli.

A wide range of viscoelastic deformation was observed across the sample set. The largest single factor affecting the amount of viscoelastic deformation was the comprising polymer type. Thermosetting polymers exhibited substantially less deformation than thermoplastic polymers. Other factors affecting the amount of deformation seen were molecular weight, and material strength. There was also a correlation to elastic modulus.

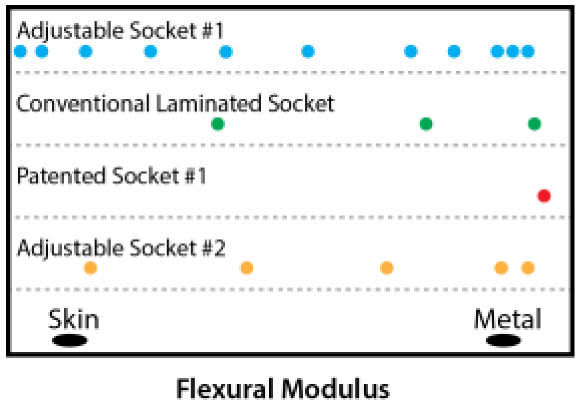

Figure 1: Range over which Flexural Modulus varies within Different Prosthetic Sockets

DISCUSSION

It is postulated that sockets with the fewest discrete moduli of elasticity rely heavily on being configured or shaped to avoid high peak pressures that can lead to discomfort and reduced function. Conversely, sockets with the highest discrete moduli of elasticity rely less on being configured or shaped to avoid high peak pressures.

Additional material properties data was collected for textile aspects of the socket since textiles exhibit different properties than structural components. This data is discussed but not directly correlated to the structural components and materials in other sockets since these tests do not apply to plastics and metals.

CONCLUSION

Socket types differ greatly with respect to various materials properties found within. We believe that sockets with less materials variability rely great on socket shape to achieve comfort.

CLINICAL APPLICATIONS

Choosing the appropriate materials combination can be used in addition to socket shape, to improve socket comfort in the short and long term.

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ASTM testing standard D638
ASTM testing standard D790
ASTM testing standard D2990

American Academy of Orthotists & Prosthetists
43rd Academy Annual Meeting &
Scientific Symposium
March 1-4, 2017

Mediating the Introduction and Use of Standardized Functional Outcome Measure Tests for Lower Limb Prosthetic Performance in a Clinical Setting

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INTRODUCTION

Functional Outcome Measure (FOM) tests administered in a clinical setting provide essential information regarding the locomotor performance of individuals with lower-limb amputation as enabled by their prosthetic device (MacKenzie, 2004). However, few clinicians routinely collect this data, in part due to their unfamiliarity with FOM set-up and execution. Creating an easy to use method of collecting and leveraging these metrics has the potential to encourage clinicians to capture this data. Standardizing the FOM data collection procedure will provide reliable and repeatable longitudinal measures.

METHOD

We reviewed the set-up and execution of multiple validated outcome measure tests.

Subjects: 33 prosthetists were trained; 5 clinicians successfully collected FOM on 6 amputee patients at baseline.

Apparatus: Three FOMs were selected for field-testing: L-test, FSST and 2MWT.

Procedures: Each test was set up by a clinician, executed by an amputee 3 times, and then evaluated and reviewed by a researcher to determine feasibility of deployment in a real-world clinical setting.

Data Analysis: Longitudinal data was collected at baseline, 1 week and 1month intervals. Tests were conducted in triplicate to calculate measure repeatability and show variance.

RESULTS

Preliminary results from our sample of clinical settings indicate both clinician and patient willingness to complete FOM data collection. Clinician reported positive feedback included: ease of FOM decal set-up, readability of instructions/video for collecting data, and analysis of collected metrics.

	T1	T2	T3	AVG + STD DEV
1	19.71	15.82	16.45	17.33 + 2.09
2	6.5	6.03	5.35	5.96 + 0.58
3	11.4	10.77	11.03	11.07 +0.32
4	11.5	10.72	10.33	10.85 +0.60
5	15.99	15.34	15.76	15.70 +0.33
6	12.71	8.80	10.00	10.32 +1.71

Table 1: Variance Range for FSST Scores (in seconds) by Clinician (n=6)

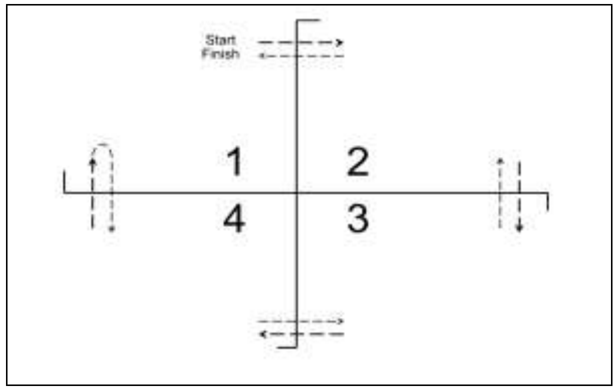

Figure 1: FSST (Derived from Dite & Temple 2002)

DISCUSSION

Improving a clinician's ability to administer and evaluate the performance of an amputee in their prosthetic socket is critical. The process must be simple, consistent and streamlined in order to obtain reliable measures. We created a set of floor decals to capture data on three validated FOM and initial clinical and patient has been positive. Expansion of this project will move towards collecting longitudinal FOM for prosthetic users, providing a mechanism for clinicians at specific practices to assess the impact of new technology on amputee mobility. Ultimately, this optimizes quality of patient care.

CONCLUSION

This pilot study aims to create a starting point for standardizing the collection of these metrics and empowering clinicians to collect, analyze and document longitudinal outcome data.

CLINICAL APPLICATIONS

FOM have the ability to provide clinician's with additional information to assist in determining the impact of prosthetic devices on patient mobility over time. Reliable collection of this data will help to improve and tract changes in patient care.

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American Academy of Orthotists & Prosthetists
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Motion in the socket between vacuum and pin suspension: A case study

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INTRODUCTION

Prosthetics is a clinical field in need of further investigation for the improvement of patient care. Engineering principles can be used in collaboration with clinical expertise to quantify key mechanical issues occurring at the residual limb to socket interface to better understand ulcer formation, which is very prevalent in the diabetic population (Boulton 2008). Quantitative data on limb motion within the socket, motion relative to the socket, shear forces at the interface, and propagation of these loads to the skin level and deeper are all lacking in current literature.

The goal of this research is to study limb interface mechanics of the prosthetic/limb boundary for better understanding pressure ulcer formation between pin and vacuum suspension in a single subject. The subject wears two prostheses one with pin and one with vacuum suspension interchangeably.

METHOD

Subjects: Case study on male age 57, height 187.96 cm and weight 80.91kg, 6.5 years since amputation, and a K3 ambulator. The individual wears two different prostheses interchangeably, one vacuum and one pin.
Apparatus: A twelve camera motion capture system (Vicon Motion Systems Ltd.; Oxford, UK) tracked the locations of all markers in three-dimensional space; the system was calibrated before each data collection.
Procedures: One main analytical parameters was developed for quantification of the residual limb within the prosthetic socket: displacement relative to the prosthetic socket both in the morning (AM) and the afternoon (PM).
Data Analysis: T-tests (p value) used to compare displacement data between the two designs in the AM and PM.

RESULTS

Results show there is more displacement in the pin system compared to the vacuum system and in the vacuum suspension between AM and PM. The values calculate to a significant difference between the AM Pin versus vacuum, PM pin versus vacuum, with the exception of the distal tibia, and the Vacuum AM versus PM. There was no difference between the pin AM versus PM.

DISCUSSION

The results of this study are significant to the prosthetics field comparing two different suspension systems and motion in the socket at different times of day. Vacuum has been stated to have better suspension (Bruinelli 2009) and the data supports this claim. Decrease in displacement, decreases strain, potentially translating to less chance of ulceration. The lack of difference in the pin suspension from AM to PM

(mm)	Tibia Prox	Tibia Dist	Fibula Prox	Fibula Dist	Medial Prox	Medial Dist
AM Pin	18.79 ± 3.57	16.51 ± 2.73	39.26 ± 6.24	35.03 ± 3.23	44.39 ± 7.31	42.00 ± 5.08
AM Vacuum	7.24 ± 1.19	4.93 ± 0.57	23.9 ± 3.82	15.83 ± 1.58	23.7 ± 2.45	21.07 ± 3.96
PM Pin	21.52 ± 2.06	17.76 ± 0.715	42.28 ± 1.52	38.29 ± 2.70	48.56 ± 3.53	43.30 ± 3.85
PM Vaccum	14.98 ± 4.27	16.51 ± 3.36	8.39 ± 1.33	6.19 ± 0.33	12.80 ± 4.48	11.04 ± 2.29

Figure 1: **Displacements of locations in mm varying with suspension and time of day relative to the socket**

	Tibia Prox	Tibia Dist	Fibula Prox	Fibula Dist	Medial Prox	Medial Dist
AM Pin vs. Vac	0.0001	0.0000	0.0016	0.0000	0.0003	0.0001
PM Pin vs. Vac	0.0150	0.4403	0.0000	0.0000	0.0000	0.0000
Vac AM vs PM	0.0045	0.0001	0.0000	0.0000	0.0014	0.0012
Pin AM vs PM	0.1769	0.3515	0.3247	0.1220	0.2838	0.6594

Figure 2: P values of displacements varying with suspension and time of day relative to the socket. Significance p<.05 and shown in red.

most likely is due to the already high displacements occurring in the socket. The lack of difference in the distal tibia between the two systems in PM needs to be evaluated further with more gait cycles to better understand what is occurring. Wounds typically occur at bony landmarks such as the anterior distal tibia (Mak 2010) where, in a pin system, prosthetists expect more displacement; however the results demonstrate less displacement occurring at the distal tibia compared to the other five locations. More displacement occurs at the fibular head where the relief may not be large enough to accommodate this displacement resulting in a wound. Wound formation at either location may not be due to only displacement only but a coupling with force. Future studies will compare displacements in more subjects in the pin suspension, analyze the force occurring at areas within the socket, and study different suspension mechanisms to be able to provide the information to clinicians for better patient care.

CONCLUSION AND CLINICAL APPLICATIONS

Less pistoning occurs with vacuum which may aid in less ulcer formation. Future studies will demonstrate if there is a coupling effect between the displacement and force that creates ulceration and analyze different suspension methods. All of this information will help clinicians provide better patient care.

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PILOT STUDY ON THE EFFECTS OF UPPER LIMB LOSS AND PROSTHESIS USE ON LOCOMOTOR STABILITY

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INTRODUCTION

During steady-state walking, natural arm dynamics facilitate locomotor stability by minimizing body angular momentum through counterbalancing leg motion [1] and reducing trunk motion to constrain body center-of-mass (BCoM) excursion [2]. Consequently, persons with upper limb loss may experience reduced locomotor stability that may be dependent on prosthesis use. This pilot study investigated the effects of prosthesis use and matching inertial properties of the prosthetic limb to the sound limb on stability during walking.

METHOD

Subjects: Two subjects with unilateral transradial (TR; 61yrs, 186cm, 90kg) and transhumeral (TH; 62yrs, 179cm, 111kg) limb loss participated in the study.

Apparatus: Kinematics were measured using an optical motion capture system (Motion Analysis Corp. (MAC), CA) and a modified Helen Hayes marker set [3] with additional trunk and arm markers. BCoM was estimated from an individual body segment model. A custom 'mock prosthesis' was designed to match the mass and inertial properties of the prosthetic limb to the sound limb (Figure 1). The mock prosthesis length, mass, and location of the center-of-mass were estimated using an algorithm based on established able-bodied anthropometric regression equations [4].

Procedures: Subjects walked over-ground on a level walkway at three self-selected speeds (slow, normal, and fast) under three prosthesis conditions: 1) without wearing a prosthesis, 2) wearing their customary prosthesis, and 3) wearing the mock prosthesis. At least five walking trials were collected and analyzed for each speed by prosthesis condition iteration.

Data Analysis: 3-D trunk rotations (relative to the global axes) were estimated using Orthotrak software (MAC). Margin of stability (MoS) was estimated as the minimum distance between the lateral foot border and extrapolated BCoM (a velocity-weighted BCoM) positions [4]. Step width and variability of step width, length, and time were also calculated.

RESULTS

Trunk rotations at a single walking speed are displayed in Figure 2 (speed-matched to data of 13 healthy subjects (51±6yrs, 172±9m, 74±15 kg)). MoS was greater on the prosthetic and sound side for the TR and TH subjects, respectively, but displayed little difference between prosthesis conditions. Minimal changes were seen in step width across conditions, but variability in step width, length, and time generally increased with use of a prosthesis (both customary and mock with less clear individual trends).

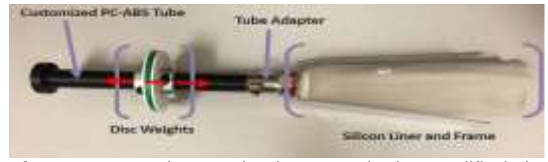

Figure 1. Mock prosthesis. Length is modified by replacing the plastic tube. Mass is modified through adding disc weights, secured in location by cuffs.

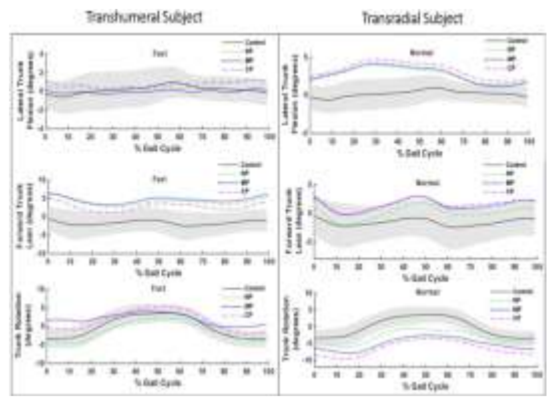

Figure 2. Frontal (top), sagittal (middle), and transverse trunk rotations (bottom) for both subjects. NP=no prosth, MP=mock prosth, CP=customary prosth.

DISCUSSION

These subjects with unilateral TR and TH limb loss displayed asymmetric trunk rotations with temporal profiles similar to controls. Trunk motion was minimally effected by prosthesis use and trends were not clear. Subjects displayed asymmetric MoS which aligned with the direction of asymmetry in lateral trunk lean, but was also not affected by the prosthesis. The side with greater MoS would suggest decreased opportunity for the BCoM to exceed the base of support. Surprisingly, use of a prosthesis increased gait variability, suggesting reduced locomotor stability.

CONCLUSION

Individuals with unilateral upper limb loss walk with asymmetric trunk motion that is not impacted by prosthesis use. However, prosthesis use may result in reduced stability and this should be further explored.

CLINICAL APPLICATIONS

Use of a unilateral upper limb prosthesis may not influence trunk movement but could affect risk of falls.

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Prosthetic Foot Frontal Plane Adaptability: Finite Element Studies

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INTRODUCTION

Through the stance phase of gait, the foot adapts spontaneously to unanticipated ground-foot contact. There is not enough time for voluntary motor control at the moment of impact. Spontaneous adaptability is especially important with poor foot prepositioning, uneven ground, decreased cognitive attention or low lighting.

The foot contacts the ground at an angle in the frontal plane during many activities of daily living including simple weight shift. Torques produced at the foot affect the socket-residual limb interface. Adaptability at the foot may minimize these forces and improve prosthetic comfort.

The purpose of this study was to evaluate prosthetic approaches to frontal plane adaptability using finite element modeling.

METHOD

The four general approaches evaluated in this study were: 1. Radius of curvature of the heel at foot strike; 2. Material compliance and thickness of compliant materials; 3. A foot prosthesis with series 4-bar linkages that allowed 26^o and 60^o rotation at the forefoot and hindfoot respectively; and 4. Split toe versus flat forefoot designs.

LS-Dyna (Livermore Software Technology Corporation, California, USA) was used for finite element modeling (FEA). The stance phase of gait was simplified using an inverted pendulum model of the leg (virtual prosthetic foot and pylon). Foot length, shank length and body mass were determined using measurements of a single research participant. Cosmetic coverings were not used for the comparisons. Initial linear and angular velocities at a gait speed of 1.3 m/s were not varied. Angled slope of 15% and raised domes (1.3 cm high, 10.16 cm diameter) simulated side-slope and uneven ground. The raised domes were positioned to contact different regions of the foot during gait. Deviation of the proximal shank from an anterior-posterior trajectory was used to evaluate frontal plane stability.

RESULTS

Heel mediolateral curvature significantly affected torques acting on the upper shank and deviation from the forward path. A flat heel contacting with 15% side-slope or a raised dome caused a torque about the proximal leg that was proportional to the width to the heel. Modifying the radius of curvature of the heel reduced the effect of heel impact and path deviation could be eliminated.

Compliant materials (CMs) between the foot and side-slope or uneven ground dampened mediolateral accelerations. CMs also allowed for a lateral shift over the base of support permitting a wider range of equilibrium positions. CMs can be used throughout the foot to adapt to various geometries depending on position of the virtual raised dome. However, overly compliant components had detrimental effects on maintaining the forward trajectory.

Forefoot frontal plane motion at foot flat was critical for mediolateral adaptability. Variations of forefoot properties at forefoot contact was the principle determinant of deviation from forward progression. The crossed 4-bar linkages adapted to the angled ground and reduced mediolateral deviation of the shank. The moving center of rotation of the 4-bar linkages increased the number of stable positions and lowered the virtual center of rotation compared to without a linkage system. Forward velocity and direction were maintained on a 15% side-slope and during contact with raised domes. A compliant split-toe design, resulting in two-point contact, permitted a tripod contact of the foot by unlinking medial and lateral forefoot motion compared with a flat forefoot.

DISCUSSION

Each approach to mediolateral adaptability tested in this study had strengths and weaknesses, suggesting that an optimization process including multiple approaches may result in superior performance compared with any individual approach.

The anatomical foot has regional differences that function in side-to-side adaptability. At the heel, normal anatomy consists of relatively limited range of motion and rounded shape. The midfoot has been considered an adaptable energy return system. The forefoot has considerable adaptability and has two-point contact. This study reinforces the anatomical structure-function relationships of the foot.

Further research on these and other variables, in combination with feedback, actuators, and control systems can improve mediolateral adaptability in prosthetic feet.

CONCLUSION

Stance phase frontal plane proximal shank trajectory on side-slope and uneven ground can be improved depending on shape, compliance, and linkage systems.

CLINICAL APPLICATIONS

Prosthetic foot design impacts comfort, performance and quality of life for people with major lower extremity amputations. Clinicians and prosthetic foot developers might consider heel and forefoot geometry, properties of CMs and linkage systems as they relate to patient needs for frontal plane adaptability.

SIMULTANEOUS 2-DOF PATTERN RECOGNITION CONTROL OF UPPER-LIMB PROSTHESES

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INTRODUCTION

Seamless sequential pattern recognition control of upper-limb prostheses has been commercially available since late 2013. While a significant improvement over conventional myoelectric control, it does not address users' strong desire to be able to perform simultaneous movements (Atkins, 1996).

Simultaneous pattern recognition control has been demonstrated in research settings (Wurth, 2014). However, a significant challenge in clinical implementation has been the burdensome amount of time required to collect all individual and combined contraction data for classifier calibration. To address this issue, Ingraham (2015) suggested the use of a neural network to map individual contractions to combined contractions. Once trained, the model can generate artificial combined data following a standard calibration, thereby not increasing the time needed for recalibration. We expanded upon this study by increasing the subject pool, including subjects with amputation, and completing real-time virtual performance testing to assess clinical feasibility.

METHOD

Five able-bodied subjects (four male, one female, average age of 29) and three subjects with transradial amputations (all male, average age of 46) completed the study. An elastic cuff with eight, equidistantly-spaced electrode pairs was placed on the forearm approximately two centimeters distal to the elbow. Subjects completed eight data collection sessions consisting of eight repetitions of the following muscle contractions: wrist supination and pronation, hand open, key grip, chuck grip, fine pinch grip, point grip, and all ten possible combinations. Ten blocks of a real-time virtual posture matching test (Simon, 2011) with both a sequential controller and the proposed simultaneous controller were completed. Analysis of variance (ANOVA) and post-hoc comparisons were conducted. Significance was calculated using α=0.05.

RESULTS

The overall accuracy for the simultaneous controller trained with only discrete data remained poor and fairly constant. For able-bodied subjects, the error rates for the systems trained using discrete and combined contraction data were significantly lower ($p<0.01$), and there was no significant difference between the error rates obtained using experimentally-collected and model-generated combined data. There was a trend toward improved accuracy over time. The classification error rates from subjects with amputation followed generally the same trends but were higher and more variable.

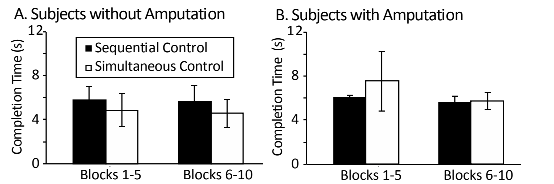

Figure 1. Real-time virtual performance testing results. Error bars denote standard deviations.

Subjects appeared to learn to use the simultaneous controller over the duration of the real-time virtual tests, while performance with the sequential controller remained static (Figure 1). For subjects with amputation, the average completion time using the simultaneous controller dropped from 7.5 s (SD 2.7 s) in blocks 1-5 to 5.7 s (SD 0.8 s) in blocks 6-10. The improvement for able-bodied subjects was more modest (4.9 s SD 1.5 s to 4.6 s SD 2.3 s). For subjects with amputation, path efficiency rose from 65% in blocks 1-5 to 70% in blocks 6-10. For able-bodied subjects it rose from 78% to 80%.

DISCUSSION

The results indicate that inclusion of combined contraction data is vital to the performance of a simultaneous control system. The performance of the classifier trained with model-generated data approached that of the classifier trained with experimentally-collected data as the size of the neural network training data set increased.

By the end of the real-time control experiments, the performance using simultaneous control was at least as good as sequential control, and in some cases better, even given the brief period of time subjects were provided to learn to use simultaneous control. We believe that with more practice, performance with the simultaneous control system would surpass that with the sequential control system.

CONCLUSION

We have demonstrated the feasibility of using a neural network mapping model to artificially generate combined contraction data for use in a clinical simultaneous pattern recognition control system.

CLINICAL APPLICATIONS

The addition of simultaneous control capabilities to a pattern recognition system would offer a significant improvement in functionality of upper-limb prostheses.

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Tactile Feedback for Object Discrimination

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INTRODUCTION

An area of rising interest is in tactile sensing for prosthetic limbs (Hsiao, Fettiplace et al. 2011). The sense of touch plays a crucial role in daily activities, particularly for grasping and manipulating objects. A primary goal of prostheses is the ability to enable an amputee and improve functionality. Especially for myoelectric devices, prosthesis control is of major interest and with good reason. As prosthetic limbs become more functional and realistic it is important to investigate the possibility and benefit of providing tactile feedback as a form of sensory perception for the both the user and the limb.

The use of tactile sensors have been demonstrated for prosthesis applications (Osborn, Kaliki et al. 2016, Tan, Schiefer et al. 2014). The continued development of tactile sensors will play an important role in the future functionality and overall benefit of upper limb prostheses.

Here we demonstrate sensory feedback to an able-bodied user to discriminate between objects grasped by a prosthesis.

METHOD

A fingertip tactile sensor was fabricated using a piezoresistive textile (Eeonyx, USA) sandwiched between stretchable conductive fabrics (LessEMF, USA) to carry the signal to a circuit for reading the sensor output. The sensor is covered with 1 mm silicone layer (Dragon Skin 10, USA). This is similar to methods described in (Osborn, Kaliki et al. 2016) and (Osborn, Lee et al. 2014). The tactile sensors were placed on the thumb, index, and middle fingers of a bebionic3 prosthetic hand (Steeper, UK). The prosthesis was controlled using a customized development board (Infinite Biomedical Technologies, USA), which also measured and recorded the tactile signals.

An Ag/AgCl electrode was placed over the median nerve on the forearm of an able-bodied subject. A constant current isolated stimulator (ADInstruments, Australia) was used to provide transcutaneous electrical nerve stimulation to the subject at 2 mA.

Three different objects of similar size but varying stiffness (soft, medium, and hard) were grasped by the prosthetic hand. Each object was presented 10 times. The prosthesis controller used the tactile signal to classify the object being grasped and subsequently chose one of three stimulation patterns (2 Hz, 15 Hz, or 30 Hz), which corresponded to the different objects. The subject was blindfolded and verbally classified the object being grasped by the prosthesis based solely on the stimulation.

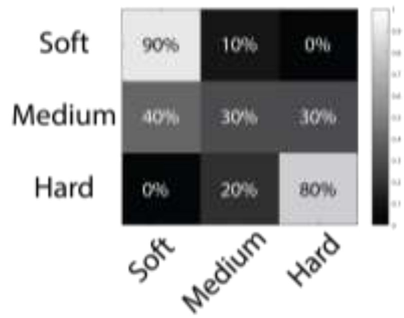

Figure 1. Results from the object discrimination task. The subject was able to identify the soft and hard objects, but was unable to reliably determine the object with medium stiffness.

RESULTS

Results show the ability of the subject to reliably identify the objects with either soft or hard stiffness. The subject was unable to reliably identify the object with medium stiffness.

DISCUSSION

The subject was able to successfully identify the hard and soft objects. This is likely due to the large difference in the two stimulation paradigms used when the prosthesis grasped these objects. This work demonstrates the feasibility of combining tactile sensors with existing prosthetic limbs for sensory feedback.

CONCLUSION

Sensory feedback via nerve stimulation allows a prosthesis user to distinguish between different objects based on varying stimulation paradigms.

CLINICAL APPLICATIONS

Tactile sensors can be used in conjunction with upper limb prostheses to provide information to the limb and the user during grasping tasks. Sensory feedback will play an important role in prosthesis functionality.

ACKNOWLEDGEMENT

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The Effectiveness of Cranial Orthotics on Head Shape in Children with Plagiocephaly

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INTRODUCTION

In 1992, the American Academy of Pediatrics began to support the national "Back to Sleep" campaign to decrease the rate of Sudden Infant Death Syndrome (SIDS). The incidence of plagiocephaly before 1992 was reported at roughly 1 in 300 live births, but in recent years has increased dramatically by 8.2-15% (Kalra R, & Walker M. 2012; Steinbok P, et al, 2007).

With this rapid increase in the incidence of plagiocephaly, the question of proper treatment, the long term effects and the financial responsibility for treatment have become more pertinent to the American healthcare system and its providers and consumers.

Current evidence related to use of cranial orthotics has been controversial; however, new techniques for fabrication have been developed, but not investigated. This investigation seeks to evaluate the effectiveness of helmet use with updated technology, the Omega Tracer system, for scanning of childrens' heads.

METHOD

Procedures: Following IRB approval, a retrospective, blind chart review was completed of the medical records of the subjects by two student physical therapists.

Subjects: 41 children (Age Range: 4-12 months)

Independent Variables: Age at initiation of cranial orthotic helmeting and duration of wearing orthosis

Dependent Variables: Head Circumference (HC), Cephalic Ratio (CR), and Cranial Vault Asymmetry Index (CVAI). Each dependent variable was measured by a Certified Orthotist utilizing the Omega Tracer System.

Data Analysis: The IBM SPSS Statistics 23 program was used to analyze the data using a paired T-test and a 2 way ANOVA for independent variable groupings. Independent variables of age and duration groupings were set as follows age grouping: subjects <6 months and subjects ≥6 months; duration grouping: subjects receiving helmet treatment <4 months and subjects receiving helmet treatment for ≥4 months. The probability of completing a type I error was set at .05 ($p \leq 0.05$) for all statistical tests.

RESULTS

Statistically significant changes were noted from pre- to post-measurements in each of the dependent variables measured: an increase head circumference ($p<0.001$), a decrease cephalic ratio ($p<0.001$), and decrease in CVAI ($p<0.001$).

A significant interaction was found for the independent variables of age ($p=0.016$; Eta squared 0.14) and duration ($p<0.001$; Eta squared 0.353) grouping on head circumference with statistics indicating a moderate effect size.

DISCUSSION

Despite ongoing controversy over the effectiveness of cranial orthotics, this retrospective chart review indicates that cranial helmets are effective in improving the head shape in children ages 4 to 12 months who elect to utilize them. Our results also indicate that the cranial orthotic is effective, even when applied to children who are over 6 months of age.

Future research on the use of cranial orthotics will utilize updated scanning systems as the medium for data collection.

Additional research is needed on the long term effects of plagiocephaly on cosmesis and child development including visual-motor and fine motor development.

CONCLUSION

In our sample, patients had a statistically significant change in HC, CR, and CVAI. No main effect was seen on any of the values when patients were grouped according to age of initiation or duration of wearing the orthosis. An interaction was found between age of initiation and duration of wear on head circumference, which is expected because as an infant ages, head size will increase.

CLINICAL APPLICATIONS

Cranial orthotics remain an effective option in improving plagiocephaly in children aged 4 to 12 months, even when the cranial orthotic is initiated after 6 months of the age.

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American Academy of Orthotists & Prosthetists
43rd Academy Annual Meeting &
Scientific Symposium
March 1-4, 2017

Use of and Satisfaction with the National Limb Loss Resource Center

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The Amputee Coalition

INTRODUCTION

Since 1997, the Amputee Coalition has operated the National Limb Loss Resource Center (NLLRC). The purpose of the NLLRC is to ensure the availability of, and access to, comprehensive information, resources, and supports for individuals with limb loss and their caregivers. The NLLRC fills an important void by providing individuals with free patient education materials and referring them to programs and services in their local community to help them address their needs.

Research suggests that the majority of persons who experience an amputation have no prior knowledge about prosthetic devices, lack a source of information about many of the topics related to living with limb loss(1). Additionally, individuals who experience an amputation feel that they are provided with an insufficient amount of information on a wide range of topics related to limb loss, including the rehabilitation process and possible outcomes(2).

This current work evaluates how well the Amputee Coalition's National Limb Loss Resource Center addresses this need for information.

METHOD

From 2012 to 2015, the Amputee Coalition conducted an online survey to evaluate the user satisfaction and impact of the NLLRC.

Subjects: A total of 911 survey participants were drawn from a convenience sample of 10,451 individuals who contacted the Amputee Coalition's NLLRC from April 1st 2012 through March 31, 2015.

Apparatus: Three separate online surveys conducted each year from 2012 -– 2015.

Data Analysis: Data analysis performed by SPSS, descriptive statistics and inferential statistical analysis conducted as appropriate.

RESULTS

Survey results suggest that individuals who contact the Amputee Coalition's National Limb Loss Resource Center are largely satisfied with the information and resources received in response to their request, find the information and resources to be useful, and are positively impacted by the materials received from the Amputee Coalition (See Fig 1 – 3).

Figure 1 – Satisfaction with materials received from the NLLRC

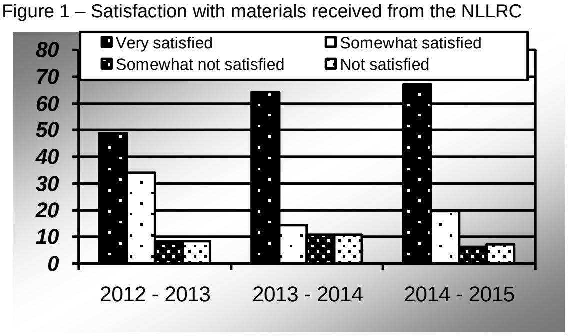


Figure 2 – Usefulness of materials received from the NLLRC

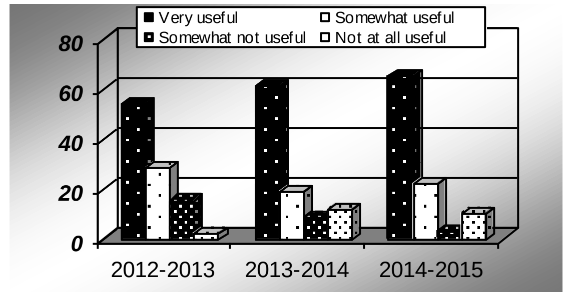
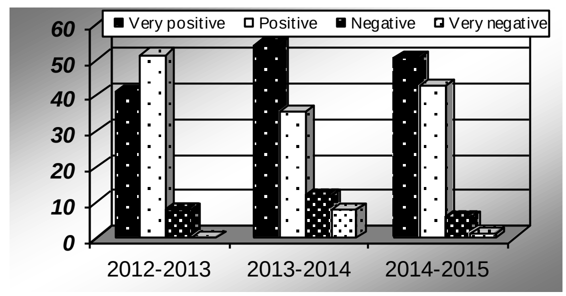


Figure 3 – Impact of materials received from the NLLRC



DISCUSSION

Based on the results from this survey, the Amputee Coalition's National Limb Loss Resource Center plays an important role in providing information and resources to help inform and educate individuals who experience an amputation.

CONCLUSION

The Amputee Coalition's National Limb Loss Resource Center provides information and resources that have a positive impact on the lives of those affected by limb loss. Users of the NLLRC are largely satisfied with the materials received.

CLINICAL APPLICATIONS

The NLLRC is a free resource that prosthetists should refer their patients to in order to address their information needs. Additionally, distributing the Amputee Coalition's cost-effective patient education materials can further enhance the quality of care prosthetists provide their patients.

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"WHAT ARE THE STONGEST DETERMINANTS OF OVERALL PATIENT SATISFACTION?"

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INTRODUCTION

Patient satisfaction, defined as a positive evaluation of one's experience, is one of the strongest indicators of healthcare quality. However, determinants of O&P satisfaction are not well known. By reviewing literature that correlates determinants with overall clinic satisfaction, this paper seeks to establish factors that drive O&P patient satisfaction.

METHOD

Searches were performed on Google Scholar and NCBI databases from 2001 to 2016 using the parameters "prosthetic", "orthotic", "satisfaction", and "clinic". Articles judged as relevant, including those found through references, were selected for research. Determinants significantly correlating with overall clinic satisfaction ($p<.05$) were recorded with their respective number of occurrences in the literature.

RESULTS

Search results with "prosthetic" or "orthotic" parameters returned determinants of device satisfaction but very little regarding overall satisfaction. After removing them, determinants from a broader field of physician clinics and hospitals were yielded (relevant papers N=7). Significant determinants are listed in Figure 1 according to their number of occurrences. Some determinants such as patient characteristics were beyond the control of the clinician and were not included in the chart data. These were level of *education* (Pakdil, et al., 2005), *expectations, age, smoking, sex, and insurance* (Bible, et al., 2015). Determinants judged as very similar were combined (i.e., physician empathy and listening were included with *physician interaction*).

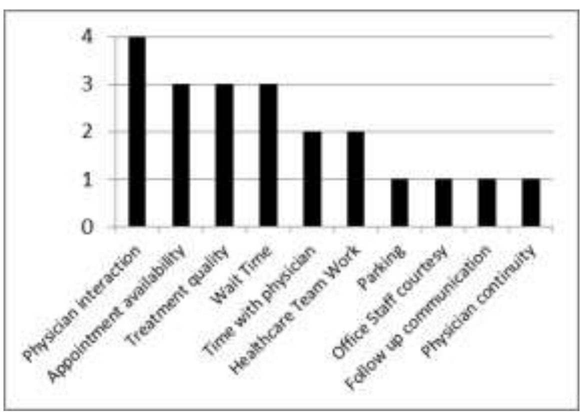

Figure 1. Determinants and their respective number of occurrences in the reviewed literature.

DISCUSSION

Although the sample size was limited, trends in the literature are evident. By frequency of correlation, we can see that building rapport with the patient (*physician interaction)* can be as important as the treatment itself (*treatment quality)* or the efficiency and organization of the clinic (*appointment availability and wait time)*. Since the patient does not have a basis to judge the clinician's decisions, it makes sense that trust in that clinician would be of major importance. Also, in our high-paced culture, it is no surprise that being respectful of the patient's time would be a strong determinant.

The strongest determinants for patients are largely based on their expectations (Pakdil, et al., 2005) which can be ascertained in a thorough evaluation. However, it is clear that much of patient satisfaction is determined by courtesy and effective communication.

Most research regarding O&P satisfaction is based on devices. However, dissatisfaction with one determinant can elicit a more critical opinion of another (i.e., a patient kept waiting for too long may be difficult to satisfy regardless of device function). Therefore, current research regarding O&P satisfaction is too focused and should be broadened to encompass other potential determinants.

CONCLUSION

It is important to understand the nature of satisfaction determinants. Although information from other fields is helpful, O&P is a unique field of medicine. Patient satisfaction with O&P is not well understood and should be researched further.

CLINICAL APPLICATIONS

Understanding determinants of satisfaction can assist the clinician with rating and improving his quality of care, increasing compliance and profitability, providing a marketing focus, and aiding in reimbursement.

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COMPARISON OF ELECTROMYOGRAPHY (EMG) AND GAIT IN TRANSITION FROM LOCKED KNEE-ANKLE-FOOT-ORTHOSIS (KAFO) TO PRE-STRIDE™ STANCE CONTROL ORTHOSIS (SCO): A CASE STUDY

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INTRODUCTION

Energy efficiency measured through muscle fatigue in KAFOs has not been investigated in detail. The clinical relevance of stance-control KAFOs and their effects on the quality of life has yet to be documented with a validated outcome measure. The purpose of this study was to systematically quantify any differences in EMG signals and gait mechanics as well as qualitative orthosis function for one subject diagnosed with post-polio wearing a custom, conventional locked KAFO and an immediate-fit stance control KAFO.

METHOD

One participant met enrollment criteria, was officially enrolled, and completed the entire study protocol. The study control was the subject's normal gait with their locked KAFO. The subject completed two sessions of data collection. Each session consisted of 10 walking trials on a 10-foot long walkway for each testing condition. Prior to the first SCO trial, the subject completed a familiarization session during which he was instructed on use and activation of the PreStride™ SCO device. For each of the 10 walking trials, data was collected using a Vicon 3D motion capture system, GaitRite portable gait analysis system, and a wireless electromyography (EMG) system. Two representative trials were chosen for data analysis from each session.

RESULTS

Vicon data supported use of the KAFO over the SCO. Hip and knee joint angles were measured closer to normal values with the KAFO. In both orthoses, the subject never reached full hip or knee extension. The subject demonstrated a more normal stance to swing ratio in the KAFO. The anterior tibialis muscle activation was also increased in the KAFO condition. However, the SCO trials showed an increased right calf, hamstrings and quadriceps muscle group activation. The spatiotemporal values derived from the GaitRite system were closer to expected normal values in the KAFO. Single and double limb support was more normalized with the KAFO. The OPUS survey demonstrated that the subject has a good outlook on his condition and quality of life. He appears to be limited more physically than emotionally.

DISCUSSION

The overall effectiveness of the SCO was reduced in part because of instability experienced with the selectively unlocked mechanical knee joint, as well as the allowed motion in the ankle joints. Additional time for gait training beyond the protocol may have improved results. The KAFO yielded more symmetric gait with improved spatiotemporal values. It is essential that further research incorporate additional SCO gait training and an extended accommodation phase. Additional trials, subjects, and data collection are necessary to determine energy expenditure differences between the SCO and KAFO.

CONCLUSION

While results indicated the locked KAFO provide more normal gait parameters for the subject, the SCO has potential to add therapeutic benefits by increasing muscle activity of lower extremity muscles for patients with similar presentations to this subject in a controlled therapy setting.

CLINICAL APPLICATIONS

The utilization of an immediate-fit stance control orthosis allowed increases in muscle activation of the lower limb of the subject in this case study; however, spatiotemporal gait parameters were closer to normal in the locked KAFO.

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Cost effective method of compression molding prosthetic foot

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INTRODUCTION

While feet that deform are common around the world, feet that deform and retain their functional purpose are less common in more rural countries (Jensen & Treichl 2007). These feet are functional, but they are typically produced using local materials and do not meet ISO-10328 standards (Jensen & Treichl 2007). To address this, feet continue to be donated from more developed countries via the Red Cross, or International Society for Prosthetics and Orthotics, but these feet cannot stand up to the various environments found in more rural countries (Jensen and Rabb 2006). The foot shell and the inner foam core fail to maintain structural integrity, and begin to rot in tropical, and sub-tropical environments. (Jensen and Rabb 2006) This leads to the feet being unsafe and possibly causing additional injuries to the user via device failure. Moreover, the feet produced in these less developed countries do not mimic an ideal gait cycle. (Sam, Hansen, Childress 2004) The best hybridization would be to develop a research based, cost effective, reliable, and mass producible foot capable of receiving a durable foot shell. Attempts at this have been less than fruitful, but one has been overlooked. Dr. Andrew Hansen designed a foot he called the, Shape and Roll Foot during his time at Northwestern University. This foot is layered copolymer plastic with a keel containing multiple cuts to allow for normal dorsiflection during rollover and thus deforming into a semi-circle while walking. This design been shown to be functional and can be produced using limited means. The findings will be useful for both producers and consumers of the feet as it will troubleshoot the process, cutting costs for fabrication by eliminating waste, and elucidating any confusing steps in the process previous knowledge of this machine. The findings will be useful for both producers and consumers of the feet as it will troubleshoot the process, cutting costs for fabrication by eliminating waste, and elucidating any confusing steps in the process.

The best hybridization would be to develop a research based, cost effective, reliable, and mass producible foot capable of receiving a durable foot shell. The aim of this project would be to design a foot that is both durable, and cost effective and can be fabricated using a low cost compression molding device that can be deployed in less developed areas of the world.

METHOD

The first step of the process involves recreating the design of the lever compression molding apparatus, based on a design by Hansen et. al. Once the apparatus was built, it was used to compression mold a foot using a copolymer.

Apparatus: The apparatus which was designed by Hansen et al. in 2006 consists of a lever, a cement molding tray, and the foot itself.

Procedures: The machine was fabricated according the manual, and has the following dimensions: height :40cm tall, and a length 2.44m long.

The cement tray has a volume of 5x20x35cm

The Copolymer plastic is acquired from Curbell Plastics and is provided by Alabama State University Dept. of Prosthetics and Orthotics.

RESULTS

The successful fabrication of the components has been completed. runs will completed to test the functionality of the machine in creating prosthetic feet.

D

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W ... ch will al ... t on a fa ... of ec ... ng foot has been fabricated.

CLINICAL APPLICATIONS

Where other feet fail to maintain structural integrity due to moisture, or mechanical wear this machine can produce cost effective prosthetic feet to survive in this environment.

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EFFECT OF CUSTOM MADE KNEE BRACE WITH 3D HINGES

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INTRODUCTION

The external joints built into knee braces are designed to be reasonably compatible with joint motion, but the main purposes of the braces themselves are to provide stability or to restrict the motion. There are several advantages to accurate reproduction of knee motion in an external joint assembly such as a knee brace, including reduction of pistoning forces, better ligament protection and kinematic compatibility (Walker, 1985).

The study of geometry and kinematics of the normal human knee can provide results applied to external joint design of knee orthoses (Walker, 1985). As such, some studies aimed at determining the congruence of the instantaneous anatomical knee joint axis and a knee orthosis joint axis (Niesche, 2008).

The objective of this study was to evaluate the effect of a custom made knee brace, in which hinges reproducing the three-dimensional motion of the tibio-femoral joint in 6 degrees of freedom is built, on three dimensional kinematics and kinetics characteristics of the lower extremity during normal walking in osteoarthritic patients.

METHOD

Eight subjects affected by osteoarthritis participated in this study (6 men and 2 women). All subjects received a custom made knee orthosis and completed an adaptation period between the delivery of the orthosis and the experiment.

Kinematic data were acquired using a VICON Motion Capture System with 18 cameras filming gait trials at 100 Hz. Kinetic data were measured with an AMTI force-plate located at the center of a 12 meters gait path at a sampling rate of 2000 Hz.

Participants were asked to walk normally on the gait path for 10 trials without the orthosis and 10 trials with the orthosis.

Paired t-tests were realized to assess differences between the average of the 10 walking trials realized with and without the knee orthosis.

Bonferroni corrections were applied following the paired t-tests to counteract multiple comparisons. Reported significant differences showed $p<0.001$.

RESULTS

With the use of the orthosis, we observed at the hip a decrease of the peak abduction moment, an increase of the peak abduction angle and a decrease of the peak external rotation angle. A decrease of knee peak flexion angle was also found with the use of the orthosis (figure 1).

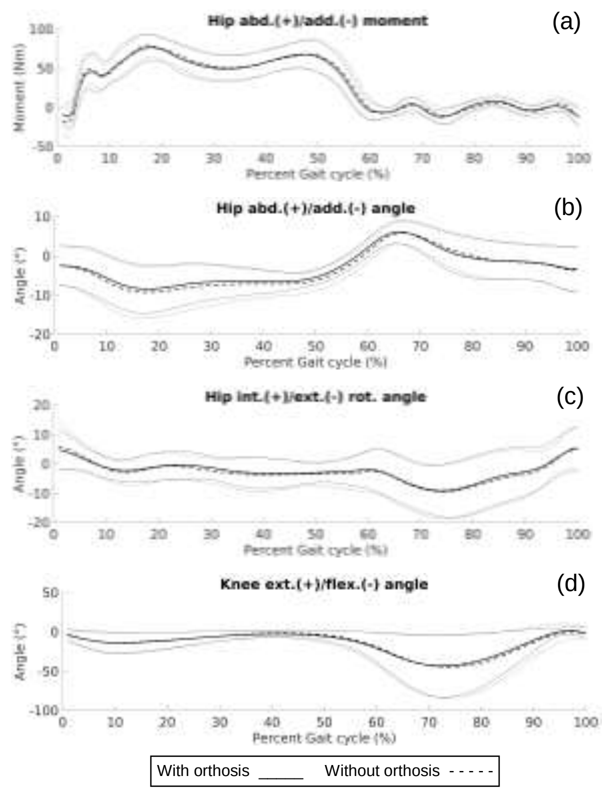

Figure 1: At the hip: abduction/adduction moment (a) and angle (b), internal/external rotation angle (c). At the knee: extension/flexion angle (d).

DISCUSSION

The net moment at the injured knee (moment of the orthosis added to the knee moment) was relatively similar to the net knee moment at the uninjured knee, indicating a normalizing effect of the orthosis.

Further studies would be needed to quantify the forces transmitted by the orthosis to the lower limb and estimate the contribution of the orthosis to the net moment of the injured knee.

CONCLUSION

More results will be needed to further verify the effect of the knee orthosis on lower limb biomechanics.

CLINICAL APPLICATIONS

This study provided preliminary data on the effect of a knee brace which reproduces the three-dimensional motion of the tibio-femoral joint.

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Induced Leg Length Discrepancy and Symmetry of Step Length; Cadence

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CSUDH

INTRODUCTION

The purpose of this study is to investigate how acute induced leg length discrepancy may impact the force loads on the limb. A subject blinded cross over study was performed assessing spatial temporal data collected on 20 healthy adults after being fit with heel lifts of varying thickness. Data was collected on a Zeno Walkway (Protokinetics, Havertown, PA) with heel lift order randomized to limit any effect of participant fatigue. It is expected that increasing leg length discrepancy will result in a greater amount of time percent spent on the longer limb through a complete stride at a self selected speed.

METHOD

Spatial temporal data was collected from all participants using the Zeno Mat walkway system both before and after the heel lift intervention was applied. The step length ratio (left/right) was analyzed as well as cadence (steps/minute). A higher value of step length ratio equates to a longer step taken with the left foot without the lift.

RESULTS

Participants ranged in age from 23 to 31 years (mean 24.7). The sample consisted of 4 male and 2 female participants. No participants reported any of the exclusion criteria and all participants completed all components of the study. Partial steps were the only data collected that were excluded from analysis. The heel lift condition is the independent variable, step length ratio and cadence are the independent variables analyzed.

No changes in spatial temporal data were deemed significant in amplitude after t-tests were performed.

Average Step Length Ratio (L/R)		
	Control	**Heel Lift**
Average	69.5	71.2
Std Deviation	3.5	2.8
	t-test=0.95; p-test=0.18	

Cadence (steps/min.)

Cadence (steps/min.)		
	Control	**Heel Lift**
Average	106.0	101.6
Std Deviation	4.9	4.6
	t-test=1.59; p-test=.072	

DISCUSSION

No conclusion can be made from these insignificant results though further research with an increased sample size and a more representative population. Our sample consisted of only young healthy adults which does not accurately reflect the demographics of AFO users. A larger sample will improve the probability of demonstrating that step length of the shorter limb increased as a result of the heel lift within an acceptable confidence interval. The sample used in this experiment was predominately male, below 30, and healthy, limiting the ability to generalize this data to the typical population of AFO users. In future research, greater lengths should be taken to blind participants to the experimental condition and to randomize trials to reduce any order effects. The data should be collected in one day rather than months apart and the side the heel lift is applied to should also be randomized.

CONCLUSION

This prospective study suggests that further research on the introduction of a heel lift as a component of orthotic intervention may be merited. No significant results were found however data trends were in line with the hypothesis that step length ration would increase and cadence would decrease, warranting further research with an adequately large and representative sample to determine if these trends are a statistical anomaly or clinically relevant.

CLINICAL APPLICATIONS

No clinical application can be made with current data.

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A COMPARATIVE ANALYSIS BETWEEN ARTICULATED AND CONVENTIONAL STUBBY PROSTHESES

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INTRODUCTION

For bilateral above knee amputees (BAKAs) becoming a prostheses user is associated with multiple physical and emotional challenges. The individual must continue to improve on their balance, stability and endurance to successfully learn to walk with prostheses (Carroll, 2009). The average BAKA consumes 280% more oxygen during the task of walking than able-bodied controls (Irolla, 2013). The recovery period between amputation surgery and full time prosthesis wearing is prolonged by the need for intensive rehabilitation training. Generally BAKAs undergo the Graduated Length Prosthetic Protocol (GLPP).

The GLPP (Carroll, 2009) consists of four phases: Building confidence, walking on short legs, graduated increases in height, and walking on full-length legs. One of the greatest challenges experienced throughout this learning experience is walking on short legs. Some, such as elderly amputees or those with limited physical capacity or who prefer a low physiological cost, will not progress beyond this stage at all (Carson, 2010).

The universal short leg prostheses stubbies are defined as "short non-articulated pylon prosthetic devices" used by BAKAs (Wainapel, 1985). Their decreased height allows users to learn how to properly fall and get back up without injury. However, the device does not facilitate any motion at the anatomical ankle, which may restrict balance and stability.

We investigated the utility of articulated alternate stubby devices (Sidekicks, College Park Industries, Frazer, MI) that allow plantarflexion, dorsiflexion, inversion and eversion at the ankle. While there is research comparing stubby prosthesis to full-length prosthesis, no research has been published on the "Sidekicks".

METHOD

Interventions were compared in a single-subject design.

Inclusion criteria: BAKA with own pair of stubbies and free of any medical condition that may restrict normal daily activity. Exclusion criteria: dependence on assistive walking device or wheelchair.

Study Design: A 10-meter walk test (10MWT) was conducted with both devices (stubbies or sidekicks) on two surfaces (level concrete and gravel). A modified timed up-and-go test (TUG) was administered with both devices as well. Balance Confidence Index (BCI) and Ratings of Perceived Exertion (RPE) were used to measure subjective data after each trial.

Data Analysis: Paired t-tests (α = 0.05, two-tailed) were run to compare completion time, BCI and RPE after the 10MWT (separate for each surface) and the TUG.

RESULTS

Data from one BAKA (41 year old, male, 323 lbs, 4'3'' without prostheses) is reported here.

Differences between devices in BCI and overall completion time were not significant. However, the subject reported noticeable changes of 2 points on the RPE scale (Figure 1).

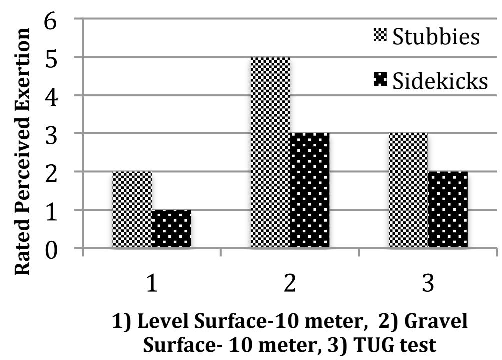

Figure 1: Average Rated Perceived Exertion based on a 10-point scale.

DISCUSSION

The data shows a consistent trend of decreased perceived exertion when wearing the sidekicks as opposed to the stubbies and the subject reported feeling increasingly more stable, when walking with the sidekicks on the gravel surface. There was no significant effect on completion time for both the 10MWT and the TUG.

Limitations of this study are the small sample size and the limited selection of floor surfaces. Further research is needed to evaluate the use of sidekicks in all populations of bilateral transfemoral amputees to evaluate their effect on this amputee population as a whole.

CONCLUSION

Our findings suggest that the use of College Park sidekicks instead of conventional stubbies had no negative effects but decreased the perceived exertion by the amputee while increasing balance and stability on uneven surfaces.

CLINICAL APPLICATIONS

This research may help inform prescription of prosthetic devices for BAKAs.

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"ANALYSIS OF TEMPORAL SPATIAL STEP SYMMETRY IN PERSONS WITH TRANS-TIBIAL AMPUTATION."

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INTRODUCTION

Kinetic, kinematic and temporal-spatial gait differences have been reported for persons with trans-tibial amputation (Aruin et al., 1997). While able-bodied gait is characterized by a high level of symmetry between the two limbs, literature suggests the opposite for individuals with amputations (Nolan et al., 2003). The reported step length and step time of individuals with trans-tibial amputations are notably longer on the affected side and shorter on the sound side, which contribute to gait asymmetry. The data recorded by Nolan et al. will be tested in the current study. Step length and step time are specific measures that previous studies have used to support a thesis. These studies have different focuses, but contain relevant data nonetheless.

The purpose of this study was to investigate possible asymmetries in the gait of individuals with trans-tibial amputations. These asymmetries can be observed through different variables. This study will focus on step time and step length ratios, which represent symmetry between the right and left sides. The aim of this study will be to replicate the findings of previous studies. Therefore, I hypothesize that data collected in this study will demonstrate shorter sound side step time and step length in persons with trans-tibial amputations

METHODS

Subjects: 22 students in MSOP graduate program (16 male; age 24.5 ± 1.6), 2 of which having a transtibial amputation and the others able-bodied.

Apparatus: The Zeno Walkway System was used with ProtoKinetics software. Together, this system has been demonstrated to be reliable & valid.

Procedures: Participants each walked along the mat at a self-selected pace for a total of 6 passes. All data collection happened prior to the creation of this thesis.

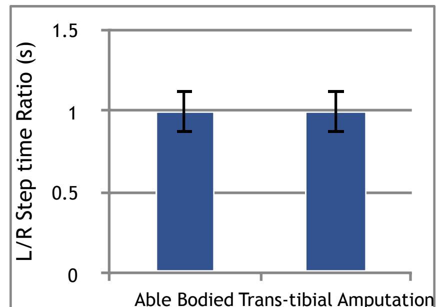
Data Analysis: ProtoKinetics generated average step length and step time of each participants right and left legs. Ratios were calculated with 1.0 representing a symmetrical step length/time.

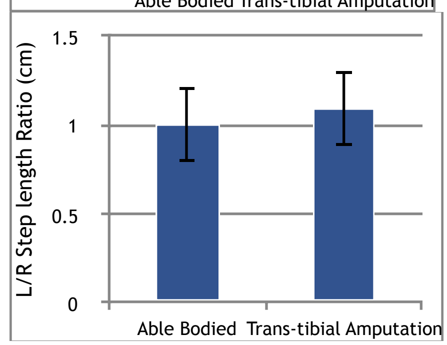
RESULTS

Able-bodied gait demonstrated a step length ratio closer to one, indicating a more symmetrical step length gait pattern. However, trans-tibial gait showed a perfectly symmetrical step time ratio. Neither difference (step time ratio or step length ratio) was statistically significant based on the p-value threshold of .05.

DISCUSSION

In this case, there was no control over the design, fit or alignment of each trans-tibial prosthesis. These were the normal prosthetic legs that the subjects were used to wearing and ambulating with on a regular basis.





CONCLUSION

The hypothesis of this study is not supported by the results. Step time and step length were symmetrical in normal gait and in trans-tibial gait. Future work should collect data from a larger sample of persons with trans-tibial amputations. The results of this study do not provide any clinical significance, but future work with a larger sample size could. Analyzing this data retrospectively is a limitation of this study because it limits control over the independent variable. However, that lack of control mimics a realistic clinical scenario. Also uncontrolled were prosthetic components and means of suspension. The results of this study are not an accurate depiction of the general population because there are only two participants with amputations. A larger sample size is necessary to determine if there is a significant difference in gait symmetry between participants with trans-tibial amputation and able-bodied participants.

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CHANGES IN TEMPOROSPATIAL GAIT PARAMETERS AT DIFFERENT FREELY SELECTED WALKING SPEEDS

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INTRODUCTION

Walking at varied cadence requires a change in gait parameters to allow balance and control of the human body. Adjusting stride width, step length, and cadence is associated with ambulating at different speeds (Helbostad, 2003). The intention of this study was to assess changes in step length, stride width and cadence at varied cadence.

METHOD

When providing your methods, you should use the standard presentation adopted in scientific papers.

Subjects: Eleven able bodied individuals between the ages of 20 and 30 with no known pathologies

Apparatus: Protokinetics Zeno Walkway with PKMAS software

Procedures: Subjects were instructed to walk at 3 self selected speeds. The initial visit involved walking over the walkway at a 'normal' pace that was comfortable. The following visit involved walking at a 'slow' and 'fast' pace. Each condition consisted of walking 12 feet over the mat, turn around and walk back. A total of 6 passes were recorded under each condition.

Data Analysis: PKMAS software processes foot placement data from a Protokinetics Zeno Walkway. Averages of kinematic data, specifically step length, stride width, and cadence, were recorded. A total of six paired T-tests were conducted between 'slow to normal' and 'normal to fast' conditions.

RESULTS

Average step length and cadence increase as walking speed increases from 'slow to normal' as well as from 'normal to fast.' Changes in stride width were not significant.

	Stride Width (cm)	Step Length (cm)	Cadence (steps/min)
Slow	8.31 (+- 3.46)	54.9 (+- 4.02)	82.82 (+- 10.70)
Normal	8.56 (+- 3.60)	71.8 (+- 4.10)	108.37 (+- 5.88)
Fast	9.06 (+- 3.25)	82.1 (+- 6.94)	128.96 (+- 19.9)

Figure 1. Averages of stride width, step length, and cadence at each freely-selected walking speed.

DISCUSSION

Kinematic variables can be used to better understand human locomotion. These principles can then be used to improve pathologic gait and assist in a clinical setting particularly prosthetic care. Further research can be conducted to truly understand gait changes and how to then better accommodate through the use of prosthetic componentry.

CONCLUSION

Temporospatial gait parameters change as an individual increases their walking speed.

CLINICAL APPLICATIONS

Enhancement of Orthotic and Prosthetic care can be achieved through better understanding of changes in temporospatial gait parameters.

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Comparing Lower Limb Step Length and Single Support time in Asymmetrical Gait in Able-Bodied Individuals

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INTRODUCTION

Symmetrical gait has been associated with able bodied individuals and asymmetrical gait has been associated with person with pathology. Resent research is now challenging the idea that able bodied individuals have a symmetrical gait pattern when taking into consideration which leg is dominant.

(Rice and Seeley (2010) examined propulsion and support between the lower limbs during gait. There findings showed that an asymmetry occurred between the limbs at a gait speed twenty percent faster than a self-selected walking speed. The dominant leg had a propulsion impulse .015 greater than the non-dominant leg.

In comparison, Riskowski et al. (2011) also found that gait asymmetry exists with the dominant leg contributing greater loading force that the non-dominant leg and the asymmetry becomes greater with gait speed is increased.

Another study done by (Wanda Forczek, 2012) measured the angles between the hip, knee, and ankle in the sagittal plane when walking at a self-selected walking speed. She found an asymmetry at the ankle that showed a thirteen percent difference on the relative asymmetry index when comparing the two limbs.

When interpreting the results from Rice and Seeley (2010) an increase in propulsion on the dominate limb should result in an increase in support time as well as a greater step length on the opposite side. I hypothesize that a decreased step length and an increased support time will occur on the dominant leg.

METHOD

The target population for this study is healthy individual's ages 20 to 35 with no prior or current injuries which could cause gait deviations. Recruitment was done by word of mouth. When providing your methods, you should use the standard presentation adopted in scientific papers.

Subjects: A convenience sample of ten able-bodied individuals were recruited and participated in the study. There were five males and five females with an average age of 23.8

Apparatus: A Zeno Mat by Protokinetics was used to measure gait. The Data was analyzed by the Protokinetics Movement Analysis Software

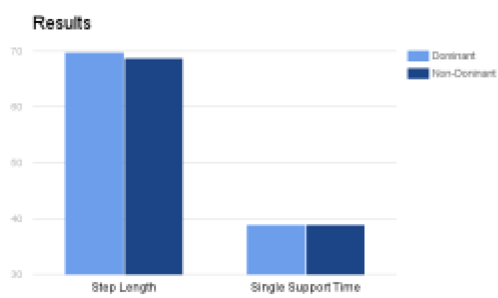
Procedures: Participants were instructed to walk across the mat barefoot at a self-selected walking speed six times.

Data Analysis: two T-test's were done to analyze the data

RESULTS

Step length for the dominant leg averaged 69.83cm with a standard deviation of 4.46. The non-dominant limb had a step length average of 68.79com with a standard deviation of 3.64.

The mean single support time for the dominant limb was 38.89 seconds with a standard deviation of 1.09. The non-dominant limb had an average time of 38.91 seconds with a standard deviation of .903. The mean for the dominant limb minus the non-dominant limb is .0076



DISCUSSION

My results were in agreement with the research done that Rice and Seeley (2010) found on able-bodied gait. The propulsion impulse was slightly higher for the dominant limb than the non-dominant limb.

CONCLUSION

A clear definition needs to be created for determining the dominant limb.

CLINICAL APPLICATIONS

If asymmetry can be found between the dominant and non-dominant limb, this could have influence on prosthetic design in the future.

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CUSTOMIZABLE RESTING HAND ORTHOSES FOR PATIENTS WITH COMPLEX REGIONAL PAIN SYNDROME

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INTRODUCTION

Complex Regional Pain Syndrome (CRPS) is a poorly understood chronic, progressive neurological disorder that results in pain and vasomotor disturbances (Galer et al., 2000). Treatment options are very limited with much of the focus centered around highly invasive procedures or specialized medications with severe side effects (Dadure et al., 2005). With few treatment options available, many patients have been shown to be unresponsive. Given the nature of this disease, patients who are unresponsive to treatment options are at risk of the CRPS progressing. Patients in Stage 3 will experience thickened joints, which will lead to deformation, decreased range of motion and osteoporosis (McBride et al., 2005). These symptoms are detrimental to a patient's quality of life, especially if it is present within the hands. Orthotic intervention, such as Resting Hand Orthoses (RHO) have been used as a preventive measure to position the hand in a neutral position to minimize the stiffness and tenderness in the joint which can progress into joint thickening (Skirven et al., 2011). Despite the availability of a variety of RHO designed for patients with CRPS, many do not accommodate for the sensitivity to touch that patients will have in the affected area. Proposed customizable RHOs can be designed in accordance with the patient's sensitivity areas incorporating high resolution casting and 3D technology.

METHOD

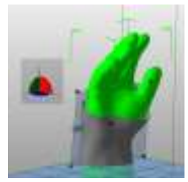
Two methods are presented: 1) Lifecasting integrated with Conventional Orthosis Design & Fabrication principles; and 2) 3D Scanning & Printing. 1) A detailed cast of the hand is acquired using alginate and plaster. An RHO is fabricated using low-temperature polymer via conventional thermoforming techniques around the high-resolution physical model. 2) A 3D-scanned model of the hand, which is used as a template to design the RHO with software, is acquired. The 3D RHO model is fabricated using a 3D printer. With both methods, the designs of the RHO consider the sensitive areas due to CRPS and incorporate the resting hand orthotic position recommended by Walsh and Muntzer.

.RESULTS

Although early in the prototype stage, the customized RHO was successfully produced using both the traditional and 3D printing fabrication techniques.

DISCUSSION

Benefits of these methods include: Method 1) More precise/intimate contouring via detailed model. Method 2) Replicates of the RHO can be produced without requiring a physical hand cast, and a patient's precise measurements can be serially documented.



CONCLUSION

Integrating 3D scanning and 3D printing into the field of orthotics is something that has become more popular as this form of technology advances. However, the designing and fabrication of customized RHO for patients with CRPS is an area that has not been explored until now. Companies such as OCSI and Orfit have RHO that are designed specifically for patients with CRPS, however they do not take into account the sensitivity that is often associated with this disease. With limited treatment options available, patients are at a higher risk of progressing into Stage 3. Introducing a customized RHO that accommodates for the sensitivity that is often present in the affected limb can not only create a more comfortable experience for the patient, but it can reduce the chance of joint thickening and osteoporosis from developing in the hand. Designing a CRPS-specific RHO using both traditional and more modern fabrication approaches that can be adapted as the field progresses could encourage patients to wear their orthoses if they can minimize pain due to sensitivity.

CLINICAL APPLICATIONS

RHO have been prescribed to patients with CRPS in their hand as they enter into Stage 3 of the disease to prevent the progression of joint thickening which can later lead to the development of osteoporosis. However, the RHO available do not accommodate for the sensitivity that the patients have in the affected area. Customized RHO that minimize contact with the sensitive areas will reduce the progression of joint thickening while providing an overall more enjoyable experience for the patient.

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DETERMINING USER SATISFACTION WITH THEIR PROSTHETIC INTERVENTION

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INTRODUCTION

It has been found that a good match between person and technology is achieved if the user is provided with a choice of appropriate and available options, and the chosen prosthetic device meets the user's performance expectations and is easy and comfortable to use (Scherer, 2002). Additionally, patient compliance tends to increase with being involved in the selection process of their device (Weilandt, 2006). The question that now presents itself is this: how does one decide what constitutes as a "good match" between person and device? Over the past 30 years numerous studies have attempted to answer that very question, yet all differ in some way.

The purpose of this research was to answer that question by integrating existing reliable and valid questions with new questions that are more specifically interested in the patient's involvement in their care. In conjunction with one open-ended question, the expected results of this survey will hopefully give clinicians a better understanding of their patients' satisfaction and the factors that affect it. It is hypothesized that the functionality of the device will continue to yield the most dissatisfaction among participants when compared to other categories, and that lack of involvement in care will yield higher dissatisfaction results in users who report lower satisfaction in their overall care.

METHOD

Subjects: Three persons with unilateral lower extremity amputation. No demographic information was collected in order to keep results anonymous.

Apparatus: An integrated user satisfaction survey was designed using five modified questions from the prosthetic evaluation questionnaire, as well as four original questions. All nine questions were answered using a Likert scale, with answers ranking from 1-5. A tenth open-ended question provided participants the opportunity to discuss any issue that had not been addressed. The questions were broken into four categories: function (of prosthesis), psychosocial experience, involvement in care, and well-being.

Procedures: The ten-question survey was provided to four local sites for distribution as deemed appropriate by clinic managers.

Data Analysis: Calculated mean scores and percent satisfaction.

RESULTS

A total of 80 surveys were distributed, three of which were completed by individuals who met the inclusionary criteria. The average satisfaction rate was found to be 91%. All participants reported that they were less than completely satisfied with the comfort of their device and that they were frustrated with their device at least some of the time. Two of the participants reported being completely satisfied in the involvement in care category, although one of these two participants reported being only somewhat satisfied in their overall experience. Of the four categories, psychosocial experience yielded the lowest satisfactory percentage at 74%, which was found by taking the reported satisfaction values and dividing them by the maximum value for that category. The remaining three categories are listed in Table 1.

Category	Mean score among participants	Percentage of satisfaction
Function (out of 15)	13.7	91%
Psychosocial experience (out of 5)	3.7	74%
Involvement in care (out of 15)	14.7	98%
Well-being (out of 10)	9	90%
Total	41	91.11%

Table 1. Rankings and percentages of user satisfaction among participants.

DISCUSSION

The low psychosocial score may be attributed to the way that the average scores are calculated, with a 3 being averaged in to the mean score, although a 3 indicates a "neutral" response.

CONCLUSION

Future efforts will attempt to further understand user satisfaction by urging patients to state their dissatisfaction in their own words.

CLINICAL APPLICATIONS

To better serve patients by understanding the facets of their satisfaction with their prosthesis.

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DEVELOPING A GAIT EVENT DETECTION FRAMEWORK FOR IMPLEMENTATION INTO A REAL TIME FEEDBACK SYSTEM BASED ON DATA FROM A PROSTHESIS INTEGRATED LOAD CELL.

Kutina.K, Fiedler, G.

University of Pittsburgh, Department of Rehabilitation Science and Technology

INTRODUCTION

Gait dysfunction is an impairment that can effect multiple patient populations (Prince,et al 1997; Perry and Burnfield, 1992), including those with limb loss, and become chronic and linger for years. It has been frequently reported that gait retraining with augmented sensory feedback improves dysfunctional lower extremity impairments and related gait patterns including those of amputees (Dingwell, et al, 1996). However, these previous studies have been criticized for the expense and tightly controlled laboratory conditions, which made translating findings to realistic clinical environments limited.

Overall goal of our research is to design a system to provide real time mobile visual feedback (RTMVF) to lower limb amputees for gait training. Feedback variables should be detectable by a prosthesis-integrated sensor and be meaningful for the user. Low latency in calculating feedback variables was another objective. We report on the development of mathematical algorithms to accurately detect gait events from a prosthesis-integrated sensor providing kinetic data only. The algorithms and mathematic models are an important first step in the process of integrating both hardware and programmatic components into a RTMVF system.

METHOD

The current prototype consists of load cell (ipecs, RCT Electronics, Dexter, MI), a laptop computer, and smart glasses (M100, Vuzix, West Henrietta, NY), connected by cables and WiFi. Initial algorithms based on raw sensor data from one subject with gait deviations unknown, determined what could be calculated given raw output. Detecting step cycles entailed sensing slopes at the approximate mean of Fz (the sensor's equivalent to vertical ground reaction force) and a lower 10N threshold crossing. Proximal and distal forces and moments of interest were extracted as possible feedback variables as well.

RESULTS

It was found that all variables of interest could be determined from the data, such as; the Peak proximal and distal moments, Peak Fz, Peak My, and range and Peak of Mz. Loading and toe off peaks were found efficiently, however refinement was needed as it was found that oscillations during swing phase were counted erroneously. For Prototype V.0 (Figure 1) a single threshold was implemented, for feasibility and latency testing. The delay is less than 1sec, however algorithms needed to be refined by the addition of several criterion including a double threshold for sufficient accuracy in detecting actual gait events.

Figure 1. Prototype of Feedback Device: Real Time kinetic feedback as relayed from sensor regarding percent stance.

DISCUSSION

The prototype allowed the evaluation of several potential feedback variables. Finding peak to peak values was insufficiently accurate (>5%) and required non-automated method to improve. Conversely, % stance suggests itself as easily calculated in real time and providing potentially meaningful information. Further testing is needed to assess the value of additional variables and to determine the appropriate target window for feedback purposes

CONCLUSION

Our findings suggest that generating and conveying RTMVF on gait variables is possible using our approach.

CLINICAL APPLICATIONS

The potential is to utilize the positive current findings regarding real-time visual feedback, to mobilize this type of training over ground, outside of the clinic, or even at home.

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ACKNOWLEDGEMENTS

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DEVELOPMENT OF LOW COST 3D PRINTED TRANSITIONAL PROSTHESES

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INTRODUCTION

There are increasing numbers of children with traumatic and congenital amputations or reductions. Children's prosthetic needs are complex due to their small size, constant growth, and psychosocial development (Krebs et al., 1991 and Zuniga et al. 2015). Families' financial resources play a crucial role in the prescription of prosthetics for their children, especially when private insurance and public funding are insufficient. Electric-powered (i.e., myoelectric) and body-powered (i.e., mechanical) devices have been developed to accommodate children's needs, but the cost of maintenance and replacement represent an obstacle for many families. Due to the complexity and high cost of these prostheses, they are not accessible to children from low income, uninsured families, or to children from developing countries (Krebs et al., 1991 and Zuniga et al. 2015). Advancements in computer-aided design (CAD) programs and additive manufacturing offer the possibility of designing and printing prostheses at a very low cost (Zuniga et al. 2015). The purpose of the present investigation was to demonstrate the manufacturing methodology of 3D printed transitional prostheses, examine improvement in perceived changes in quality of life, daily usage, and activities performed with these types of devices.

METHOD

Nine children (two girls and seven boys, 3 to 16 years of age) with upper-limb reductions (one traumatic and eight congenital) were fitted with our 3D printed transitional prostheses and were asked to complete a survey. Inclusion criteria included boys and girls from 3 to 17 years of age with unilateral upper-limb reductions. Exclusion criteria included upper extremity injury within the past month and any medical conditions that would be contraindicated with the use of our 3D printed prostheses prototypes, such as skin abrasions and musculoskeletal injuries. The study was approved by the Creighton University Institutional Review Board and all the subjects completed a medical history questionnaire. All parents and children were informed about the study and parents signed a parental permission. For children 6 to 17, an assent was explained by the principal investigator and signed by the children and their parents. The survey was developed to estimate the impact of our prosthetic device including items related to quality of life, daily usage, and type of activities performed.

RESULTS

After approximately 1 to 3 months of using our 3D printed prostheses, 11 children and their parents reported some increases in quality of life (4 indicated that was significant and 7 indicated a small increase), while 1 indicated no change. Nine children reported using the device 1 to 2 hours a day, 3 reported using it longer than 2 hours and 1 reported using it only when needed. Furthermore, children reported using our 3D printed prostheses for activities at home (9), just for fun (10), to play (6), for school activities (4), and to perform sports (2). Four children reported malfunctioning and/or breaking of the 3D printed prosthetic device.

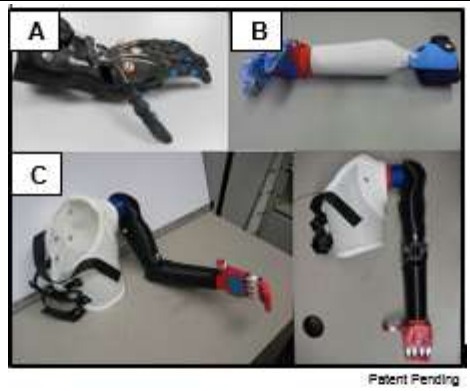

Figure 1. Shows some of the 3D printed transitional prostheses prototypes developed by our research team. A: Hand prosthesis (Cyborg Beast); B: Below Elbow Device; C: Prosthetic Shoulder.

DISCUSSION

The main finding of our survey was that our 3D printed transitional prostheses have a great potential to positively impact quality of life, daily usage, and can be incorporated in several activities at home and in school. However, 36% of our research participants reported durability issues and/or malfunctioning of these devices. Unfortunately, some observed inaccuracies with collected survey results have been noted in related studies, and a more quantitative method for determining usage is desired. A prototype of an appropriate test apparatus for usage has been constructed, and will be validated in future studies. There is a need to develop medical grade 3D printed prosthetic devices to solve the durability constraints.

CONCLUSION

Although durability and environment are factors to consider when using 3D printed prostheses, the practicality and cost effectiveness represents a promising new option for clinicians and their patients. 3D printing technology for the development of prosthetic devices is at a very early stage. The supervision of a certified prosthetist is crucial for the proper development and use of 3D printed prostheses.

CLINICAL APPLICATIONS

3D printed transitional prostheses have a great potential in positively impact quality of life, daily usage, and can be incorporated in several activities at home and in school. The supervision of a certified prosthetist is crucial for the proper development and use of 3D printed prostheses.

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"DIVISION OF ATTENTION DURING DUAL-TASKS: EFFECTS OF UNFAMILIAR TEXTING TECHNOLOGY ON CAUTIOUS GAIT."

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INTRODUCTION

When dual tasking, attention must be divided to supply the brain with stimuli from both environments (Yogev-Seligmann et al., 2008). It has been suggested that dual tasking sacrifices the quality of our attention, which also lowers the quality of the performed tasks. (Yogev-Seligmann et al., 2008). In a specific dual tasking event, results indicate that the quality of walking is reduced & resembles "cautious gait" when paired with texting. Various factors, such as age, modulate the intensity of cautious gait while texting. Studies have shown that cautious gait parameters are more intense in older participants when walking & texting. Although some research suggests this is due to age-related brain deterioration, others attribute it to unfamiliarity with texting technology (Agostini et al., 2015; Licence et al., 2015; Parr et al., 2014; Schabrun et al., 2014; Yogev-Seligmann et al., 2008).

To further investigate how texting familiarity influences gait, this study uses two different texting methods, one familiar to the participant & one novel. The purpose of this study is to examine the effects of a familiar texting technology versus a novel texting technology on parameters that define cautious gait while performing the dual-task of texting & walking. It is hypothesized that slower walking velocity, shorter stride lengths, & wider stride widths will be observed with the novel texting technology (Swype) compared to the familiar texting technology (iOS).

METHOD

Subjects: 10 students in MSOP graduate program (6 male; age 24.5 ± 1.6), Participants must be iPhone user with no exposure to Swype texting technology.

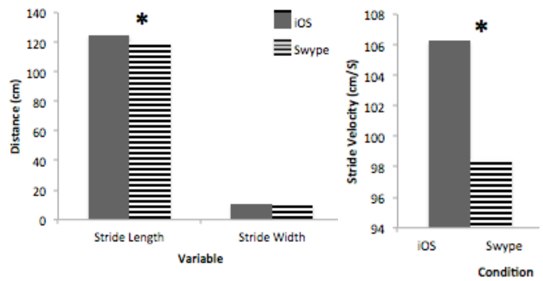
Apparatus: The Zeno Walkway System was used with ProtoKinetics software. Together, this system has been demonstrated to be reliable & valid.

Procedures: While walking on the Zeno mat, participants received 4 prompt texts & sent 2 texts in response. Two trials were performed: one with iOS keyboard, one with Swype keyboard.

Data Analysis: ProtoKinetics generated average stride length, width & velocity with standard deviations for each participant's trial. Microsoft Excel was used to calculate means & standard deviations of all participants for each variable for each trial. Two-tailed t-test compared differences between the conditions, ($p \leq .016$).

RESULTS

Participants had significantly shorter stride lengths for the novel method than the familiar method ($p=0.005$) & significantly slower stride velocity for the novel method than the familiar method ($p=0.006$). There was no significant difference between conditions for stride width.



DISCUSSION

Participants significantly performed a more cautious gait with the novel method compared to familiar. Considering all participants were young adults, the potential influence of age-related brain deterioration on ability to dual task was negated. Therefore, only familiarity with texting technology influenced participants' ability to walk while texting. This supports the theories proposed by Agostini et al., Licence et al., Parr et al., & Schabrun et al. Future work should investigate if this trend persists in a) an older population that is familiar with texting technology & b) other dual tasks. If familiarity still proves to be the main influence, it would suggest that practice can improve one's ability to dual task, regardless of age.

CONCLUSION

Task familiarity, i.e. texting technology, did influence the ability to perform the dual task of walking while texting in young adults.

CLINICAL APPLICATIONS

O&P patients' ability to successfully dual task is influenced by their familiarity with those tasks. Therefore, the use of a new orthotic or prosthetic device could hinder their ability to perform another task. Patients should practice using the device without distractions from other tasks until he/she gains experience with the device.

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DOES INCREASED NUMBER OF SOCK EDUCATION SESSIONS EFFECT A NEW TRANSTIBIAL PROSTHETIC USER'S UNDERSTANDING OF PROPER SOCK MANAGEMENT?

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INTRODUCTION

There is a strong correlation between skin breakdown and improper sock management in people with transtibial amputation. A majority of people with transtibial amputation experience volume fluctuation of their residual limb during the course of a single day; however, teaching patients with amputation how to maintain proper socket fit with sock ply is an issue faced in clinical practice. The purpose of this study is to verify if increasing the number of sock management education sessions a patient receives will affect the prosthetic user's understanding of proper sock management.

METHOD.

***Subjects*:** 14 new transtibial amputees were randomly put into an experimental group consisting of 6 subjects and a control group consisting of 8 subjects.

Apparatus: Data was collected using a sock management questionnaire and a checklist utilized by the prosthetist at each visit. Measures that were recorded include: optimal sock ply, presented sock ply and skin condition.

***Procedures*:** Each group received sock education at the initial delivery visit and at routine follow-up visits. At each clinic visit, optimal sock ply, presented sock ply and skin condition were recorded. Unlike the control group, the experimental group was given additional sock education on a weekly basis by phone. This additional sock education was the independent variable.

***Data Analysis*:** Average sock ply difference between the control and experimental group was processed using a two-sample t-test assuming unequal variances.

RESULTS

Three of the six experimental group subjects improved in sock ply difference over the course of the study (Table 1). The asterisk denotes that the patient was unable to fit in the prosthesis due to excessive edema at that clinic visit. Two of the six experimental group subjects presented at 0-ply difference on the first follow-up and remained at optimal ply for the duration of the study. In the control group, four of the eight subjects improved in sock ply difference over the course of the study and three of the eight subjects got worse over time.

Correlations and trends were analyzed between additional education sessions and sock-ply difference in each group, however no significant correlations or trends were found.

EXPERIMENTAL					
Follow-Ups	TOTAL # of Additional Education Sessions	Presented Ply	Optimal Ply	Sock Ply Difference	Skin Breakdown
Subject 1					
#1	4	5	15	10	N
#2	4	5	8	3	N
Subject 2					
#1	2	14	13	1	N
Subject 3					
#1*	1	0	0	0	N
#2	7	1	1	0	N
#3	11	6	6	0	N
#4	16	12	12	0	N
Subject 4					
#1	2	1	5	4	N
#2	4	3	8	5	N
#3	7	8	8	0	N
Subject 5					
#1*	1	N/A	N/A	N/A	N
#2	8	9	14	5	N
#3	8	3	3	0	N
Subject 6					
#1	2	3	3	0	N
#2	5	4	4	0	N

Table 1. Experimental Group Measures

DISCUSSION

50% of the experimental group subjects improved in sock-ply difference over the course of the study and 33% presented in optimal ply at every follow-up. 50% of the control group subjects also improved in sock-ply difference over the course of the study, but 37% of the subjects got worse over the course of the study. No significant trends were found between additional sock education and a decrease in sock-ply difference and the average sock-ply difference was not significantly different between the two groups.

CONCLUSION

The experimental group performed better over the course of the study than the control group when analyzing sock-ply difference. The lack of a significant correlation between sock education and sock-ply difference can be attributed to a limited sample size and research duration.

CLINICAL APPLICATIONS

Understanding proper sock management continues to be a significant problem among amputees. In clinic, improper sock management is seen frequently and sometimes results in significant skin breakdown. This study aimed to prove that increased sock management education would facilitate an amputee's understanding of proper sock management.

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March 1-4, 2017

DOES INCREASING PHYSICAL ACTIVITY MEASURED BY STEP COUNT AFFECT INTENSITY OF LOW BACK, RESIDUAL LIMB, AND PHANTOM LIMB PAIN IN TRANS-TIBIAL AMPUTEES?

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INTRODUCTION

Chronic Pain is highly prevalent in individuals with limb loss, particularly low back, residual limb, and phantom limb pain. 95% of surveyed amputees in one study reported at least one type of amputation-related pain in the previous four weeks (Ehde et al., 2000).

Several approaches have been proposed to reduce amputation-related pain through medication, surgery and injection procedures. However, there is insufficient evidence to guide clinicians on appropriate treatment for pain in amputees (Halbert et al., 2002).

Physical activity (PA) is known to reduce chronic pain such as associated with fibromyalgia, musculoskeletal disease, osteoarthritis, and low back pain. However, chronic pain often leads to lower PA levels compared to healthy controls (Raijmakers, 2015). The effects of PA on pain levels in lower limb amputees are yet to be investigated.

Recording daily step counts has been proven to be clinically relevant for the purpose of prescribing PA. We investigated the hypothesis that increasing daily step count would lead to decreased pain in amputees.

METHOD

Participants: Trans-tibial amputees that were at least one year post-amputation and had a baseline score of 2 or higher in at least one pain category on the 0-10 Numeric Pain Rating Scale (NPRS) were recruited for the study. Exclusion criteria were baseline daily step counts of less than 1,000 or more than 12,500, assistive device use, and residual limb neuropathy.

Study Design: A repeated measures design was conducted where each participant was evaluated on baseline measures, followed by the intervention, after which outcome measures were assessed again.

Data Collection: Initial baseline pain intensities for low back, residual limb, and phantom limb pain were collected using NPRS. Participants were then provided with a pedometer and instructed to spend one week performing activities as normal. During the subsequent intervention week, each participant was instructed to increase their daily step counts by 60% over their respective week-one average. Participants filled out the pain assessment form at the end of each day for the entire two-week study period.

Data Analysis: Paired t-tests (α = 0.05, two-tailed) were run to compare the three types of pain after baseline and intervention week.

RESULTS

Preliminary data from five subjects were collected (two male and three female, ages 24 to 70 years). Changes in combined pain level across the sample were not statistically significant, yet individual subjects reported changes between 4.3 points of pain decrease and 1.47 points of pain increase (Figure 1).

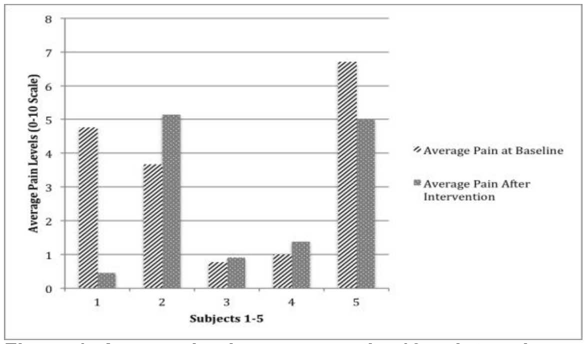

Figure 1: Averaged pain scores on the 10-point scale

DISCUSSION

Our data shows no consistent trend across the sample, yet individual responses suggest a positive effect of increased PA. A change of 1.7 on the NPRS is considered clinically significant, making the pain decreases in subjects 1 and 5 the only noteworthy changes after a week of increased PA. Any of the reported changes in the negative direction are small enough to not be considered clinically meaningful.

Limitations of the study include the small and heterogeneous sample and subjects' inconsistent adherence to the prescribed step count increases.

CONCLUSION

Our findings appear to suggest that increased PA in lower limb amputees has no substantial negative effects and can have a positive effect in some people. Further research is needed to generate conclusive evidence on exercise as a means for decreasing pain in amputees.

CLINICAL APPLICATIONS

This research may lead to amputee-specific guidelines for PA to help reduce chronic pain.

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EDUCATING EARLIER: A PRE O&P PROGRAM

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INTRODUCTION

A path into the O&P field can be difficult to navigate if a prospective student does not have help. It appears to be a little known career track unless the prospective student knows someone in the field. Choosing a graduate program is a difficult task when the student knows little about this career track. An advisor who has knowledge of the field is necessary to guide the student to the program that fits him or her best and answer any questions along the way. Furthermore, if the student does not have an advisor who is knowledgeable of the field, the student could be pointed in the wrong direction as far as helpful courses and prerequisites. The prerequisite aspect of the graduate programs is another challenge. Therefore, students thinking about entering the field need to be educated further about O&P beyond promotional materials and videos that are commonly seen. This is where a Pre O&P Program, similar to other pre-professional programs, could be of use.

METHOD

Many students do not learn about this field until later on in their college experience. As a student going through this process, the author gained first-hand experience in what it takes to enter the O&P field. In order to best study the 12 graduate O&P programs, the author compiled a table to compare and contrast the schools, specifically listing the prerequisites for each. In order to gain experience, a volunteering position was sought. After having gained some exposure to the field through shadowing at an O&P facility, the author realized that the prerequisites taken thus far had very little to do with the actual volunteer work. Using the obstacles faced and experiences gained, the author was able to start a discussion indicating the need for a Pre O&P Program.

RESULTS

The prerequisites were found to be a particular area of concern. What was found was that most of the programs had the same or a similar list of prerequisites. However, a class that may be acceptable to use as for a prerequisite at one school may not be acceptable at another school. For example, some of the programs list the number of credit hours needed for each prerequisite while others do not. The student must be very careful when selecting classes. Some of the programs are fine with a 3 credit hour course, whereas others specify that the same prerequisite should be 4 credit hours. If a student is not aware of this, he or she may end up taking a class that does not fulfill the required number of credit hours and must retake it depending on the chosen program. This confusing situation leaves the student trying to find another option that will satisfy the requirements of multiple programs. Another challenge faced was finding a volunteering opportunity. The experience and knowledge gained by volunteering is imperative. However, some places seem skeptical of letting someone volunteer who has no previous background in the O&P field. It becomes difficult for the student to gain experience when experience is needed just to get a volunteering position. As a result, a Pre O&P Program would prove useful in these situations to provide guidance, as well as experience to the students so that they are fully prepared.

DISCUSSION

Early on, the author thought that completing the prerequisites would provide some preparation to the field. After having gained some exposure to the field through shadowing at an O&P facility, the author realized that the prerequisites taken thus far had very little to do with the actual volunteer work. Almost everything was learned on the spot and was not related to what had been previously taught in a classroom. This was an eye-opening experience, which would not have been learned if the author had not completed volunteering time. A Pre O&P Program could help solve these issues faced by prospective students. Students would no longer have to wonder or guess if they are on the right track, or turn away discouraged if they think they are behind. They would have guidance when looking for a volunteering position or applying to graduate O&P programs. Students would have resources readily available to them such as advisors, other students, books, and technology which would allow them to thrive. With a Pre O&P Program, students could be sure that the prerequisites they are taking will be accepted by all of the programs. Instead of a list of prerequisite courses, a list of prerequisite topics to be covered could be given. The program could have its courses approved by the graduate programs, so that the students learn the essential topics rather than a broad range of information, most of which is not used. This Pre O&P Program would not only help to find volunteering positions, but provide the students with background knowledge and helpful hand skills before applying. Gaining confidence in theory and in practical applications will help the students to be prepared for their continued education and their future.

CONCLUSION

Overall, the purposes of a college level Pre O&P Program are to introduce the O&P field as a career choice, to establish relationships with O&P companies to foster shadowing opportunities, to guide students through the process of completing the prerequisites for successful application to graduate O&P programs, and to provide a community for prospective O&P students.

ACKNOWLEDGEMENTS

I would like to express my deepest appreciation to Dr. Kevin Meade for guiding and encouraging me throughout the process of this project. Without him it would not have been possible.

EFFECT OF A UNILATERAL BALANCE TRAINING PROGRAM ON BILATERAL BALANCE: A CROSS-EDUCATION EFFECT

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INTRODUCTION

The purpose of this pilot study was to examine the neuromuscular phenomenon of cross-education, and its relationship to the act of balancing. Otherwise known as cross-activation or cross-transfer effect, cross-education is an adaptation to a unilateral training intervention from which gains are seen to both the trained and untrained side (Zhou 2000). This is due to neural adaptations whose mechanism and location of action have been hypothesized to be situated in supraspinal regions of the nervous systems (Ruddy et al. 2013).

Cross-education has been investigated with a resistance training intervention where strength increases have been observed in both the trained and untrained sides. Literature reviews have found a baseline gain of 7.8-9.8% for the untrained side (Munn et al 2004) and a 35-60% strength increase of the total increase seen with the trained side (Zhou 2000). There is very limited and inconclusive literature on the relationship between balance and cross-education (Oliveira et al 2013).

In light of the fundamental differences between balance and strength, we aimed to investigate a unilateral balance intervention to observe the adaptations to balance of the trained and untrained sides. If such a relationship can be shown in the amputee population it would become possible to attenuate the learning period and decrease the high fall risk associated with receiving a new prosthesis.

METHOD

Subjects: Able bodied individuals who were free of any lower extremity and vestibular disorders in the past 6 months, have not had lower extremity surgery and were not participating in regular exercise training programs were recruited for this study

Apparatus: NeuroCom EquiTest Balance System

Procedures: Subjects completed a Sensory Organization Test (SOT) using Computerized Dynamic Posturography (CDP) pre and post intervention. Intervention consisted of a three week progressive unilateral (dominant side) balance training program.

Data Analysis: SOT composite scores were analyzed using percent change for pre/post test in bilateral and single leg stance (Trained and untrained) as well as percent change for sensory components (Visual, Vestibular, and Somatosensory) for bilateral and single leg stance (SLS).

RESULTS

Four subjects (1 Female, 3 Male) aged 23-26 years, right-side-dominant, participated in this pilot study.

The mean percent changes for bilateral stance, SLS right and SLS left were respectively 7.3 (SD=1.2), 1 (SD=4.4), 5.2 (SD=9.3) (Figure 1).

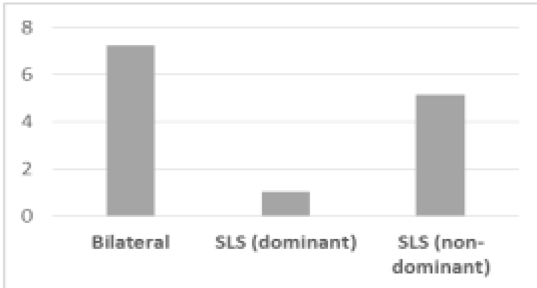

Figure 1: Mean percentage change in outcome variables after 3 week unilateral training protocol.

DISCUSSION

Preliminary results give some indication that the unilateral balance training program did produce balance improvements in bilateral stance. The results for SLS left and right are overall inconclusive due to the variance of effects across the sample. Additional data collection as part of the ongoing study is expected to clarify the observed trend that there are improvements with all three sensory inputs for bilateral stance but inconsistent effects in SLS for right (trained) and left (untrained) side showing improvement only in some subjects.

CONCLUSION

Preliminary data suggests that the intervention was competent in eliciting balance improvements based on the improvements of all subjects in bilateral stance. However due to the variance in SLS results not conclusion can be made on the effect of cross-education on balance. Further work is required to establish the relationship of cross-education and balance in people with lower limb loss.

CLINICAL APPLICATIONS

Applicability of our findings on post-amputation balance training depends on additional evidence on the effect of cross-education on balance.

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Effect of prosthesis mass configuration on energy cost for individuals with trans-tibial amputation: Case report

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INTRODUCTION

The energy cost (or metabolic cost) of walking is a concern in people with trans-tibial amputation (TTA). Individuals with TTA on an average spend approximately 33% more energy than healthy individuals while walking at the same speed[1-3]. Amongst other factors, energy cost in this population could be affected by the mass and mass distribution (mass configuration; MC) of the user's prosthesis[1,2]. While it is known that mass symmetry between both limbs, prosthetic and non-prosthetic, is detrimental to the energy cost of walking for the user with TTA[1,2], it remains unknown whether any prosthesis MC exist which can reduce the energy cost of the individual. Hence, the purpose of this pilot study is to investigate the effects of altered prosthesis MC on the energy cost of people with TTA.

METHOD

Subjects: 1 male with TTA. Age: 29yrs; Height: 1.80m; Weight: 75.8kgs; Prosthesis weight: 2kgs.

Procedures: 5 visits, ~1 week apart, during which, the participant completed a 6 minute walk test (6MWT) while metabolic activity was collected (K4b[2]COSMED, USA). Following the test, the participant's prosthesis MC was randomly altered by placing mass either proximal (P) (~20% length) or distal (D) (socket/pylon interface) on the prosthesis and adding either 30% :10.5oz (Light; L) or 50%: 16oz (Heavy; H) of the mass difference between limbs. After each alteration the participant was sent home and given ~ 1 week to acclimate before the next session. Following testing on the 5th session, the prosthesis was returned to its original MC.

Data Analysis: Descriptive statistics were used to investigate distance covered during 6MWT, velocity (vel), mean VO_2 uptake, peak VO_2 and VO_2/meter, for each MC. Additionally, VO_2 uptake was averaged during the first 10secs (resting) and 60sec intervals between 1 and 2min, 3 and 4min and 5 and 6min of the 6MWT.

RESULTS

Table 1. Distance and VO_2 parameters

MC	6MWT (m)	Peak VO_2	VO_2/m (mL/kg/min)	Vel (m/s)	% Δ Dist to BL	% Δ Peak VO_2 to BL
BL	643	33.9	5.49	1.78		
LP	705	28.7	5.37	1.95	9.4%	-15.3%
LD	675	43.5	7.70	1.87	5.0%	28.3%
HP	650	28.0	6.44	1.80	1.1%	-17.4%
HD	668	26.3	6.12	1.85	3.9%	-22.4%

MC: Mass configurations; BL: Baseline; LP: Light proximal; LD: Light distal; HP: Heavy proximal; HD: Heavy distal

During the 6MWT the participant walked farthest and fastest with LP, 705m, while consuming least VO_2 per meter, 5.37 (Table 1). Compared to baseline prosthesis MC, the participant had a lower peak VO_2 (Table 1) and VO_2 uptake during the last min (Fig 1), while using LP and HD. Peak VO_2 (Table 1) and VO_2 uptake during the last min was highest (Fig1) with LD.

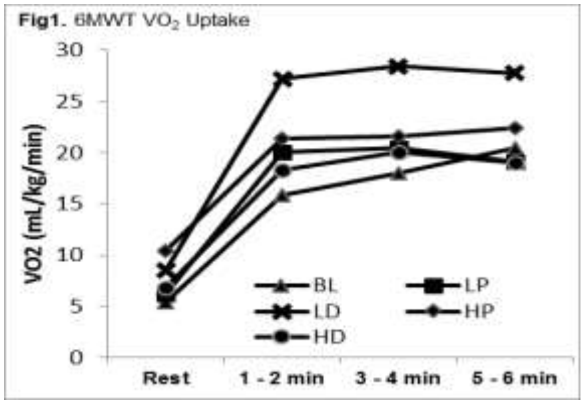

Fig1. 6MWT VO_2 Uptake

DISCUSSION

The results of this pilot study suggest that the prosthesis MC might alter the energy cost of the user. Two of the 4 selected MC, LP and HD, reduced the participant's energy cost while allowing them to walk further and faster, as compared to baseline. Amongst the 2 (LP and HD), the participant had a better performance with LP (Table1), which was also the participant's reported most liked configuration. The participant's better performance with HD (compared to HP), as seen by the more distance covered, lower peak VO_2 (Table 1) and lower VO_2 uptake during the last min (Fig 1), is in contrast to previous evidence[1,2] and is possibly due to the heavier distal portion of prosthesis assisting in swing of the limb, similar to a pendulum. Interestingly, HD was the least favorite configuration of the participant. Similar results however, were not seen for LD. An investigation with a larger sample size is needed to better highlight prosthesis MCs that are most appropriate for the user.

CONCLUSION

The user's energy cost of walking may be affected by certain prosthesis MCs.

CLINICAL APPLICATIONS

During design and fabrication clinicians should be mindful of the mass distribution of the prosthesis as it may alter energy cost of the user.

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EFFECTIVENESS OF CRANIAL REMOLDING ORTHOSES IN REDUCING ASYMMETRY IN PATIENTS WITH PLAGIOCEPHALY IN RELATION TO START AGE AND SEVERITY

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INTRODUCTION

In the mid 1990's the American Academy of Pediatrics instituted the Back-to-Sleep program to reduce the risk of SIDS (Lima, 2002). The program was successful however, the number of infants who developed nonsynostotic plagiocephaly (NP) increased dramatically. Repositioning therapy is an extremely effective way to treat NP, but it does not work in all cases. For those cases where the misshapen skull persists, cranial remolding orthoses (CRO) have become the preferred treatment method. Although there are numerous studies that have concluded CRO treatment is a beneficial intervention for treating NP, there have been studies that refute this claim. (van Wijk, 2014). This current study aims to find more concrete conclusions about the benefits of CRO intervention and when to start CRO treatments. Specifically, the goal of this study is to determine if the overall effectiveness of cranial remolding orthosis in NP is correlated to severity and age at start of treatment.

METHOD

Subjects: Out of 1177 charts reviewed, 218 patients with a diagnosis of NP varying from mild to very severe met the inclusion criteria of the study.

Procedures: Researchers collected data from Level-4 P&O clinics using the clinic's patient database.

Data Analysis: 4 unbalanced two-way ANOVAs and Excel analysis

RESULTS

ANOVAs comparing the data revealed that children with mild head shapes and minimal time in the CRO had similar positive outcomes as those who spent extended time in the device. ANOVAs comparing the factors to severity indicated that based upon severity, time plays a significant factor in the overall treatment, with a p value of 0.018. There was not a significant difference found when comparing severity and the age group of each participant. From the final analysis comparing severity to torticollis and prematurity, there was no indication that either of these factors caused a significant impact on the overall severity of the patient at the start of treatment.

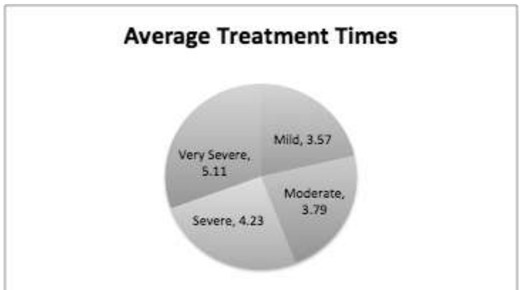

Figure 1. Differences in average treatment times among the four severity groups.

DISCUSSION

The results of this study support the hypothesis that cranial remolding orthoses are effective treatment of NP. Furthermore, the data suggests that subjects that started treatment before nine months of age obtained significantly more correction than those that starting at nine months of age or later. This should transfer to clinical practice in the collaboration of insurance providers, the referring physician, and the orthotist to start treatment before nine months of age for the greatest correction. Data also suggest that more severe deformation requires longer treatment time to obtain a fully corrected head shape, and that severe cases obtained significantly more correction if treated longer than six months.

CONCLUSION

This adds to the literature that supports treatment and weakens the few studies that have been used by insurance companies to deny coverage. Based on the positive treatment results in this study, insurance companies should cover CRO treatment as a low risk treatment option. Conductors of this study suggest a larger sample size for future studies. This would provide more power to statistical analysis and might provide more meaningful results.

CLINICAL APPLICATIONS

The results of this study suggest starting treatment for NP as early as possible, but particularly before nine months of age, for maximal correction. It is also suggested that more severe cases be treated longer than six months, and that the presence of torticollis or prematurity does not negatively affect treatment outcomes.

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Effects of Arm Swing During Gait

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INTRODUCTION

Arm swing affects the efficiency (distance/time) with which one ambulates, specifically velocity and balance (Long et al., 2011). Therefore, arm swing efficiency during the gait cycle may allow an able-bodied ambulator to increase velocity and balance. The use of arm swing promotes more efficient walking, while reduction of arm swing will negatively affect the ambulator's walking speed by slowing him/her down and decreasing stability (Punt et al., 2014).

The purpose of this study is to evaluate toe in/out angle and velocity (stride length over time) in able-bodied persons with three different levels of arm swing to determine if arm swing influences ambulation efficiency, which will be defined as velocity (distance/time). It is hypothesized that when decreasing able-bodied arm swing during ambulation that velocity will decrease, while increasing toe in/out angle for a greater balance. Furthermore, that an increase in arm swing will increase the participant's velocity, while decreasing toe in/out angle.

METHOD

Subjects: Twelve healthy young adults, 9 males and 3 females, averaged 25.17 years of age.

Apparatus: The Zeno Walkway

Procedures: Participants walked across the Zeno Walkway, which was 230 and 5/16 long and 27 and 1/2 inches wide, for six passes to collect temporal spatial data. During the first two passes, participants were instructed to walk with restricted arm swing, allowing no movement of the upper extremities. The second set of two passes the participants were instructed to walk as they normally would and for the third set of two passes, the participants were instructed to walk with exaggerated arm swing. Data was collected consecutively for all six passes, respectively.

Data Analysis: Data variables analyzed were: toe in/out angle, stride length, stride time, velocity. Data was analyzed using PKMAS software from ProtoKinetics.

RESULTS

The toe in/out data showed an increase in toe out angle from restricted arm swing to normal arm swing to a then decrease in toe in/out Stride length showed an increase from restricted arm swing, to normal arm swing, to exaggerated arm swing. Stride time showed a gradual decrease in seconds from restricted, to normal, to exaggerated arm swing. Lastly, stride velocity showed an increase in cm/s from restricted, to normal, to exaggerated arm swing.

	Restricted	Normal	Exaggerated
Toe in/out angle	3.65°	3.74°	2.53°
Stride Length	136.7	137.43	162.74
Stride Time	1.129	1.126	1.085
Velocity	122.109	122.585	151.52

DISCUSSION

While this research may suggest that an increase in AS will shorten the stride time, it would need to be further researched with a greater number of participants to see exactly how an increase in AS effects stride time and hopefully data could be collected to reach statistical significance that is outside of the standard deviation. Furthermore, the two previous studies discussed and reported that slower/less arm swing resulted in decreased stability. Long et al. (2011) confirmed their hypothesis that negative alterations in arm swing would slow walking speed, shorten stride length, and that restraint of the arms would result in changes to lower extremity joint moments with greater kinetic changes at more distal articulations, causing instability. However, with the results from this study, nothing can be concluded, but there are results that encourage further and more in depth research.

CONCLUSION

In conclusion, and increase in arm swing could allow for a decreased toe in/out angle and stride time. Moreover, an increase in arm swing could also result in an increase in stride length.

CLINICAL APPLICATIONS

It is suggested with this research that arm swing does effect gait efficiency and we know that persons with amputation and pathology already expend more energy while trying to ambulate and it is important to note that arm swing also effects balance. Therefore, by utilizing arm swing, one can ambulate with more balance and efficiency.

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

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INTRODUCTION

This study investigated the effect of prosthetic socket suspension type on knee proprioception and dynamic balance in transtibial amputees. Participants were placed into three groups according to their suspension types: suction, locking-pin and vacuum assisted suspension system (VASS). We hypothesized that VASS will improve both knee proprioception and dynamic balance compared to locking pin and suction.

METHODS

Subjects: 31 legs (13 locking-pin, 9 section, 9 VASS) were tested with 19 total subjects (16M/3F with transtibial amputation). One subject was bilateral and additional sockets were made to test different suspension styles within our population.

Apparatus: An electric goniometer was used to measure knee angles and a YEI accelerometer measured accelerations while walking on a treadmill.

Procedures: The electric goniometer was placed at anatomical knee center of both the sound and amputated sides. Participants flexed their knee to the preset target six times and held for about three seconds each time. For dynamic balance, the accelerometer was placed on the lower lumbar of the participant. They walked at a self-selected speed, two times for three minutes each with at least one minute rest.

Data Analysis: Data was processed using MATLAB and the dynamic stability was quantified by the local dynamic stability (LDS). For knee proprioception, a repeated measures ANOVA was used with factors including: WB vs. NWB, amputated vs. sound side, targets, and suspension. For dynamic balance, a MANOVA was conducted.

RESULTS

Statistical analysis was found for knee proprioception in weight bearing vs. non-weight bearing (p=0.017).

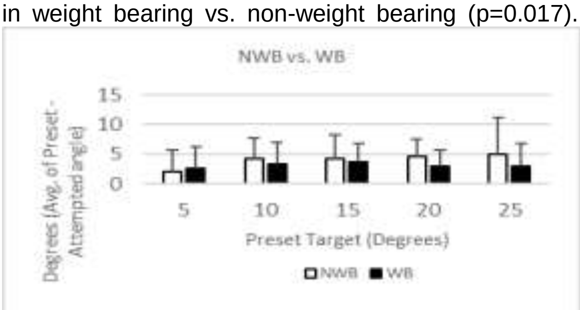

Figure 1. Averages of trial preset target minus attempted angle for all participants at each given preset target for NWB and WB. Standard deviation is shown and significance was found with α set at 5%.

Marginal significance was found in the LDS of the AP plane while utilizing locking-pin and VASS suspension methods in the ST (p= 0.056).

DISCUSSION

The increased proprioception in weight bearing and improved balance in local dynamic stability are relevant findings. These characteristics are worth noting as proprioception and dynamic stability are important factors in gait for decreasing the risk of falls. VASS has also been shown to decrease the risk of falls in previous studies (Ferraro, 2001 & Wernke, 2015)

CONCLUSION

The types of suspensions tested showed no statistical significance in affecting knee proprioception on amputees. With locking-pin and VASS suspension styles there is marginal significance in the AP plane during the initiation of gait through the first stride. This suggests the patients possibly felt more confident at the beginning of gait in the locking pin and VASS suspension styles.

CLINICAL APPLICATIONS

VASS, suction, and locking-pin suspension all provide the same amount of proprioception. With the marginal significance found in local dynamic stability with locking pin and VASS suspension, one could use this in discussing suspension styles with a new amputee. However, these findings were marginal and more research with larger sample size is needed to confirm this finding.

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ACKNOWLEDGMENT

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Functional Anatomical Model for Visualization of Excessive Socket Pressure

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INTRODUCTION

Learning in the medical field is often done in the workplace and involves exposure to complex issues that arise in the work environment (Kamphuis, 2014). Nursing and other medical health professions have deemed 3D functional anatomical models to be beneficial during the educational process (Biglino, 2016). Some advantages include cost effectiveness, ease of production, ease of preservation, and the possibility of multiple models for larger class sizes (Biglino, 2016). Medical functional models can be useful to learn about issues that will arise once students work with patients. Understanding the importance of alignment of prostheses and how pressures on the residual limb affect amputees is one such complex issue.

About 30% of amputees experience complications from the use of their prosthesis that include pain, pressure ulcers, and infections that prevent them from wearing their prosthesis. This leads to a decrease in activities and a reduced quality of life (H.A.M. Seelen, 2003). The alignment of the socket relative to the foot affects both the functional performance and the comfort of the prosthesis by altering the location of the weight bearing load being transferred between the limb and the ground. Inappropriate alignment may lead to reduced functional mobility (Kobayashi, 2012).

Prosthetist training in proper alignment of prostheses is essential for ensuring high standards for quality of care and visual feedback is one way to identify these pressures, as blanching of the skin can be observed. This project was initiated to create physical models to be used in prosthetic education to illustrate how alignment affects pressure.

METHOD

A simulation of an amputated limb was created based on an existing clear transtibial prosthetic test socket. Multiple thin layers of translucent, skin-tone silicone were slush-casted into the socket. Several layers of white urethane were then slush-casted into the silicone "skin" (representative of areas on the leg with minimal tissue between bone and skin) that can be pressed against the "skin" to mimic blanching. Finally, the innermost portion of the cast was created using expandable high-density polyurethane foam. As the foam was expanding to fill the void, a plastic model of a tibia and fibula were aligned so they approximated their anatomical location in the leg. After the model was completed, the prosthetic test socket was connected to a pylon and prosthetic foot.

RESULTS

The initial proof-of-concept of the model did not clearly identify points of high pressure sufficiently, due to the opacity of the silicone and the durometer. A second model was created with more translucency and an additive that reduced durometer substantially.

This allowed visualization of areas where uneven pressure occurred, as the white urethane mimicked blanching of skin when compressed. Applying uneven loading (due to misalignment) results in demonstrable visual cueing.

DISCUSSION

This functional model of a residual limb within a prosthetic check socket is able to show how altering alignments result in differing local pressures within the socket. For example, there is increased pressure proximal-medially and distal-laterally if the prosthetic alignment results in a more medial foot with increased varus moment. This tool facilitates visual observation of an analog to pressure. As the "blanched" area experiences more pressure, the color of the "skin" will become more pale.

CONCLUSION

This functional anatomical model is able to show increased areas of pressure due to the socket interaction with the model of the residual limb. The ability to see the locations of these pressures will be useful in teaching the concepts of pressure and how alignment affects pressure distribution.

CLINICAL APPLICATIONS

This model may be used in training orthotic and prosthetic students, therapists, and patients in both the importance of pressures distributed to the residual limb and how prosthetic alignment affects the location of pressures.

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GAIT COMPARISON OF A PERSON WITH AN OSSEOINTEGRATED PROSTHESIS AND AN ABLE- BODIED PERSON

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INTRODUCTION

Within lower limb prosthetics, the socket is responsible for linking the patient and his/her componentry to the ground. Various configurations of the socket have been developed for the transfemoral amputee with the hope of accomplishing a reduction in energy expenditure (Gailey et al., 1993), an improvement in function and stability, and a positive report of comfort and cosmesis (Schuch and Pritham, 1999). The late twentieth century saw the advent of connecting the patient directly to the prosthesis, thus bypassing the socket with osseointegrated prosthesis.

Osseointegration is a two-stage surgical process involving the use of titanium implants to anchor the prosthesis to the patient's residual femur. This procedure is generally considered after the patient has had little success in achieving rehabilitation with conventional sockets (Sullivan et al., 2003). This study was designed to analyze the gait and satisfaction of a patient currently using an osseointegrated prosthesis.

METHOD

Subjects: One male with a unilateral transfemoral amputation with osseointegration; age: 27, height: 5'9", weight: 205 lbs, time with amputation: 6yrs, and time with osseointegration: 1yr, 3 mon. One able-bodied male; age: 23, height: 6'4", and weight: 178lbs.

Apparatus: The subject's prosthetic componentry consisted of a transverse rotation unit, an Ottobock Genium X3 knee, and an Ottobock Triton foot.

Procedures: The participant walked on an instrumented dual belt treadmill at 1.2 m/s [Gait Real-time Analysis and Interactive Laboratory (GRAIL) from Motek Medical Inc.]. Kinematic data was recorded with a twelve camera motion capture system (100Hz) and ground reaction force data (1000Hz) was collected simultaneously. The participant then filled out the Prosthesis Evaluation Questionnaire (PEQ).

Data Analysis: Gait data was analyzed with the Gait Offline Analysis Tool (Motek Medical Inc.) then exported to Matlab to time normalize ten strides to 100 data points and compile for statistical analysis. A two tailed t- test was completed to ascertain if there is a significant difference ($p<0.05$) between the gait of an able-bodied person and a person with an osseointegrated prosthesis.

RESULTS

No significant statistical difference was found between the subject with osseointegration and the able-bodied subject regarding hip power ($p=0.161$) during the loading response and midstance of the gait cycle (12-31%). Results from the PEQ indicated a generally positive response to osseointegration, seen in Table1.

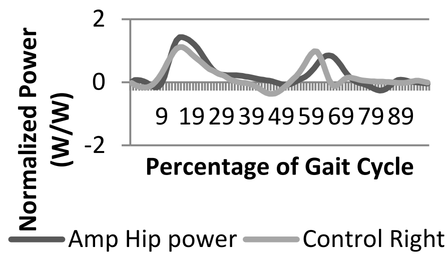

Figure 1. The hip power measured by the GRAIL throughout the patient's gait cycle

Category	Score
Ambulation	83.375
Appearance	100
Frustration	100
Perceived Response	100
Residual Limb Health	100

Table 1. PEQ Scale Scores

DISCUSSION

A normalized comparison of the data was done to determine if any significant differences caused by the prosthesis, with hip power being used as an indicator of amputee energy expenditure. The PEQ was performed to provide a measureable form of subjective feedback.

CONCLUSION

Data suggests the subject with osseointegration can produce similar hip power to an able-bodied person. This Along with the positive PEQ response, makes osseointegration a viable prosthetic interface. Future studies should incorporate gait of a subject who uses a prosthesis with a socket.

CLINICAL APPLICATIONS

This data will provide more information to assist in critical decisions regarding osseointegration.

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Gait Response to Backpack load During Level Walking

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INTRODUCTION

People regularly use a variety of bags to transport their belongings from one place to the next. Whether it is a handbag, backpack, athletic bag, golf clubs, or shoulder packs, carrying a bag can they have an influence on a person's kinematics People grow accustomed to utilizing bags and potentially neglect the consequences that carrying a load can have on the human body. Improper carrying methods and carrying heavy loads can result in alterations in walking patterns, abnormal posture, muscle strain, and chronic spinal issues.

The purpose of this study is to investigate how carrying a load unilaterally (over one shoulder) affects a person's step width. The effect of mass and load position in relation to the body must be considered. Walking is a synergistic and complex set of movements that can be described in terms of biomechanical principals. When the spine, torso, head and lower extremities are aligned, the body is able to efficiently ambulate in an orthograde posture. I predict that walking while carrying a heavy load over one shoulder will produce an increase stride width when compared to normal ambulation.

METHOD

The subjects recruited for this study were a convenience sample of seven abled-bodied individuals.. Subjects needed to be capable of carrying up to 40 pounds while walking up to 100 meters. There was no exclusion based on gender, age or activity level. Verbal consent was obtained by all participants prior to testing.

The equipment used for this experiment consisted of a Zeno GAITRite mat that is 230 5/16'' long by 27.5'' wide. In order to analyze the results, Proto Kinetics movement analysis software (PKMAS) was utilized. The GAITRite mat paired with PKMAS has been proven to be valid and reliable (McDonough et al. 2001). The backpack that subjects carried over one shoulder was a Jansport "big student back pack" (dimensions: 17.5" x 13" x 10" / 43 x 33 x 25 cm). The back pack had standard weights inside of it, adding to a total weight of 36.1 lbs. l

Initially participants were asked to walk barefoot at a self-selected walking speed (SSWS) across the Zeno matt 6 times (down and back 3 times). This test was used to get a baseline of participants gait walking patterns. All trails were then averaged together to give a better representation of walking patterns. The variable that was recorded was the subjects average step width (cm). On a future date, the same participant were asked to follow the same protocol as the initial recording (barefoot, SSWS, 6 passes) this time while carrying a 36.1 lbs. back pack suspended unilaterally over the shoulder. Each participant was asked to carry the bag over their dominant side, conveniently all participants were right handed so all subjects wore their backpacks on the right side. Each backpacks height was adjusted to be level with his or her iliac crest.. The same temporal spatial variable was recorded and later compared.

RESULTS

GROUP:	BASE	BACKPACK (36 LBS)
MEAN:	9.59	8.52
SD:	3.67	3.59
SEM:	1.39	1.36
N:	7	7

P VALUE- 0.2717

DISCUSSION

Based on the results average step width decreased while walking with a backpack, however a paired t-test showed the two variables to be not significant. This could be because the subjects had observable lateral trunk lean towards the shoulder suspending the backpack, therefore further compensation for step width wasn't needed. It has been reported that an increase in the load asymmetry applied to the foot during stance phase decreases step width (Kim et al.). An asymmetry between weight on each side of the subjects shoulders results in instability and relocation of the COP. In response, a mechanism for posture adaption activates to maintain physical balance by postural changes in the trunk and extremities (Son. 2013)

.**CONCLUSION**

In conclusion, this study reports that when carrying a heavy bag over one shoulder, the subjects resulted in a decreased average step width that was proven to be not significant.

CLINICAL APPLICATIONS

By understanding the biomechanical effects of Carrying heavy objects, we can decrease the likelihood of developing postural problems and increase ambulation efficiency.

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Gender Differences in Gait Patterns Under Varying Light Conditions During Level Walking

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INTRODUCTION

Falls are the second leading cause of accidental or unintentional injury deaths worldwide. With the increasing elderly population, fall incidents are continuously increasing (World Health Organization, 2012). Vision plays a predominant role in ambulation, and understanding the effect vision has on human locomotion performance is important for the prevention of falling. The purpose of this study is to investigate the effects of poor lighting on gait patterns of healthy college aged men and women. In healthy individuals under poor lighting conditions, gait kinematics may be affected.

METHOD

Subjects: A convenience sample of healthy individuals, four men and three women between the ages of 21 and 30 gave verbal consent to participate. The participants were recruited from the California State, Dominguez Hills O&P Program.

Apparatus: The Zeno Walkway was the only equipment used in this experiment. The Zeno Walkway contains a 16-level pressure-sensing pad with three separate layers. The mat comes in various lengths and sizes but the one used in this experiment was 20 ft. long and 2 ft. wide. The Zeno Walkway has been found to be valid and reliable (Menz, 2004).

Procedures: Participants were given a brief description of the study tasks. They were instructed to walk barefoot at a self-selected walking speed across the mat for two different trials: six passes at full light and six passes at low light.

The first trial was obtained in a well-lit classroom where the participants were able to clearly see their surroundings. The second trial was completed in a dark classroom where the windows were covered and the lights were off. The low-light condition simulated walking in the house with only a night-light.

Data Analysis: Spatial and temporal gait parameters were collected using the Zeno Walkway. This study collected data on step length, stride length, velocity, and stance phase duration. Descriptive statistics were computed including mean and standard deviation. Inferential statistics were computed to test the hypothesis using a two-way ANOVA.

RESULTS

Mean values of all parameters and results from the statistical analysis are summarized in the table. The results from the two-way ANOVA are also summarized in the table. Graphs comparing the mean between conditions between genders of each parameter have been created.

		Male	Female	between conditions	F-test	p
Velocity	light	131.39 ± 27.06	124.24 ± 7.34	*p*=.67	*F(1,7)*=.34	*p*=.58
	low light	121.79 ± 4.31	60.94 ± 1.09			
	between genders	*p*=.87				
Stance Phase Duration	light	61.32 ± 1.69	60.94 ± 1.09	*p=.80*	*F(1,7)=.03*	*p=.87*
	low light	61.73 ± 0.35	61.08 ± 6.82			
	between genders	*p=.58*				
Stride Length	light	145.22 ± 30.19	140.12 ± 39.53	*p=.61*	*F(1,7)=.15*	*p=.71*
	low light	130.11 ± 3.86	129.35 ± 25.81			
	between genders	*p=.049*				

DISCUSSION

The results of this study were consistent with previous findings that after adjusting to light conditions low light alone had no effect on gait pattern (Helbostad, 2009). There were no significant differences with the main effect of light condition on the parameters. There were no significant findings with the main effect of gender on the parameters. There were no significant differences with the interaction effect between gender differences by light condition on the parameters. There was a significant difference with the main effect of gender differences on stride length between men and women.

CONCLUSION

It was not concluded how men and women's gait differ between level walking under varying lighting conditions. However, the result of decreased stride length between genders is enough to conclude that there are changes in gait parameters between genders, however no other conclusions can be drawn at this time.

CLINICAL APPLICATIONS

Clinically, the results from this study indicate that future studies need to be conducted utilizing larger sample sizes and more varying light conditions. If we understand the gait patterns of young able-bodied individuals we can then apply this knowledge to other populations to create programs to prevent falling when ambulating in different environment.

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Helping athletes with amputations reach their potential as they run the curves on the track: a Critically Appraised Topic review

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November 2016

INTRODUCTION

Clinical Question*:* Do athletes with unilateral right transtibial amputations have advantages resulting in faster race times compared to left transtibial amputations in competitive sprinting events that include turns?

Background: Both Paralympic and Olympic athletes who compete in the 200 or 400-meter sprinting events must maintain high speeds as they navigate curves. The 400-meter is one full lap on the track with two curved sections; the 200-meter is half a lap with one curve. Keys to success for these sprinters require strategies that improve their ability to run a curve. The International Paralympic Committee (IPC) levels the playing field for athletes with limb differences by providing classifications that group together similarly impaired athletes. At this time, limb-side amputation is not considered a factor for classification. Earlier studies provide a good foundation that describes the physics of running on a flat (not banked) curve and the generation of leg-specific centripetal force (Greene, 1985). Recent studies examine the movements of sprinting and curve running in able-bodied athletes that may have implications for athletes with limb differences (Nemtsev, 2010). One such study shows differences in foot and shin biomechanics when curve sprinting. These joint kinematics help to counter the centrifugal forces being generated. This study has implications for an athlete with a transtibial amputation missing a foot and some of his calf. Other studies look at lower limb musculature and found that curve sprinters with larger right side psoas major muscle are faster curve sprinters (Alt, 2014). One study reports that the hamstrings and other lower extremity musculature are not significant factors in predicting speed (Tottori, 2015). For athletes with unilateral amputations and thus varying residual musculature, these findings may be quite relevant. Another earlier study concludes that sprint performance is more a function of the application of the support forces to the ground and not the repositioning ability of the swinging limb to reach top speeds (Weyand, 2000). These results suggest that a biomechanical difference between inside and outside leg exists and that research exploring curve how this impacts an athlete with a transtibial amputation.

METHOD

Search Strategy:

Databases Searched: *CINAHL, PUBMED and Google Scholar,*

Search Terms: *Curve, bend, sprint, prosthetic, Paralympics. References cited on reviewed and title and author searched relevant journal articles.*

Inclusion/Exclusion Criteria*: 2007-2016 for Reviewed Articles; 1985-2016 for history and background references.*

RESULTS

Synthesis of Results: Five articles were reviewed, which included analyzing past race results, and doing trials with subjects running on the track that are able bodied or have amputations of right or left side. All but one of these articles found that athletes with the amputation on the inside leg seemed to have slower running times (Hobara, 2015). Because track events are run in a counterclockwise direction, this puts athletes with left side amputations at a disadvantage compared to athletes with a right side amputation. One article[9] compared a left side amputee athlete's personal times on a straight sprint, a counterclockwise curve, and a clockwise curve. The results showed that he ran faster going clockwise, with his amputation side on the outside of the track, than he did going counterclockwise, with his amputation side on the inside of the track. However, this study was done with a transfemoral amputee, so the results may vary with a transtibial amputee, so further studies should be performed. Only one article found that there was no difference in race times of right vs. left sided amputations (Hobara, 2015). This study was done analyzing data from elite-level competitions, such as the Paralympics and the International Paralympic Committee Athletics World Championship. These are the top athletes with advanced training, and these results cannot be applied to non-expert level athletes. The slower running times can be explained by factors such as reduced stride frequency, centrifugal forces, side and level of amputation, or decreased generated forces by the inside leg (Taboga, 2007)

Helping athletes with amputations reach their potential as they run the curves on the track: a Critically Appraised Topic review

Iurato, J., Spears, M., and Swopes, J.

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November 2016

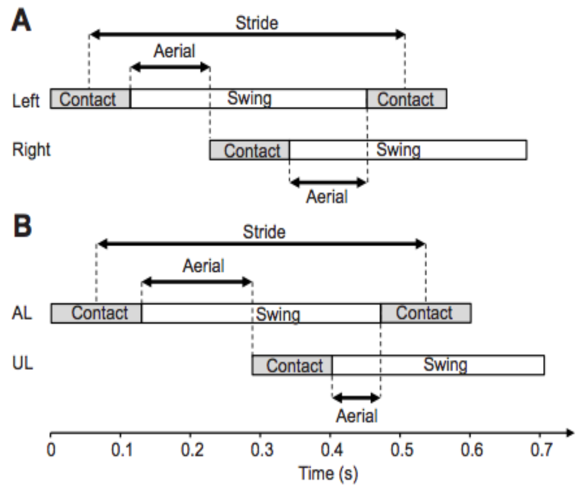

Figure 1. Schematic view of the measured stride kinematics versus time. (A) Non-amputees. (B) Sprinters with an amputation. Stride time is the time from mid-stance to ipsilateral mid-stance. Aerial time is the time from the end of foot–ground contact to the beginning of contralateral foot–ground contact. Non-amputees (A) have a symmetric running gait, while sprinters with a unilateral amputation (B) have longer contact times and aerial times with their affected leg (AL) compared with their unaffected leg (UL) (Taboga, 2007).

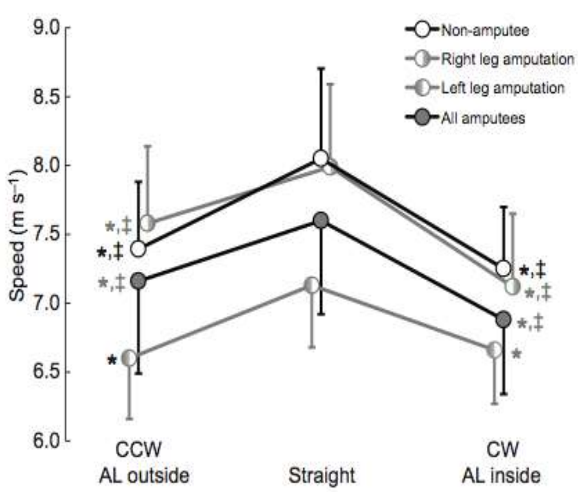

Figure 2. Mean (±s.d.) maximum speed for straight, CCW and CW curve running. Curve radius was 17.2 m. Non-amputees were slower during CCW and CW curve running compared with straight running (P=0.001 for both conditions) and ran slower on CW compared with CCW curves (P=0.042). All athletes with amputations ran slower during curve running compared with straight running (P<0.001). Moreover, they were slower during curve running when their AL was on the inside compared with on the outside of the curve (P=0.032). Asterisks represent significant differences between straight- and curve-running trials. Double daggers indicate significant differences between CCW and CW directions or between the AL on the outside and the AL on the inside of the curve (Taboga, 2007).

DISCUSSION, CONCLUSION AND CLINICAL APPLICATIONS

Clinical Message: Sprinters with a right-side amputation have competitive advantages over those with left-sided amputations on turns. Research and development for prosthetic blade technology should consider curve running demands as well as on which side the foot will be worn. There is a unique and greater demand on the inside leg, but more experimental data is needed to determine the specific needs of the athlete with the left side amputation. Possible considerations include inversion/eversion ability of the blade and increased ability to create centripetal forces with the prosthetic running blade. Prosthetic blades designed specifically for left legs could even the playing field for these athletes. This literature review also highlights a need for trainers and physical therapists working with athletes with left transtibial amputations to take special consideration of how to better prepare the athlete for competition.[7] Changes could be made by the IPC for future events for these athletes. Future classification could have athletes with left side amputations run track events on the curve in the clockwise direction, opposite of the traditional counterclockwise. Alternatively, the IPC could classify sprinters also by the side of their amputation. Based on our review of current literature, there is a deficit of studies that examine, either empirically or theoretically, clinically relevant data that can be related to the athlete with a transtibial amputation. More research is needed to better understand the biomechanics of the competitive sprinter with a transtibial amputation to increase the success of these athletes on the competitive level. Future research could offer more insight for prosthetic foot design, competitive training regimens, and Paralympic classification systems for transtibial sprinters grouped by amputation side.

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EVIDENCE TABLE

Do athletes with unilateral right leg amputations have advantages over those with unilateral left leg amputations in competitive sprinting events that include turns?

	Hobara et al, 2015	Funken et al, 2016	Chang et al, 2007	Funken, et al, 2014	Taboga et al, 2016
Population	n= 59, male/female unilateral lower limb amputation competin g in elite 200 meter races; 27 right, 32 left amputees; all used RSPs	n=9; 3 lower limb amputees, 6 able bodied; all elite athletes; Ampute e Levels and side: 1 right transtibial, 1 bilateral BK, 1 left knee disarticulation	n=5; recreationally fit; 29.4 +/- 5 years old; body mass 80.7 +/-9.0 kg	n= 1 left sided unilateral transfemoral amputee (male), medalist in 2012 Paralympic games	n= 17; 6(5 male/1 female) non amputee sprinters, 6(5 male/1 female) right transtibial amputees, 5(2 male/3 female) left transtibial amputee
Study Design	Case Report; retrospective observation; Empirical Research	Case Control Study, Quantitative studies, empirical research	Case Report, Qualitative studies, empirical research	Quantitative studies, Empirical Research	Randomized counterbalance d trials
Intervention	Running on a curve on a track with a prosthesis	Running on a curve on a track with a prostheses	Running on a curve on a track	Running on a straight track, clockwise curve, and counterclockwise curve with prosthesis	Running on a curve on a track with a prosthesis
Comparison	Right sided versus left sided amputees during 200 m sprint	Mean peak GRF, impulse (braking) and velocity for all three amputees separately and the able bodied as a group of right and left limbs.	Inside versus outside leg velocities, x, y. z components of GRF, average force applied by sprinter to the tether, step length	Straight run vs. running around a curve clockwise, Straight run vs. running around a curve counter clockwise.	Non-amputees, left side transtibial amputees, right side transtibial amputees and their speed running on a curve

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Methodology	Statistical analyses were performed using SPSS version 19; performances analyzed from internet broadcasts races: Athletes categorized by Race times, gender, amputation side and stump length	Statistical Analysis of kinematic data using MATLAB: Indoor track course, three curved runs, maximal speeds for amputees and submaximal speeds for able bodied, standard curvature of 36.3 m radius for track	Statistical analysis of kinematic data using various robust methods; 30 min warm up; Subjects sprinted on circular tracks of 1, 2, 3, 4 and 6 m radii after a 30 m straight path; one time they were tethered axially and one time they were not	Athlete ran many trials, including straight, counter clockwise curve, and clockwise curve. Kinematic data was collected by 3D camera. 4 force plates recorded kinetic data. 34 reflective marks on the blade, knee joint axis, and pelvis were analyzed using MATLAB	Six 40m sprints on a standard, synthetic track surface wearing their own shoes; 2 straight sprints, 2 on CCW curve (radius 17.2m) and 2 CW curve (radius 17.2m) trials. 8 min rest between each trial.
Outcomes	Race times of 200-m sprints of tournament finals and reported amputation side	Retro-reflective markers; 16 infrared cameras, four force plates collected kinetic data 3D motion capture system; Force plate on curves	Kinematic data collection recorded by high speed video cameras, researcher stop watches, force plates on curves; infrared sensors	Speed of trial, stance time in each trial, GRF, eversion moment, torsion moment, and flexion moment	Speed of trial, contact time of each leg during a trial, stride frequency, stride length, aerial time, leg swing time
Key Findings	No difference in race times and, no significant differences in participation as a function of amputation side	-Prosthetic curve sprinting kinetics depends on level and side of amputation. -Athletes with amputations at the inside leg (unilateral or bilateral) seem to be disadvantaged in terms of generating high curve running velocities.	-Peak forces generated by the inside leg decreased twice as much for a given decrease in radius compared to the outside leg; maximum sprint velocity on curves is not only limited by a	-He ran faster going clockwise and straight, and slowest going counter-clockwise. The stance time with the prosthesis was highest in counterclockwise. -The ML ground reaction force of counterclockwise show a peak in	-Sprinters with an amputation ran 3.9% slower with their affected leg on the inside of the curve -All sprinters reduce stride length on the curve, but only amputees with affected leg on the inside of

			physiological limit to axial leg force	medial direction of the inside leg, causing a centrifugal force. However, the ML ground reaction force of clockwise shows medial force of the outside leg, causing a centripetal force.	the curve reduced stride frequency
Study Limitations	-Cannot extrapolate results to novice or non-expert level athletes -Results based on retrospective, not experimental observations; stump length and knee componentry vary among athletes -Race was only 200m, which only involves one curve.	-Small Sample size of amputee athletes -Results cannot be extrapolated to novice or non-expert level athletes -No discussion of componentry, surgical considerations, cause of amputation or body mass or age comparisons -No discussion of warm up or rest periods	-Small sample size -No amputees studied -Cannot extrapolate to novice runners, older or heavier patients -No mention of co-morbidities, leg length discrepancies, shoe choice, neuromuscular insufficiencies.	-Small sample size: Only tested one athlete. Would need more athletes with amputations on right and left side. -No discussion of what the order was for the runs. If all the runs were done back-to-back, athlete may have become tired toward the end. -Athlete had a transfemoral amputation, so more research would need to be done on transtibial amputees	-Only measured one curve radius -Need future measurements of ground reaction forces during curve running in athletes with amputations -Small sample size

HOW ADDING WEIGHTS ON VARIOUS LOCATION OF PROSTHETIC DEVICE AFFECT KINEMATICS DURING GAIT IN A PERSON WITH UNILATERAL TRASTIBIAL AMPUTATION

Yongjin Lee; CSUDH

This paper presents how altering location of prosthetic device's center of mass and adding weight affect kinematics during gait in a person with unilateral transtibial amputation. Single subject was used in this study with one prosthetic device. Subject had walked 5 trials with various setting(no weight, 1lb&2lb weight attached on both proximal and distal end of device) on the ZENO mat. Proximal weight cuff placed in 7 inch above from the ground. Distal weight cuff place in 3 inch above from the ground. The experimental result showed decrease in the stride length and stride velocity as weight increases distal place than proximal place. Stance phase percentage also increased in 65~70% range and swing phase percentage stayed in 30~35% range.

According to experimental result, regardless of center of mass location change, study supports that adding weight on the unilateral prosthetic device decreased stride length, velocity, and increased stance phase percentage relation to swing phase, which indicates decrease in gait efficiency and limb stability. Moreover, collected data also showed that adding weights at distal end of the prosthetic device negatively affect gait kinematics more than adding weights at proximal end of the prosthetic device.

HOW CADANCE AND CENTER OF PRESSURE ARE EFFECTED BY PROSTHETIC CAST WEIGHT

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INTRODUCTION

There is limited research on the effect of load on center of pressure distribution. Studying the effects of load on gait is increasingly important because of the potential negative effects of lifting loads on professionals in the orthotics and prosthetics field. As patient size increase to obesity so do the cast volumes (Margolis, 2011; Ogden,2009). Studies exist where a load is carried on the back but rarely from a load carried in front of the body as done in orthotic and prosthetic field (Chansirinukor, 2001; Johnson 2001).

Work place load carrying should be studied and analyzed as "there is strong epidemiological evidence that physical demands of work (manual materials hand lifting, lifting, bending, twisting and while body vibration) can be associated with increased reports of back symptoms, aggravation of symptoms and injuries" (Waddell, 2001). With lower back pain being the second leading cause of sick time concerns, minimizing such injuries is not only advantageous to the employer but also to the health of the individual (Chaffin, 1973). Understanding how ones job and the lifting that frequency can detrimentally affect their health can help lead to safer workplace practices.

METHOD

Subjects: 10 health individuals from the Masters in Orthotics and Prosthetics class

Apparatus: Gait Rite Mat

Procedures: participants were instructed to walk holding a transfemoral cast on the right side of their body as they made 6 passes on the Gait Rite mat. Patients also did a baseline run in the shoes they used to carry the cast.

Data Analysis: A two tailed T-test was done to analyze the data.

RESULTS

There was a significant relationship between cadence with a standard p value of 0.05 and a tested p value of 0.01187. The center of pressure was also significantly affected yielding a p value of 0.02232. However, the sample size of just 10 participants is not representative of the entire population. In order to see if there really is a significance in the data, a larger sample would have to be collected for an accurate representation of the population.

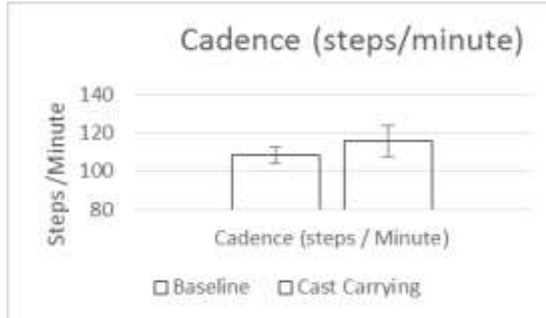

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Figure 1. Indicates the difference in cadence between normal walking and carrying a transfemoral cast.

Participants	SS COP Distance (cm) Mean (SD)	Cadence (steps/min) Mean (SD)
Baseline	12.4654 (+/-) 2.764	108.194 (+/-) 4.56
Cast Carrying	11.3138 **(+/) 3.131**	115.4719 (+/-) 7.98
P value	0.02232	0.01187

Table 1. States the Average for the baseline and tested data during

DISCUSSION

Results stated that there was a change in COP and n cadence. Further research could be done by study casts of multiple weights. The medium sized cast was done for this data set due to time constraints. Also further testing would need to be done one more than just 10 participants.

CONCLUSION

The current data supports that as the load increases cadence will increase and center of pressure distance will decrease. With the decreased COP distance and an increased cadence, risk of falls increases with workers (Liu, 2013).

CLINICAL APPLICATIONS

In a profession where loads must be carried it is important to keep in mind proper body mechanics to keep from becoming a patient of your own practice in orthotics.

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HOW TENNIS SHOES AND FLIP FLOPS AFFECT TEMPORAL SPATIAL DATA"

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INTRODUCTION

Flip-flops and tennis shoes can affect the way people walk and may also lead to excessive joint loading (Shakoor et al, 2010). Shakoor et al., (2010) studied how stability shoes, clogs, flat walking shoes, and flip-flops affected walking in people with osteoarthritis of the knee and concluded that heel height and rigidity both contribute to differences such as stride length, joint loading forces, and moments. Understanding the relationship between shoes and stride length and stride time is important because it can help practitioners understand and account for potential effects on gait patterns.

The purpose of this study is to determine the differences in stride length and stride time of the foot when ambulating with flip-flops compared to tennis shoes. The population for this study will be able-bodied young adults. The participants will complete walking trials with each pair of shoes on the Zeno Walkway System. The researcher hypothesizes that stride length will decrease in flip-flops compared to tennis shoes and stride time will decrease in flip-flops compared to tennis shoes.

METHOD

Participants for this study were recruited via convenience sampling.

Subjects: There were 10 able bodied participants who participated in this study, 8 male participants and 2 female participants. Participants ranged in age between 23 and 31 years old.

Apparatus: Zeno Walkway System, flip-flops, and tennis shoes.

Procedures: Each participant made a total of 12 passes across the walkway, six with tennis shoes and 6 with flip-flops. The researcher instructed the participants when to begin walking and when to stop walking. The participants were asked to walk at a self-selected walking speed and were told to walk as they normally do on a daily basis.

Data Analysis: Two separate *t*-tests were conducted using a 95% confidence interval.

RESULTS

The value of the Bonferroni correction brings the statistical significance threshold to 0.025 for stride length. The calculated p-value was 0.003.

The value of the Bonferroni correction brings the statistical significance threshold to 0.025 for stride time. The calculated p-value was 0.325.

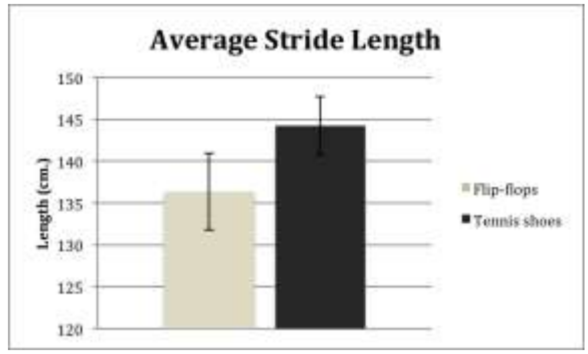

Figure 1: Average Stride Length (mean $\pm$ SD)

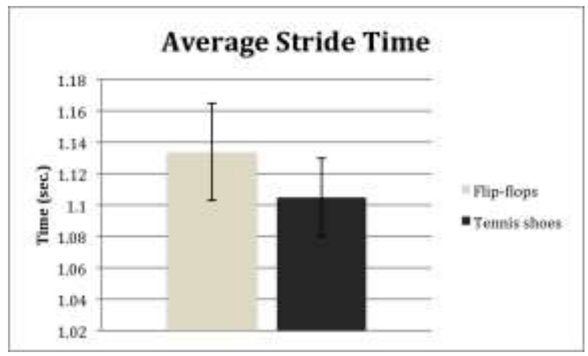

Figure 2: Average Stride Time (mean $\pm$ SD)

DISCUSSION

Based on the results, it was determined that the average stride length was statistically significant, but average stride time was not statistically significant when comparing gait in different shoe types.

CONCLUSION

This study was conducted in order to gain further insight about the affects shoe wear has on temporal spatial data in able-bodied individuals. Flip-flops and tennis shoes are common shoe types, and it is important to know how either can influence gait patterns.

CLINICAL APPLICATIONS

It is important to consider different types of shoe wear when analyzing gait because there are variances in temporal spatial data.

REFERENCES

Shakoor, N., Sengupta, M., Foucher, K. C., Wimmer, M. A., Fogg, L. F., & Block, J. A. (2010). Effects of common footwear on joint loading in osteoarthritis of the knee. *Arthritis care & research*, *62*(7), 917-923.

IMPACT COMPARISON OF MEDICAL-GRADE HELMET MATERIALS

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INTRODUCTION

Physicians prescribe medical-grade helmets to people who are believed to be at a high risk for experiencing a brain injury. Typical patients include those with post-operative craniectomies, cranial vault reconstructions, skull anomalies, seizures, self-injurious behaviour, and or poor balance. With 40% of traumatic brain injuries occurring as the result of a fall, protecting the head in patients who are prone to falling or have compromised head integrity is extremely important (CDC, 2010). There is much research being done on different helmets for athletes involved in sports like football, lacrosse, and cycling, but medical grade helmets lack a sound evidence base for what materials work best and why they do. The purpose of this study was to test the amount of linear acceleration absorbed by custom medical-grade helmets comprised of differing materials and compare the protective qualities of the various materials and layup combinations.

METHOD

Nine helmets of different materials were fabricated and tested in this study, with a no helmet group acting as the control. A casted urethane headform was attached to dual-wire guided drop tower. A triaxial accelerometer was planted inside the headform and data was collected from it at 2000Hz. Each helmet was placed on the headform and dropped onto a steel anvil from a height of 45mm. Each helmet was tested 10 times at 3 different drop sites (anterior, lateral, and posterior sides of the head), as was the control test without a helmet. The data was collected in MATLAB and converted to peak linear accelerations. The 6 best representative trials from each test site and each helmet were chosen and ANOVA and paired T-tests were run to analyze the data.

Helmet Number	Plastic	Aliplast
1	Copoly	Soft (23)
2	Copoly	Medium (34)
3	Copoly	Hard (60)
4	Surlyn	Soft (23)
5	Surlyn	Medium (34)
6	Surlyn	Hard (60)
7	Low Density Polyethylene	Soft (23)
8	Low Density Polyethylene	Medium (34)
9	Low Density Polyethylene	Hard (60)
10 (No Helmet)	N/A	N/A

Table 1. All plastics were 1/8" and Aliplast was ½".

RESULTS

All results were grouped by plastic type. Of the 9 helmets, 2 were found to be statistically significant ($p<0.05$). The significant helmets were Helmet 5 (Surlyn with medium durometer Aliplast) and Helmet 7 (LDPE with soft durometer Aliplast). No significant difference was found between helmets 5 and 7.

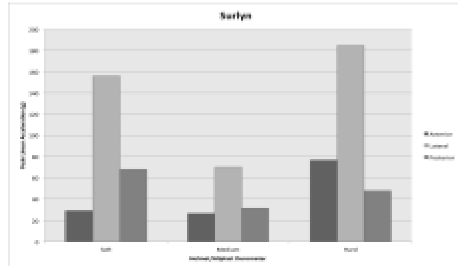

Figure 1. Surlyn helmets

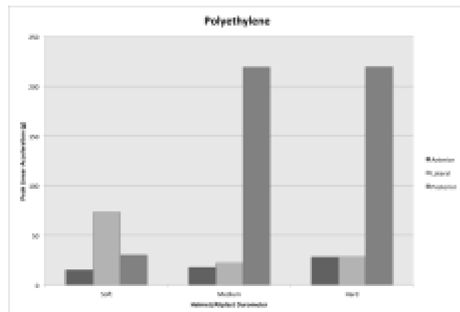

Figure 2. Low Density Polyethylene helmets

DISCUSSION

The Abbreviated Injury Scale assigns levels of brain injury according to the degree of peak linear acceleration upon impact. The 2 statistically significant helmets both kept the acceleration force below 100g at all 3 impact locations, the level at which a brain injury occurs (Ziejewski, 2014). These materials, Surlyn with medium Aliplast and LDPE with soft Aliplast, are similar materials to what most off-the-shelf helmets are made from.

CONCLUSION

Much research is still needed to determine the optimal material selection for medical-grade helmets. This study begins to verify the material selection that is currently being used in many medical-grade protective helmets.

CLINICAL APPLICATIONS

With no real standard for choosing materials with which to fabricate protective helmets, this study can give some guidance in selecting the most protective materials for medical-grade helmets.

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Neuromuscular Electrical Stimulation and Balance in Trans-Tibial Amputees

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INTRODUCTION

The effects of undergoing a lower-limb amputation are life altering. After surgery, the patient face a lengthy rehabilitation process. This process includes limb volume management, wound closure and healing, physical therapy, prosthetic fittings and subsequent gait training. In the immediate weeks and for several months, the health care team will have to work in coordination with the patient to ensure that he or she can return to his or her highest possible level of functioning.

A key component of ensuring optimal functioning following lower limb amputation is restoring efficient and functional gait. Complications to reestablishing effective gait include severity of amputation, comorbidities, quality of the surgery, familial support, patient motivation, and many more. In addition, the act of walking itself is much more difficult for the amputee because of the reduced musculature available, leading to increased energy demand (Douglas G Smith, 2004), and because walking is made exceptionally more difficult as the amputee must devote a great deal more energy to stay balanced(Gailey et al., 1994; Huang et al., 1979; Mengelkoch, Kahle, & Highsmith, 2014; Phil Stevens, 2010). Therefore, it is necessary to incorporate an effective balance training program into the rehabilitation plan for the lower limb amputee so that they can have a more symmetrical and efficient gait (J. Perry, 2004).

In addition to physical and occupational therapy, Neuromuscular Electrical Stimulation (NMES) has been shown to be effective in improving strength (Son, Lee, & Kim, 2014) and reducing pain in amputees(Finsen et al., 1988; Mulvey et al., 2013; Rauck et al., 2012). The use of NMES has also been found to be effective in improving balance-related gait parameters in other populations, such as individuals with chronic stroke and children with cerebral palsy(Daichman, Johnston, Evans, & Tecklin, 2003; Lee, Lin, & Soon, 2007; Park, Seo, Choi, & Lee, 2014; Yavuzer et al., 2006). Applied electrical stimulation as also shown to be particularly effective when combined with exercise on lessening spasticity and improving balance in chronic stroke patients(Park et al., 2014). One study also specifically demonstrated the use of NMES to improve certain gait parameters related to balance by measuring cadence, swing/stance ratio, period of single limb support, and double limb support(Lee et al., 2007). From these studies, it has been demonstrated that the use of NMES has been effective in helping to regain strength and balance in certain patient populations. ***Based on the outcomes demonstrated in previous studies, it is hypothesized that the application of NMES to the muscles of the amputated lower leg will improve balance, as measured by certain gait parameters, in trans-tibial amputees***

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METHOD

This study is a two group randomized controlled trial. 10 participants will be selected to participate. Inclusion criteria for participation in the study is as follows: unilateral transtibial amputee over the age of 18, with at least a 4 inch residual limb and a score of at least 70% (be able to sense 7 out of 10 tests) or higher on a monofilament test. Participants will be excluded from selection if they are self-reported severely diabetic, exhibit Loss of Protective Sensation (LOPS), use a pacemaker, have a cardiac condition (hypertension, congestive heart issues), a BMI over 42 kg/m, and/or have experience with either Trancutaneous Electrical Stimulation (TENS) or NMES in the past 6 months.

Participants will be separated into two age and gender matched groups of 5, one control group and one NMES intervention group. The participants will initially be brought in for a baseline test, which involves having the participant walk on the GaitRite (CIR Systems,Franklin, NJ, USA) . The participants will perform a 10-meter walk test at a self-selected speed. They will complete the walk test 3 times per testing session and the data averaged for all 3 tests. The GaitRite is a portable gait analysis system that has been used as the standard by which other gait analysis systems have been tested, and has also been shown to have both concurrent validity and test-re-test reliability(Baldewijns, Verheyden, Vanrumste, & Croonenborghs, 2014; Bilney, Morris, & Webster, 2003; Egerton, Thingstad, & Helbostad, 2014; Greene et al., 2012). The system consists of a walking mat with force sensors embedded that can capture 41 different temporal and spatial parameters (Figure 1). The accompanying software records and stores this information, which can be combined and exported to another system for analysis. All subsequent walk testing will also be performed on the GaitRite system. Following the baseline test, participants will be instructed to return at 4, 8, and 12 weeks for more walking data collection on the GaitRite.

Neuromuscular Electrical Stimulation and Balance in Trans-Tibial Amputees

Bell, E.L., Peterson, S., Fiedler, G.
University of Pittsburgh

At the baseline testing session, the NMES intervention group will be instructed on the use of the Empi Continuum (DJO Global, Vista, CA, USA), an at-home electrical stimulation unit that has 4 settings: Neuromuscular Electrical Stimulation, Transcutaneous Electrical Stimulation, Edema, and Configuration (Figures 2 & 3). The participants will be instructed on the placement of the pads to the quadriceps, tibialis anterior, and gastrocnemius. Additionally, participants will be tested until each of the 5 individuals found the level of stimulation required to generate a forceful quadriceps contraction resulting in full knee extension. This will be done by placing the pads on the quadriceps, tibialis anterior, and gastrocnemius, and the lowest level of stimulus applied. The stimulus will be gradually increased until a level is reached where the participate gets a full extension of the knee without severe pain or discomfort. The level will be noted for the participant to use at home. Intervention participants will be instructed to use the NMES device once a day, for 15 full contractions.

At 4, 8, and 12 weeks, data will be collected from each of the ten patients as they walk on the GaitRite, and the two parameters analyzed for this study are Swing Time and % Swing time of the Sound limb, as well as Heel-to-Heel Base of Support.

Gait analysis studies have shown that individuals with amputation or weakness on one limb will spend less time on that limb during gait in order to stay stable. Therefore, corollary to the hypothesis, it is supposed that the Swing Time and % Swing time of the contralateral (sound) limb should decrease with the use of NMES on the prosthetic side. Additionally, gait analysis studies have shown that individuals with weakness, paralysis, paresis or amputation tend to stabilize themselves during gait by walking with their feet further apart, thereby employing a wider base of support when compared to able-bodied individuals, because a wider base of support reduces the risk of falling(Bolger, Ting, & Sawers, 2014; Hak, van Dieen, van der Wurff, & Houdijk, 2014; Hak et al., 2013; Hordacre, Barr, Patritti, & Crotty, 2015; Tokuno, Sanderson, Inglis, & Chua).

At the conclusion of data collection at 12 weeks, a Pearson's Correlation test and Repeated Measures ANOVA will be used to analyze the outcomes and examine any differences between the intervention and control group.

RESULTS

Data is still being gathered

	BASELINE	WEEK 4	WEEK 8
NMES H-H	13.8	n/a	n/a
Control H-H	11.82	17.11	17.29
NMES % Sw	38.58	n/a	n/a
Con % Sw	35.53	42.22	40.19

Table 1. Figures and Tables should be designed to fit within the column width if possible.

DISCUSSION

Data still being gathered

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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Normative Backward Walking Data in Graduate School Students

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INTRODUCTION

Clinically, it is difficult to state if backward walking should be recommended as an alternative form of exercise, as there is minimal research on backward walking. From the available data, Laufer (2005) drew the conclusion that backward walking is potentially dangerous for the elderly population, as they may be prone to falling whilst walking backward. Conversely, other researchers found prospective benefits of walking backward. Wright and Weyand (2001) demonstrated walking backward as an effective exercise because of this task's increased energy expenditure as compared to walking forward. Flynn and Soutas-Little (1993*)* found that walking backward decreases the eccentric loading of the knee extensors, indicating that backward walking may be beneficial for persons with knee joint pain. Currently, there is sufficient temporal spatial literature on backward running, but little normative data on backward walking. The aim of this study is to add to the existing knowledge of backward walking through measuring and comparing stride lengths for 10 healthy adults when walking forward and backward. This study provides normative data for backward walking in graduate students from the United States. The researcher in this study hypothesizes that individuals will have shorter stride lengths during backward walking compared to forward walking.

METHOD

Subjects: Participants were recruited via convenience sampling. Participants did not have any current medical issues that would prevent them from participating in this study. Inclusion criteria were that the participants were currently enrolled in California State University, Dominguez Hills' graduate level prosthetic and orthotic program, and expressed willingness to participate in the experiment. Exclusion criteria included individuals who had a medical condition that would have prevented them from being included in this study, a desire to not participate in the study, for were not currently enrolled in a graduate level education program. *Procedures*: Data was collected under two conditions, forward walking and backward walking. For all data collection, subjects were instructed to start walking at a self-selected walking pace, beginning a few steps away from the mat, so that the data would better represent steady-state walking. For the forward walking condition, participants were instructed to make 6 barefoot walking passes on the Zeno Walkway at a self selected walking speed. For the backward walking condition, participants made 6 barefoot backward walking passes at a self selected speed, and were instructed not to look behind their back for visual feedback. One camera was positioned at one end of the walkway to capture a coronal view of the subject, and a second camera was placed midway through the room to offer a sagittal view of the subject. The recordings from the cameras were utilized to determine end of passes during data analysis. *Data Analysis*: For this experiment, a two-tailed paired sample *t*-test was used. The null hypothesis for this scenario is that there is no difference between the backward walking and forward walking condition on stride length.

RESULTS

Summary: After analyzing the data using the two-tailed paired sample *t*-test mentioned above, stride length was found to decrease significantly in the backward walking condition (p = 0.00000145). The forward walking condition had an average stride length of 137.95 cm (+/- 12.51cm), and the backward walking condition had an average stride length of 88.61 cm (+/- 11.68cm.

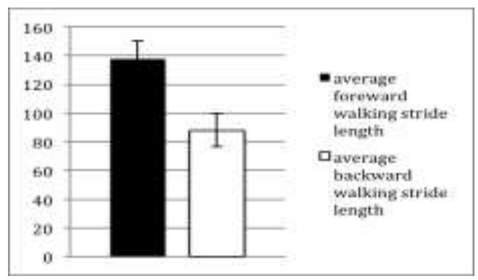

Figure 1

DISCUSSION

As discussed earlier, stride length decreased significantly in the backward walking condition (p-value <0.05), which rejected the null hypothesis, and reinforced the hypothesis that backward walking leads to a decreased stride length compared to forward walking.

CONCLUSION

Future studies should investigate if backward walking can aid in proprioception and balance in different pathological or aging populations.

CLINICAL APPLICATIONS

This data could be used to compare healthy individuals to persons with pathology for future studies.

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Pressure Gradient Response of Prosthetic Insert Materials

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INTRODUCTION

Elevated pressures between an amputee's residual limb and prosthetic socket can lead to discomfort, skin abrasion, and even skin breakdown (Mak et al., 2001). In addition, large pressure gradients (changes in pressure over distance) can lead to acute pain and irritation. To mitigate these high pressure regions, specific areas of the socket are often inset with softer materials, patients wear whole-limb gel-liners or socks, or patients receive a combination of gel-liner and insert. Pressure values in the literature range from as low as 121 kPa to as high as 400 kPa (Mak et al., 2001; Sanders et al., 1993). However, the pressure gradients at these locations were not reported. The purpose of this study was to compare the peak and gradient pressures of typical prosthetic materials and gel liner materials under standardized loading and geometric indenter conditions (simulating a bony-prominence).

METHOD

Five different prosthetic insert materials, Pelite® (P), medium density Plastazote® (PZ), a Solflex® soft crepe material (SC), Aliplast 4E® (A4), and Aliplast XPE® (AX), were prepared in square samples with dimensions of 50 cm by 50 cm and a thickness of at least 6 mm. Two different 3 mm gel liner materials, silicone (gS) and urethane (gU), were prepared following the same methods. A simulated tissue+bony-prominence indenter was developed, consisting of a polymer sphere (ball with radius=27 mm, hardness of Shore OO 69.8), within which a spherical-tipped (radius=11.12 mm) oak dowel was imbedded, 12.7 mm from the contact surface. A one degree of freedom compression platen was used to apply a 64.5 N force and a pressure mapping system (I-Scan System, Tekscan, Inc., Boston, MA) with sensor resolution of 62 sensel/cm^2 was used to capture pressure maps.

RESULTS

Average peak pressure and average pressure gradients were calculated using a custom program. Pressure gradients are represented as a change in pressure from the center of the pressure map to the outermost point of the pressure map (reported as kPa/mm). Average peak pressure values ranged from 99 kPa (A4,gU) to 275.67 kPa (AX,gU). Observed pressure gradients ranged from 4.12 kPa/mm (A4,gU) to 13.74 kPa/mm (AX,no liner). The average contact area was determined from the pressure maps (Figures 1 and 2) and ranged from 6.13 cm^2 (SC,no liner) to 13.70 cm^2 (A4, gU). Total contact area increased as material hardness decreased (Figure 2) and with the addition of a gel liner (Figure 1). The magnitude of the peaks of the pressure maps shown in the figures corresponds to pressure magnitude. Higher 3D map peaks indicate higher pressures.

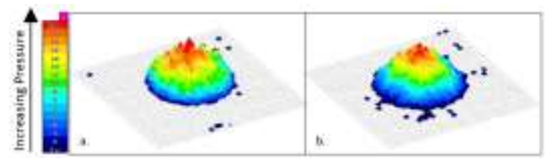

Figure 1.a) 3D pressure map, SC, No liner condition. b) 3D pressure map SC, sU condition 3D peak magnitude indicates pressure magnitude.

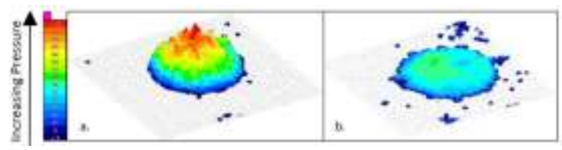

Figure 2.a) 3D Pressure map SC, No liner condition. b) 3D Pressure map PZ, No Liner condition. 3D peak magnitude indicates pressure magnitude.

DISCUSSION

Softer materials exhibited lower peak pressure, larger total contact areas, and thus lower pressure gradients. Softer materials were able to distribute the applied pressure over a larger contact area, reducing the peak pressure value. With the addition of a gel liner the increase in contact area is not as evident from the pressure maps, but for all materials the contact area increased by at least 1 cm^2 with the addition of a gel liner. Larger value pressure gradients and distinct gradient changes over the contact area are indicative of problem areas. High value pressure gradients could indicate the potential for pain or for surface blood flow occlusion leading to dermatological issues. The ability of the softer materials and the gel liners to distribute applied pressure over a greater contact area results in lower pressure gradients.

CONCLUSION

The addition of a gel liner on top of the traditional prosthetic insert materials increased the contact area and decreased the overall pressure gradient. As well, the gel liner reduced overall pressure gradient values and inter-contact area pressure gradient changes.

CLINICAL APPLICATIONS

Certain insert materials may not be suitable for all patient types. Understanding how each material distributes pressure can provide assistance to clinicians in achieving a successful prosthetic fit.

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PSYCHOSOCIAL ADAPATATION IN PEOPLE WITH LIMB AMPUTATION: A SCOPING REVIEW

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INTRODUCTION

Limb amputation has a drastic impact on individuals' physical, psychological and social functioning and long-term implications. Psychosocial adaptation is the complex and interactive process in which a person shifts from a state of disablement to state of enablement by the transformation from negative to positive well-being. Various studies have yielded a number of factors to account for the differences in psychosocial responses and successful adaptation to limb amputation. To successfully support adjustment and adaptation to limb amputation, a rehabilitation approach that is practically tailored to the diverse and complex needs of people with limb amputation is required in conjunction with a comprehensive understanding of the psychological complexities pertaining to the therapeutic context.

The aim of this study are;

- To examine and map the extent of scientific literature on psychosocial adaptation in people with limb amputation
- To examine the extent of the depth of evidence surrounding key factors of psychosocial adaptation in people post-limb amputation in different life stages at time of amputation
- To examine the potential future direction of research on psychosocial adaptation in people with limb amputation.

METHOD

The study has been undertaken by using Arksey's and O'Mally's scoping review methodological framework, in conjunction with the recommendations proposed by Levac and colleagues to enhance and clarify the scoping review methodological framework. The stages of the methodological framework for scoping review are: 1) identifying the research question; 2) identifying relevant studies; 3) study selection; 4) charting the data; 5) collating, summarizing and reporting; and, 6) consultation exercise. To identify relevant studies, the search strategy included electronic databases, reference lists of relevant articles, and hand searching of websites of relevant networks and organizations. Relevant search key words were developed in collaboration with an experienced librarian to ensure the quality of the search strategy. Literature published in English between 1995 and 2015 was searched through Medline and PubMed, CINAHL, PsycINFO, and EMBASE. A key term search strategy is employed using e.g. "psychosocial adaptation", "psychological adjustment", "quality of life" and "amputation". Study populations included children, teenagers, adult and older adults. Two reviewers utilize inclusion and exclusion criteria, based on research questions, to identify relevant articles. After selecting the articles, key information and data of the selected studies is charted. The results of the finding is collated, summarized and reported in a thematic construction to present a narrative explanation of existing literatures.

RESULTS

This study is under process. The current steps are study selection (the total of 666 papers from 4 databases; Medline and PubMed, CINAHL, PsycINFO, and EMBASE) by 2 reviewers, and data chart preparation by the first reviewers and information re-check by the second reviewer. The next step is to collate, summarize and report the findings, and is expected to be completed by February, 2017.

DISCUSSION AND CONCLUSION

In people with limb amputation, rehabilitation is primarily dependent on patients' psychological adjustment and adaptation to the injury. The adjustment process is influenced by various factors therefore healthcare professionals need to be aware of the complexity and diversity of psychological responses, issues and adaptations that may influence rehabilitation outcomes. With the comprehensive, systematic methods to explore the recent literature, the extent of scientific literature and the depth of evidence surrounding key factors of psychosocial adaptation in people with limb amputation is assessed and represented.

CLINICAL APPLICATIONS

The adjustment process is influenced by various factors therefore healthcare professionals need to be aware of the complexity and diversity of psychological responses, issues and adaptations that may influence rehabilitation outcomes.

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REPETITIVE LOADING SKIN TRAUMA: THE EFFECTS OF SOCK MOISTURE ON THE COEFFICIENT OF FRICTION AGAINST ORTHOTIC MATERIALS

Degner-Ell, K. H.
Concordia University, St. Paul, Minnesota

INTRODUCTION

The primary aim of this study was to quantify and compare the change in the coefficient of friction (COF) between commonly worn sock materials and common foot orthosis materials when moisture is introduced to the sock. Research has established four primary forces contributing to wounds caused by repetitive loading: pressure, friction, shear and moisture (Carlson, 2006). Research exploring the onset of wounds has found that the greater the interface COF, the more likely for wounds to occur in fewer repetitions than lower interface COF (Naylor, 1955). Therefore, a material interface with a lesser COF keeps skin safer from repetitive loading injury than a high COF interface.

METHOD

All testing was conducted at Tamarack Habilitation Technologies, Inc. in Blaine, Minnesota.

Independent variables: Six 8.89cm x 7.62cm samples of four different sock materials: cotton, nylon, polyester and wool were tested against five different orthotic materials: Spenco®, Poron®, Plastizote®, leather, and ShearBan®(PTFE).

Apparatus: The static COF was measured by a tilt-slip machine. The machine records the angle at which the sled slides across the orthotic material to determine the static COF of the interfacing pair. (COF = tan θ, where θ is the angle of slippage.)

Procedures: Each dry sock sample was weighed and cycled through the tilt machine against an orthotic material. After being fully saturated with distilled water, samples were weighed before each cycle of testing until all samples achieve their initial dry weight. This was performed for each sock to orthotic material interface combination. Sock moisture saturation was determined by the equation: $(S_w - S_d)(1/S_d)(100)$; where S_d = dry weight and S_w = wet weight.

Data Analysis: The data were best compared using graphical analysis due to the small sample size and the exploratory nature of the study. Relevant data selected from testing corresponded to COF values representing dry and damp socks only: 0% and 20-30% moisture saturation, respectively.

RESULTS

In general, average COF increased with the presence of moisture. For some tested pairs, the presence of moisture influenced the COF greatly, such as the testing of nylon or cotton socks. Other testing pairs demonstrated very little change in COF values, such as pairings with wool and polyester socks.

DISCUSSION

Plastazote® had the greatest average COF value for all dry and damp sock pairings. Conversely, ShearBan® had the lowest average COF. This data can be combined with knowledge of additional material characteristics and patient presentation to guide wound management and prevention decisions.

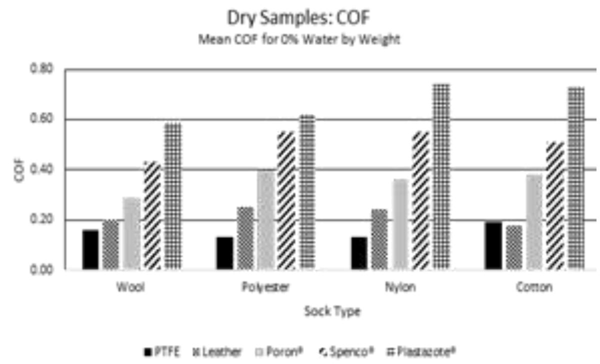

Figure 1. Dry Samples COF: 0% Water by Weight

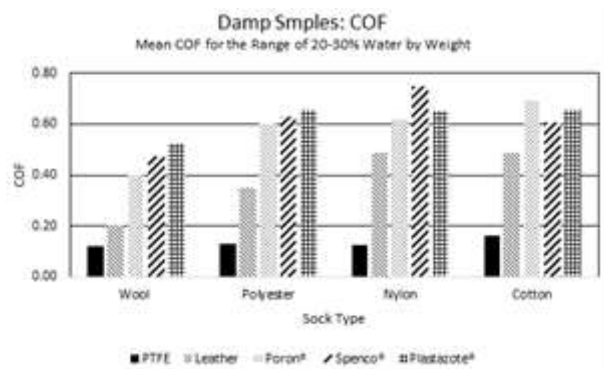

Figure 1. Damp Samples COF: 20-30% Water by Weight

CONCLUSION

ShearBan® maintained a low COF across each sock type as well as throughout saturation levels. A consistently low COF interface such as ShearBan® can protect high risk skin from exposure to damaging forces by allowing more repetitions before elevating wound risk.

CLINICAL APPLICATIONS

Exploring how forces change with different material interactions/environmental conditions pertaining to a foot within a shoe builds a basis for clinical recommendation to reduce repetitive loading foot wounds. This inherently reduces wound related costs, infection risk and decreases lower extremity amputations due to non-healing foot wounds.

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STUDY OF NEW MEASUREMENT METHOD FOR CENTER OF PRESSURE AND FOOT SHAPE

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INTRODUCTION

Evaluation of the center of pressure (COP) in walking analysis is an important indicator in determining whether walking is efficient, and it is often used in design conformance evaluation for shoes and arch supports.

The main evaluation methods use ground reaction force plates and insole-type pressure sensors.

With ground reaction force plates, it is difficult to identify the location of the COP position even if the COP trajectory is shown.

With insole-type pressure sensors, the maximum pressure point in the plantar surface can be determined, but since these sensors use pressure-sensitive conductive ink, their precision is low compared with force plates. Moreover, because they are inserted into shoes, it is difficult to make evaluations with bare feet.

In this study, using a force plate and three-dimensional motion analyzer, we devised a system that measures COP coordinates in the plantar surface.

METHOD

The subjects were 10 healthy female university students and 20 feet. The task was normal walking. The measurement devices used were 12 three-dimensional motion analyzers with infrared cameras and six force plates.

The subjects wore sportswear and leggings, and were barefoot. Infrared reflection markers with a diameter of 10 mm were attached in 18 places each leg and foot. The markers were attached on the first, second, and fifth distal phalanxes, metatarsal head, metatarsal base, navicular tuberosity, foot high point, sustentaculum tali, peroneal trochlea, and calcaneal tuberosity.

The measured marker coordinate positions and ground reaction force were calculated using Body Builder data processing software, and synchronized using Scilab numerical calculation software. With regard to the foot position, the timing at which the value of each marker was the smallest on the Z-axis was judged to be a state of contact with the floor.

The foot shape measures were foot length, foot width, and navicular bone height. The values calculated from the distance between markers were compared with manual measurements made using a foot gauge, measuring tape, and height gauge.

Tests of significant differences between the two groups were done using a two-tailed Wilcoxon t-test, with <5% indicating statistical significance.

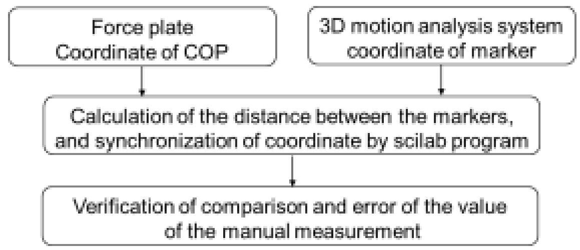

Figure 1. Procedure of analysis

RESULTS

No significant differences were seen between any of the items, and the error between manual measurements of foot shape and the new measurement method was approximately 1–2 mm. The trajectory of the COP in the plantar surface could be shown by synchronizing the foot marker coordinates and COP coordinates.

	Error(mm)	Significance difference
Foot length	**1.3±0.6**	n.s.
Foot width	**1.4±0.3**	n.s.
Navicular bone height	**1.7±1.2**	n.s.

Figure 2. Error and Significance difference

DISCUSSION

The small error between the manual measurements and the measurements with the new method likely stems from the bone landmarks projecting from the vertical plane, and being attached so that they were superimposed on the center of the markers.

It is conjectured that since the calcaneal markers could not be projected vertically from the calcaneal shape, the error could be corrected by adjusting the position at which the markers are attached to the distal phalanx of the hallux.

CONCLUSION

The proposed method overcomes the disadvantages of using force plates and insole-type pressure sensors for evaluation of the COP in walking analysis.

CLINICAL APPLICATIONS

The COP trajectory was obtained with high precision even with measurements in bare feet, and useful in evaluating walking efficiency.

SYMMETRICAL KINEMATICS DOES NOT IMPLY SYMMETRICAL KINETICS IN GAIT INVOLVING PERSONS WITH A UNILATERAL TRANSTIBIAL AMPUTATION

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INTRODUCTION

In the field of prosthetics it is fundamentally understood that there is asymmetry in gait among those with unilateral lower-limb amputation. This asymmetry has been associated with increased energy costs as well as long-term complications such as increased joint loading, joint pain and resulting osteoarthritis (OA) in the intact limb. There remains an uncertainty among prosthetists regarding whether or not this asymmetry is disadvantageous or functional for the amputee. Restoration of independence and reducing the likelihood of comorbidities remains a primary goal for the clinical prosthetist. The goal of this study is to better understand the relationship between kinematics and kinetics of gait. We hypothesize that with controlled kinematics, kinetic aspects of gait required by each limb will be asymmetric.

METHOD

Subjects:1 unilateral trans-tibial amputee

Grail Protocol: 12 infrared cameras (Vicon Motion Capture) 100 Hz; 6 DoF force platforms underneath split-belt treadmill (ForceLink) 1000 Hz; EMG- 14 channel wireless EMG (Delsys Trigno) operating at 2500 Hz

Data Collection: kinetic and kinematic data collection will begin with symmetrical belt speeds at 1.2 m/s; belt speed will then be adjusted in .05 m/s increments until symmetrical stride length is attained and data will be collected.

Analysis: Gait Offline Analysis Tool (GOAT) will be used to analyze the kinematic and kinetic data. With further progression of data collection, a paired two-tailed t test will be used to compare the percentages of asymmetry.

% asymmetry = (sound limb data - amputated limb data)/(average of sound and amputated limbs)X100

RESULTS

In figure 1, the subject reached the maximum knee abduction moment at 1.3 m/s. Asymmetry of peak ground reaction force (GRF) increased as belt speed increased. Increasing asymmetry indicates increasing loading on sound side. Step length asymmetry of amputated side increases as belt speed increases.

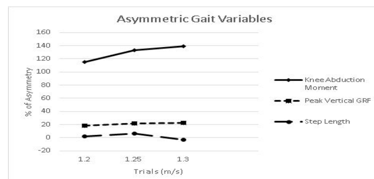

FIGURE 1; A positive percentage indicates the sound limb measured a greater magnitude for the variable in question.

DISCUSSION

Knee moments and GRFs are used in this study because of their role in the mechanical joint loading associated with OA for lower limb amputees. The data shows that there is a positive correlation between knee abduction moment and peak GRF when the belt speeds increase; therefore, it may not be advantageous for the amputee to ambulate at increased speeds.

CONCLUSION

Preliminary data shows that, as the belt speed increases the amputee's sound leg experiences an increase in peak vertical GRF. We can therefore postulate that in an attempt to create symmetry gait in amputees, the resulting outcome could lead to increased joint loading and long term OA.

CLINICAL APPLICATIONS

In the prosthetic profession, the main goal is to restore functional independence and reduce the likelihood of developing comorbidities such as osteoarthritis. In trying to achieve this goal, a prosthetist will align a person with a lower limb amputation so that they walk with a symmetrical gait pattern. Therefore, this study is to explore the validity of assuming symmetrical kinematics lead to symmetrical limb loading in a laboratory environment.

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The Effectiveness of off-the-shelf TLSO's in Restricting Gross Motion of the Spine

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UT Southwestern Prosthetics-Orthotics Program

INTRODUCTION

The purpose of this research is to quantify the motion limiting effects of off-the-shelf thoracolumbosaccral orthoses (TLSO), more specifically the DeRoyal Ultralign TLSO (DR) and the Orthoamerica AirBack TLSO (OA).

There is little research on the effectiveness of off-the-shelf TLSOs and no current research examining gross motion restriction provided by the DR or the OA TLSO. This study compares each subject's gross spinal flexion (GSF) and gross spinal extension (GSE) in both non-braced and braced conditions. Each subject was fit with each orthosis by a certified orthotist or orthotic resident.

Using two 3D accelerometers that capture motion in all planes, the subject's gross spinal motion was calculated in the non-braced and braced conditions. In order to evaluate patient satisfaction in each braced condition a comfort questionnaire was distributed after data collection of each research participant. The data collected was analyzed using Microsoft Excel.

This hypothesis is that the subjects GSE and GSF will be restricted >50% in the TLSOs compared to the non-braced condition.

METHOD

Subjects: 10 participants; 5M, 5F *two male subjects were used to process data due to signal contamination.

Apparatus: 2 Yost lab 3-space Wireless 2.4GHz DSSS sensors

Procedures: The sensors were calibrated for each subjects resting standing position. 3 trials of maximum gross spinal flexion and extension were performed in the non-braced condition. The subjects were then fit with the TLSO by a certified orthotist. 3 trials were then performed in each TLSO. Lastly, the subjects completed a 10-question comfort satisfaction survey.

Data Analysis: The data was exported into Excel and analyzed. Clinical significance will be set at a motion restriction greater than 50%

RESULTS

Subject 1's average gross spinal flexion (GSF) and gross spinal extension (GSE) in the non-braced condition was greater than Subject 2's (GSF: 73.47°, 71.43°; GSE: 50.2:41.3°). The values for the in-brace GSF and GSE were normalized for each subject. Subject 1 retained 74.17% of GSE compared to Subject 2 who retained 61.50% of GSE while wearing the DR. Subject 1 retained 50.80% of GSE compared to Subject 2 who retained 24.54% of GSE while wearing the OA. Subject 1 retained 52.90% GSF compared to Subject 2 32.76% of GSF while wearing the DR. Subject 1 retained 27.54% compared to Subject 2 who retained 51.52% of GSF while wearing the OA.

DISCUSSION

The data processed did not lead to any conclusive results; mainly due to the small sample size. The research team expected each orthosis to limit motion compared to the non-braced condition; however, it is unclear how much motion was restricted. The OA was better at restricting both GSE and GSF compared to the DR (GSE: 62.33% OA: 32.17% DR; GSF: 60.47% OA: 57.17% DR). Only the OA was able to reject the null hypothesis and limit >50% of GSE, however, both the OA and DR rejected the null hypothesis and were able to limit >50% of GSF. The results of the comfort satisfaction survey from all 10 original subjects showed that the DR was more comfortable and easier to don, and the OA seemed more hygienic and easy to clean.

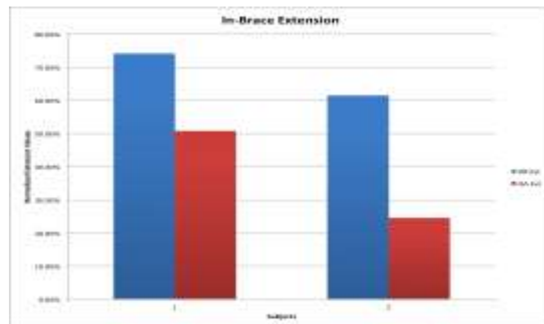

Figure 1. Normalized values of subject's GSE wearing the DR (blue) and OA (red)

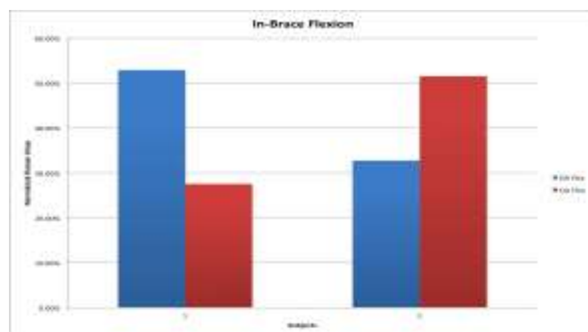

Figure 2. Normalized values of subject's GSF wearing the DR (blue) and OA (red)

CONCLUSION

Considering the aforementioned limitations, the findings are inconclusive. Future studies should include a larger number of subjects to provide better inter-brace comparison. Digital fluoroscopy would also provide the most accurate measure of motion restriction within a brace.

CLINICAL APPLICATIONS

Despite widespread use of spinal orthoses, proof of their effectiveness is lacking. Practitioners need the most current evidence based research to make the best clinical decisions for their patients, and to backup observed benefits.

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The Effects of a Modified Golf Stance on Transverse Plane Socket Reaction Moments in Unilateral Transtibial Amputees

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INTRODUCTION

The conventional golf stance has been extensively studied for able-bodied golfers; however, it has not been documented for unilateral transtibial amputee golfers. The conventional golf stance can be detrimental to the musculoskeletal system of the golfer (Cole, 2016). Even though these detriments have been studied in intact individuals, it would seem apparent that the stance can be just as detrimental to unilateral transtibial amputees.

The transverse plane is the least studied and least understood plane of the human body (Meister, 2011). There are few reliable methods for measuring moments in this plane of motion. By using advanced technology that can attach directly to the prosthesis, this plane can be further explored. The most important factor of studying the transverse plane in relation to socket reaction moments is trying to understand how those moments affect the human body.

METHODS

Subjects: 3 male subjects, ages (45-68) (K3-K4), with no co-morbidities. All subjects used their own prosthesis and their own golf clubs.

Apparatus: Intelligent Prosthetics Endoskeletal Component System (iPecs) to measure magnitude and timing of socket reaction forces and moments in the prosthesis, Trackman Golf System to measure ball distance (DIST).

Procedures: The iPecs was attached to each subject's prosthesis for each set of conditions (stance type). On each of two test days, the subjects were asked to hit 7 – 10 balls using each of the following clubs: a driver (D), a mid-iron (5 or 6 iron) (I), and their typical wedge (W). During the first session, each subject used their own conventional stance (C). One week later, subjects performed the same number of swings using the same clubs a week later using the modified golf stance (M) they learned during the previous week. All testing was done on a standard driving range with ambient conditions monitored and documented. For each trial, the iPecs device measured Fx, Fy, Fz (axial) and Mx, My and Mz (axial) at a sampling rate of 500 Hz. The iPecs was zeroed between trials. The Trackman measured ball speed, club head speed, and ball distance for each trial.

Data Analysis: The means of the distances, axial socket reaction moments (ASRM), and time for peak-to-peak ASRM (TPASRM) for each stance (TYPE) using each club (CLUB) were calculated and compared for all of the subjects

RESULTS

Preliminary results comparing the ASRM and TPASRM for each TYPE indicate that ASRM and TPASRM are reduced with M when compared with C after controlling for ball distance (DIST). Statistical analyses are currently in process.

TYPE	CLUB	DIST	ASRM	TPASRM
C	D	233.9 (5.12)	34.6 (2.53)	0.408 (0.059)
M	D	240.0 (8.6)	22.2 (1.0)	0.292 (0.035)
C	I	149.0 (9.88)	30.3 (2.53)	0.446 (0.058)
M	I	163.4 (11.0)	25.5 (3.6)	0.419 (0.024)
C	W	115.3 (1.58)	30.9 (2.53)	0.444 (0.035)
M	W	115.2 (5.0)	23.6 (2.24)	0.424 (0.015)

Table 1. Mean (SD) Distance (DIST) (yd), Axial Socket Reaction Moment (ASRM) (Nm), and Time to achieve peak-peak torque (TPASRM) (s) for one subject.

DISCUSSION

The results of the study indicate that the modified golf stance reduced ASRM while using each club type when compared with the conventional golf stance. Aside from the average distance of the wedge shots for each stance, the distance slightly increased using the modified stance. The reduction of ASRM suggests smaller shear forces are exerted on the residual limb and its surrounding tissues, areas that are susceptible to injuries and skin breakdown from shear forces (Sanders, 1993). If a reduction in shear on the residual limb decrease the risk of injuries to the residual limb of lower limb amputee golfers, it may encourage them to participate in the activity. More regular participation could lead to improved quality of life (Bragaru et al., 2011).

CONCLUSION

In this pilot study, altering the posture of the body during the golf swing reduced axial socket reaction moments with no detrimental effect on ball distance. Further data analyses are being conducted.

CLINICAL APPLICATIONS

The application of a potentially less detrimental golf stance linked with better performance may improve quality of life of patients by encouraging amputee golfers to participate in their sport more regularly.

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THE EFFECTS OF AFO FOOTPLATE LENGTHS ON KNEE EXTENSION MOMENT DURING TERMINAL STANCE

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INTRODUCTION

Footplate length of an AFO is thought to effect knee moments during the gait cycle; however, an industry-wide standard for a footplate length determination is not currently available. The purpose of the study was to investigate the effects of AFO footplate length on knee extension moment in terminal stance to help orthotists make clinical decisions that most benefit their patients.

Several studies show a significant difference between being braced with an AFO and non-braced, and that AFOs can significantly increase stability at the ankle. A study by Tyson et al. found that solid ankle AFOs would improve gait abnormalities, therefore decreasing energy expenditure. Malas concluded that a solid ankle AFO can provide indirect stabilization of the knee and hip. Thomson et al. and Hullin et al. found significance between the patients being braced or non-braced, but they did not focus on footplate length as a variable in their studies. Finally, Fatone et al. concluded that full length footplates increased peak extension moment. Of all of these studies, very little conclusive evidence was found concerning the effects of the length of the footplate on knee kinetics.

METHOD

12 subjects from a healthy population free of any gait abnormalities were recruited to wear a custom right thermoplastic solid ankle AFO and undergo walking tests over an AMTI force plate. Temporal and spatial parameters were collected using an OptiTrak 3D motion capture system with 8 cameras and Motive software. Raw data was processed using Matlab and Visual 3D. Three lengths of footplate were used (full length, sulcus, and metatarsal heads), and the data from each condition were compared using one-way repeated measures ANOVA ($p<0.05$) and paired t-tests. It was hypothesized that subjects would experience a greater knee extension moment in terminal stance with longer length footplates compared to shorter length footplates.

RESULTS

The results of the study showed a significant difference between the non-braced condition and an AFO with full footplate, as well as between the non-braced condition and the AFO with sulcus footplate (Figure 1). There was no significant difference found between the non-braced condition and AFO with a footplate trimmed behind the metatarsals. There was a trend between footplate lengths, with extension moment increasing as footplate lengths increased, but there was no statistical significance.

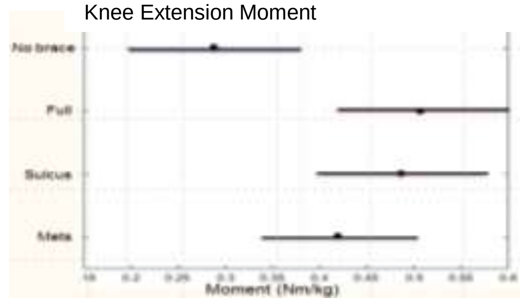

Figure 1. One-way repeated measures ANOVA showed significance in the knee extension moment ($p=.0105$). Results of the post hoc analysis with paired t-tests are shown in the graph.

DISCUSSION

There was not enough evidence to support the hypothesis, as there were no statistically significant differences in knee extension moments observed between the different footplate lengths. However, a trend was seen that the knee extension moment decreased as the footplate was shortened. No significant differences were found in the temporospatial data. However, walking speed was self-selected and not controlled for.

CONCLUSION

These results lead to the conclusion that stopping dorsiflexion at terminal stance must be accompanied with a sulcus footplate or longer to create a significant knee extension moment in patients with non-pathological gait.

CLINICAL APPLICATIONS

Clinically, it can also be concluded that metatarsal length footplates are more appropriate for patients for whom an excessive knee extension moment is to be avoided, such as those with genu recurvatum and ligamentous laxity, since that length did not significantly increase extension moment from a non-braced baseline.

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THE EFFECTS WHILE CARRYING A DUAL STRAP BACKPACK OVER BOTH SHOULDERS

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INTRODUCTION

As the human body carries a load, the body's posture, gait and center of pressure are altered to keep the body mass centered. The center of mass location is dependent on the center of pressure (CoP) location. CoP is the point of the location of the vertical ground reaction force vector (Jamshidi, 2010). Adding a load results in an impact increase of the gravitational force for the body, challenging the body's ability to maintain balance. Adding a load also requires larger muscle forces and moments to control balance, leading to an increase in CoP displacement (Costello, 2012).

With normal walking, the center of pressure shifts in all directions to maintain symmetry and balance. During ambulation with a load, the demand to maintain stability and balance is heightened. The body's CoP location can be altered impacting the patient's ability to control their balance. The purpose of this study is to investigate the effect of backpack carriage on CoP distance during stance and single support phases of gait. A young adult student population will carry a backpack weighing 25 lbs. over both shoulders while walking normally. I hypothesized that the CoP distance will increase with weight carriage during stance and single support phases of the gait cycle.

METHOD

Subjects: 4 males and 6 females; ages 23 to 31, mean age of 25.7 years old; one participant had a transtibial amputation and used a prosthesis.

Apparatus: The ProtoKinetics Zeno Walkway Mat was used to collect data for this study. Four books with a total weight amount of 25 lbs. were placed in a backpack weighing 2.6 lbs.

Procedures: As each participant entered the room, they were instructed to stand just before the beginning of the Zeno Walkway mat. The participants were handed the backpack weighing 27.6 pounds and were were instructed to make 6 passes on the mat at a self-selected pace. The anthropometric data that was collected was stance CoP distance (cm) and single support CoP distance (cm) (SS CoP).

Data Analysis: The variables collected for this study were CoP distances (cm) during stance and single support. CoP stance and SS distances were compared with and without a backpack. A two-tailed, paired T-Test was conducted in order to test the possibility of the relationship in both directions.

RESULTS

There was no significant difference for CoP during stance phase when comparing backpack carrying to baseline, however, there was a significant difference between conditions during single support. The P-value for single support CoP distances with a backpack versus without a backpack were 0.0009, showing a statistical significance.

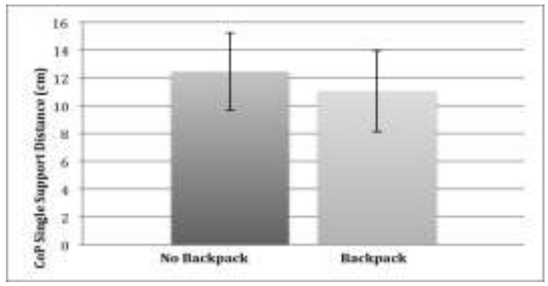

Figure 1. CoP distance (cm) during single support

	BASELINE	INTERVENTION
MEAN	12.457	11.064
STANDARD DEVIATION	2.764	2.901
	P-VALUE = 0.0009	

Table 1. Single Support CoP distance (cm) results

DISCUSSION

Once a heavier weight was added to ambulation, CoP distance was altered and decreased during both stance and single support. In a study conducted by Yamaguchi et. al (2016), they discovered that shorter step lengths result in reduced COP distances during human bipedal walking. When the participants took shorter steps, the CoM was moved anteriorly causing the CoP distance to decrease.

CONCLUSION

Further examination needs to be conducted to examine long term effects of heavy backpack carriage on the development of the body.

CLINICAL APPLICATIONS

Adding a load to our body can cause alterations in gait that can lead to impairments that may affect the body long term. Additional variables need to be recorded to determine how else the body is affected during ambulation while carrying a backpack.

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"The effects of DE-ROTATION Strap Harness on temporal-spatial data in able bodied individuals"

Tovar. M.A.

INTRODUCTION

De-rotation (Twister) straps, twister cables, and TheraTogs© have been be examined as a therapeutic intervention technique to decrease the degree of tibial torsion, internal rotation, and external rotation in children with spastic cerebral palsy and other associated pathologies. However, although there is limited research has been conducted highlighting the relationship between twister traps and temporal-spatial in children, there is no known research examining the benefits of de-rotation straps as an effective orthotic intervention in adults with gait abnormalities.

METHOD

Day 1

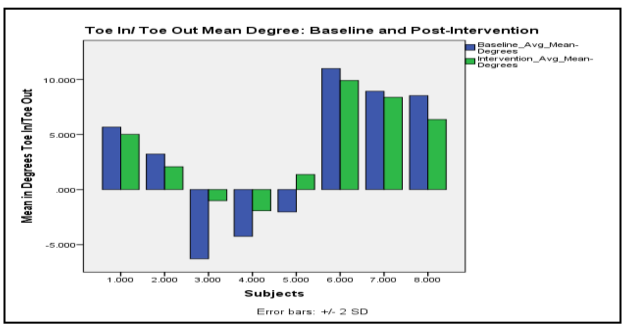
- 6 passes at self-selected walking speed (Zeno Walkway)
- Mean Toe-In Toe-Out angles recorded

Day 2

- De-Rotation harness applied to reduce clinical presentation
- 6 passes at self-selected walking speed (Zeno Walkway)
- Mean Toe-In Toe-Out angles recorded

RESULTS

Average mean of toe in/toe out angle data of able bodied college students presenting with internal or external rotation of the lower limb will be analyzed using IBM SPSS statistical software. Results from this data show A p-value of .493 ($p \geq 0.05$) determining no statistical significance in toe-in, toe-out angle from the line of progression with the application of the harness as compared to baseline.



Graph 1: SPSS Output graph reflecting the average means between baseline and intervention

Subjects ID	Sex	Age	Clinical Presentation
1	Female	25	Internal Rotation
2	Male	22	Internal Rotation
3	Male	24	External Rotation
4	Male	25	External Rotation
5	Female	24	External Rotation
6	Male	23	External Rotation
7	Male	27	Internal Rotation
8	Male	28	External Rotation

DISCUSSION

There is currently limited research on the effectiveness of these devices to eliminate excessive tibial torsion, anteversion and internal/external rotation in able-bodied adult populations during gait. The results yielded from this study determined that the effectiveness of a custom made de-rotation strap harness on the toe in/toe out angles after correcting excessive internal or external rotation during self-selected walking was not statistically significant. However, the sample size recruited for this study was too small to determine true statistical significance. Another limitation of the study was the unavailability of subjects who presented with severe toe in/toe out angles during gait as you would normally expect in more physically abnormal gait characteristics of those with pathologies.

CONCLUSION

Further research needed to investigate effectiveness of de-rotation strap orthosis in adults with rotational deformities/pathologies.

CLINICAL APPLICATIONS

De-rotation strap harnessing may be an alternative and less invasive intervention technique to help decrease abnormal joint rotational movements during walking.

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THE EFFECTS OF ISOKINETIC TRAINING OF HIP MUSCLES ON GAIT PERFORMANCE IN ABOVE-KNEE AMPUTEES

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INTRODUCTION

The weakness of hip muscles is a negative predictor of ambulation performance in above-knee amputees (Sansam, 2009). The isokinetic method is an effective exercise to improve strength of the targeted muscles in below-knee amputees (Klingenstierna, 1990). However, there is no evidence demonstrating the effect of hip strengthening exercises on gait performance. Furthermore, there are no studies of isokinetic exercise in patients with above-knee amputation. The purpose of this study was to evaluate the effects of isokinetic training of hip muscles on gait performance in above-knee amputees.

METHOD

Eight participants (6 male and 2 female, aged 25 to 70) from Southern Medical Rehabilitation Center, Songkhlanagarind Hospital, with unilateral above-knee amputation were included in this one group pre- and post-intervention, prospective study. The study was conducted from July to September 2016. Participants performed isokinetic training of hip muscles of the amputated limb, twice a week for 3 consecutive weeks. Outcome measures included gait analysis by Tailgait® system and peak torque of hip muscles of the amputated limb by isokinetic dynamometer (CON-TREX®) before and after exercise training program. Shapiro-Wilk test was used to normalize the data. Each parameter for pre- and post-training was analyzed with paired *t-test.* The level of statistical significance was set at *P*-value less than 0.05.

RESULTS

All eight participants showed significant improvement of mean peak torque of the hip muscles (Figure 1). However, there was no significant difference in the mean of velocity, cadence, step length, step time and percentage of stance and swing phase (*P*-values >0.05). For the amputated limb, there was a significant decrement of anterior-posterior pelvic tilt during stance phase. Furthermore, there were no significant changes on pelvic motion in horizontal and coronal planes as shown in Table 1.

DISCUSSION

This three-week isokinetic training program showed significant improvement of hip muscle strength. The main mechanism describing the result was neural adaptations. However, only muscle strengthening effected no significant change on gait parameters. The insignificant result may be due to an inadequate exercise training period. Since the participants had equipped their prostheses for over 5 years, they were used to the gait pattern which was gradually adapted. Another finding showed prolonged step time in intact limb compared with prosthetic limb. It was resulted from push off deficiency (Adamczyk, 2015). Further study should be conducted using the powered prosthesis system.

CONCLUSION

This study provides evidences of the efficacy of a three-week isokinetic training of hip muscles can improve hip strength and better pelvic control without any significant change in gait parameters.

CLINICAL APPLICATIONS

The aforementioned conclusion could provide some instructions to improve the above-knee amputee training program. To accomplish the better gait performance, the program should be accompanied with prosthetic training and gait re-education. However, the improvement of a prosthetic component to resolve the push off deficiency might be required.

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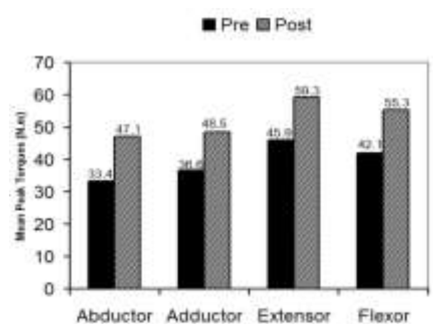

Figure1. Mean peak torques (N.m) of hip muscles in the amputated limb measured at pre- and post-training.

Parameters	Amputated limb		Intact limb	
	Pre	Post	Pre	Post
Velocity (m/s)	0.54(0.10)	0.53(0.13)	-	-
Cadence (step/min)	66.25(8.99)	64.50(7.67)	-	-
Step length (m)	0.46(0.04)	0.42(0.08)	0.43(0.07)	0.42(0.09)
Step time (s)	0.77(0.07)	0.73(0.05)	0.88(0.07)	0.92(0.07)
Stance phase (%)	54.67(2.56)	54.35(2.76)	71.62(4.31)	71.50(4.99)
Swing phase (%)	45.33(2.56)	45.65(2.76)	28.38(4.31)	28.50(4.99)
Gyro Y axis (stance phase)	6.22(3.01)	3.18(2.12)	-4.03(2.39)	-3.13(1.19)
Gyro X axis (stance phase)	-6.70(2.76)	-5.36(2.33)	-0.74(0.23)	0.85(0.37)
Gyro Z axis (stance phase)	4.25(2.01)	2.43(1.12)	-2.09(1.34)	-2.20(1.09)

Table 1. Mean(SD) of gait parameters measured at pre- and post-training.

THE EFFECTS OF POSTERIOR STRUT WIDTH OF A PLS ON ANKLE AND KNEE KINEMATICS

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INTRODUCTION

One common indication for ankle foot orthoses is foot drop, which occurs when the foot can no longer be actively dorsiflexed due to muscular weakness or paralysis. Often seen in pathologies such as stroke and spinal cord injury, footdrop affects both swing and stance phases of gait. Posterior Leaf Spring AFOs are commonly used to treat footdrop by both clearing the toes during swing and controlling plantarflexion (PF) during loading response to reduce footslap. Resistance to dorsiflexion (DF) and PF in PLS AFOs has been shown to decrease almost proportionally to reduction in posterior strut width (Sumiya et al 1996), however no standard for PLS trimlines currently exist based on patient presentation (Novachek, 2007). In the previous iteration of this study, different heights, plastic thicknesses, and strut widths of PLS AFOs were shown to achieve similar DF range but significantly different PF range using a motorized ankle device (Keith & Marsh 2015). The purpose of this study was to investigate the effects of posterior strut width on ankle and knee kinetics and kinematics on healthy subjects. It was hypothesized that as posterior strut width decreases, peak DF/PF angles would increase, and peak DF/PF moments and knee flexion/extension moments would decrease.

METHOD

Subjects: 12 subjects, 4 male, 8 female, ages 22-32,

Apparatus: OptiTrack motion analysis system, AMTI force plates, overground walkway

Procedures: We performed a standing trial to establish a baseline for each subject and collected three walking trials with the subjects wearing the PLS for each of the 5 trimline percentages. Trimline percentages tested were from 40% of the malleolar circumference to 20%, decreasing in 5% increments. Ground reaction force, joint angles, and joint moments were collected.

Data Analysis: We used custom MATLAB software to synthesize the force plate data and synchronize it with the camera data. Custom Visual 3D script was used to analyze the processed data. A two way ANOVA was performed with an alpha=0.05.

RESULTS

This study analyzed peak plantar flexion and DF angle, peak plantar flexion and DF moments, and peak knee extension and flexion moments during stance. No statistical significance was found in these measures between subject height or trimline percentage. However, there was a trend that as strut width decreased, ankle range of motion increased.

We also compared our peak values to plus or minus one standard deviation of normal gait. Peak plantar flexion angles remained within the standard deviation from normal, while DF was slightly limited. Values for peak ankle moments during stance were all within the normal gait range. Finally, peak knee flexion moments during gait were decreased while peak extension moments were slightly increased.

DISCUSSION

We rejected the hypothesis that change in strut width or patient height had an effect on peak ankle angles or moments, and peak knee moments during stance.

While not significant, a general trend existed in increasing peak angles at the ankle as strut width decreased, effectively allowing more normal gait parameters to be achieved. No undesirable moments at the ankle were observed. Of high clinical importance, there was no significant knee flexion moment at loading response removing the concern of instability. The peak knee flexion response was found to be less than normal gait, while the knee extension moment was greater when compared to normal gait. This would need to be isolated to determine cause.

In the future, we aim to examine how PLS strut width changes affect those with pathological gait, and if a PLS is appropriate for patients with genurecurvatum.

CONCLUSION

For able bodied subjects with normal gait patterns, there is no statistically significant affect on peak angles and moments at the ankle, nor peak moments at the knee, when reducing the trimline from 40-20% of malleolar circumference for short, average, and tall subjects.

CLINICAL APPLICATIONS

The findings further support current clinical indications for a PLS AFO that are common practice. By finding that peak values fall within (or near) one standard deviation of normal gait it can be suggested that the PLS AFO provides assistance during swing phase while having minimal effects on the remainder of the gait cycle. This study also shows that strut widths between 20%-40% of malleolar circumference provide negligible differences at the knee and ankle, and therefore can save time during fabrication and fitting.

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THE EFFECTS OF STRUT LAYUP AND WIDTH ON CARBON FIBER AFO STIFFNESS

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INTRODUCTION

Carbon fiber is a resilient, lightweight material that can store and return energy (Hastings, et al., 2015). Carbon fiber AFOs have improved ankle range of motion, angular velocity, and power generation in patients with impaired plantar flexors (Desloovere, et al., 2005). The stiffness of a carbon fiber AFO must be appropriate for each patient in order for them to deflect the strut and see improved gait parameters (Hastings, et al., 2015; Arch, et al., 2016; Hawkins, 2010). Design of these AFOs affects their stiffness (Bartonek, et al., 2007; Hawkins, 2010; Hastings, et al., 2015; Wach, 2015). This study sought to determine the effects of strut layup and width on carbon fiber AFO stiffness. Strut width reductions might allow for post-fabrication stiffness adjustability.

METHOD

Apparatus: Computer-controlled motorized device (Danaher motion Inc., USA) with inline torque sensor (Transducer Tech Inc., USA) and optical encoder.

Procedures: Three carbon fiber AFOs were fabricated from the same average sized model with a height of 16 inches. The three AFOs differed only in the composition of the strut layup. Strut layups were comprised of 3, 5, and 7 layers of unidirectional carbon fiber between bidirectional twill carbon fiber. Each AFO was attached to the computer-controlled motorized device and moved into 20° dorsiflexion and 10° plantarflexion. Three, 60 second trials were completed for each strut width from 2.5 inches down to 1 inch. Templates of each strut width were used to decrease the strut width by 0.5 inches.

Data Analysis: Angular deformation and torque resistance data from the computer-controlled motorized device was digitally filtered. A two-way ANOVA with repetition and paired T-tests were performed to determine significance for layup and strut width in all conditions. The level of significance for this study was set at $p < 0.05$.

RESULTS

	Stiffness (Nm/°)		
Strut Width (in)	**3-Ply Layup**	**5-Ply Layup**	**7-Ply Layup**
2.5	3.06	5.91	7.02
2	2.43	5.86	7.61
1.5	3.56	5.49	7.97
1	2.39	4.86	6.73
Average	*2.86*	*5.53*	*7.33*

Table 1: Average stiffness of each carbon AFO layup and strut width condition.

Stiffness values were calculated as torque resistance over angular deformation. Table 1 shows average stiffness of the carbon fiber AFO for each condition. For each strut width, stiffness increases as the number of carbon layers in the strut layup increases. When looking at strut width, the 5-ply strut layup is the only layup that shows a linear decrease in stiffness for each strut width reduction. The 3-ply strut layup and 7-ply strut layup do not consistently decrease in stiffness with each strut width reduction.

A two-way ANOVA showed significance for layup, strut width, and interaction. Post hoc paired T-tests showed that stiffness of all conditions regarding layup were statistically significantly different, but only some conditions regarding strut width were significant.

DISCUSSION

The study demonstrated the impact of altering strut layup thickness. No overlap in stiffness values was found between the 3-ply, 5-ply, and 7-ply layups, regardless of strut width. Coincidentally, stiffness values averaged near the ply count for each orthosis. Clinicians might use this as a simple estimate of the stiffness of the AFO they would be providing. Future studies should consider in-between ply counts, such as 4-ply and 6-ply. Strut width reductions might then be effective in bridging gaps in stiffness between similar layups.

CONCLUSION

There was a significant difference in the stiffness of the three carbon fiber AFOs in regards to layup thickness. The data does support the importance of identifying an appropriate strut layup thickness to match the activity level, body type, and deficit of each patient. This study was not able to confirm whether strut width reductions could offer post-fabrication alteration to the stiffness of carbon fiber AFOs. These reductions were successful in only one of the three conditions tested. A range of stiffness values was achieved through layup alteration, supporting layup as the crucial component in the adjustability of these orthoses.

CLINICAL APPLICATIONS

Clinicians should carefully select a strut layup based on the patient's activity level, body type, and deficit because strut width reductions were not confirmed to offer post-fabrication adjustability of stiffness.

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THE EFFECTS OF TOTAL CONTACT INSOLES WITH METATARSAL PADS IN HIGH HEELS DURING THE GAIT CYCLE

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INTRODUCTION

High heels have been a staple of a woman's wardrobe for hundreds of years. Although the styles and heel heights have varied, the one thing that unchanged is the wearer has experienced more condensed pressure in the forefoot. Increased forefoot pressure can lead to pain, discomfort, and tension on the plantar aponeurosis (Yung-Hui & Wei-Hsien, 2005). Besides pain in the forefoot, increases in heel height have also caused various compensations such as lower back pain, shortened stride, muscle fatigue, and Hallux Valgus.

The aim of this study was to investigate whether a total contact insert (TCI) with a metatarsal pad (MT pad) would allow a woman wearing high heels to walk with a more efficient gait by spreading the impact force from the 1st and 2nd metatarsal to the entire forefoot.

METHOD

Subjects: Eight healthy women, between the ages of 23 and 33 and accustomed to walking in high heels.

Apparatus: Zeno Walkway by ProtoKinetics, total contact inserts with metatarsal pads, high heels

Procedures: The participants were instructed to walk in their heels for a total of twelve laps, six with the total contact insert (TCI) with metatarsal pad and six without the TCI

Data Analysis: Single Stance Center of Pressure and Stride Length were analyzed with the PKMAS software by ProtoKinetics. Two-way t-tests were employed for the statistical analysis, with the level of significance set at 5% ($p < .05$).

RESULTS

For single stance center of pressure, there was a significant increase ($p=0.048$) while there was not for stride length ($p=0.283$). All the participants claimed that the metatarsal pad increased their comfort level while wearing their high heels.

	WITH PAD	W/OUT PAD
SS COP Mean	5.221	5.077
SS COP Std. Dev	0.691	0.662
Stride Length Mean	132.920	133.599
Stride Length Std. Dev	3.400	3.828

Table 1.

DISCUSSION

The purpose of this study was to investigate if, while wearing high heels, perceived comfort could be increased by adding padding under the metatarsal heads. Stride length was used as a proxy for efficiency and SS COP for impact force.

For SS COP between conditions, there was a significant increase while there was not for stride length. All the participants claimed that the metatarsal pad increased their comfort level while wearing their high heels. The finding of increased comfort in using TCIs in high heels was consistent with those of Hong et al (2005).

Limitations of this study will be addressed in future studies. These limitations included small sample size, differing shoe construction (height, type), ununiform fabrication and placement of MTP in TCI, and not having the appropriate data measurement system to collect in-shoe pressures.

CONCLUSION

The results of this study were inconclusive and future work on the subject will need to have the limitations of this study addressed.

CLINICAL APPLICATIONS

The clinical relevance of this study is that further studies need to address how high heeled shoes impact gait and how gait can be improved while wearing high heels.

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The Effects of Visual Deprivation on Gait of Able Bodied Individuals

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The purpose of this study is to investigate how visual occlusion (VO) affects the gait stability of able bodied subjects. The effects of induced visual occlusion have not been widely analyzed in previous research. Understanding how visual occlusion affects gait may help prosthetic and orthotic clinicians provide better patient care. This study was designed to test the hypothesis that individuals walking with an eye patch will have a decrease in walking speed (WS, m/s) and single limb support (SLS, % of gait cycle). WS and SLS are used in this study as indicators of an individual's overall stability. Subjects gait was analyzed using a ProtoKinetics GAITRite® Walkway while walking with and without wearing an eye patch over their dominate eye. Results from this data show that there is a significant change in WS (p=.04). Data also show that there is no significant change in SLS (p=.57). Further study is needed to determine additional effects of VO on normal gait. However, decrease in WS may indicate less stability through gait and should be considered clinically relevant.

“THE INFLUENCE OF SOLE RIGIDITY IN SIMULATED BAREFOOT GAIT CENTER OF PRESSURE”

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INTRODUCTION

Currently, the difference between barefoot COP and shoed COP with varying sole stiffness has been examined during running, but not applied to a walking gait (Greenhalgh et. al, 2014). Many minimalist shoes, which often have flexible soles and low to no heel height, make claims that they simulate barefoot experiences (Ellingson, 2016) while providing protection from external physical threat such as sharp objects or weather conditions. Previously, it has been found that a traditional running shoe results in less forefoot function while running, decreasing forefoot influence over balance and stability (Greenhalgh et al, 2014). It was reported time spent reaching foot flat is related to ankle stability, with an ankle that is weight bearing greatly decreasing the likelihood of a sprain related injury. A variety of minimalist shoes are available on the market, ranging in sole stiffness that may affect dynamic COP. For individuals choosing a minimalist shoe, the range of available stiffness in shoe soles may be affecting the degree to which they are simulating a barefoot experience based on how their dynamic COP is changed with the sole stiffness.

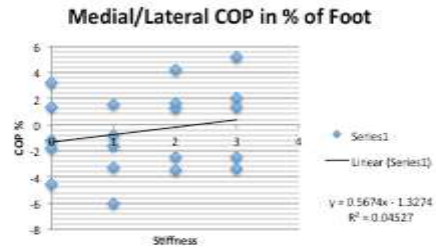
The purpose of this study is to examine the relationship between the sole stiffness of minimalist shoe COP measurements. Having a controlled and stable motion in joint kinematics, specifically that which affects the ankle, during able-bodied gait would in theory present without dynamic COP deviations from normal gait. These deviations are expressed in anterior/posterior (A/P) and medial/lateral (M/L) travel of the COP. If the dynamic COP movement with minimalist shoes is similar to that of a “normal” gait seen in barefoot ambulation, then it would be hypothesized for this study that as sole stiffness is decreased, there should be a detectable change in the dynamic COP, examined in A/P and M/L percentage

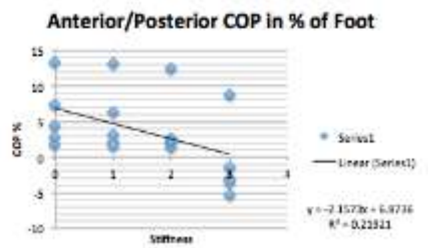
METHOD

Subjects: five females, ages 23-30
Apparatus: GAITRite, nike crossbionic free size 7.5
1/16”, 2/16”, 3/16” polypropylene footplate
Procedures: data was collected for six passes under four conditions: no plate, 1/16”, 2/16”, & 3/16”, under shoe insoles, respectively.
Data Analysis: COP % of foot in A/P and M/L were examined separately. An r^2 value was assigned to represent the data trend and the p-value was evaluated at p=.05 to determine if the data was significant.

RESULTS

The value of R for the anterior/posterior is -.4682, showing a negative correlation but with a weak realationship between variables. The p-value for anterior posterior is not signifacant at a p-value of $p < .05$. The value of R for the medial/lateral is .2128, showing a positive correlation but with a weak realationship between variables. The p-value for medial/lateral is not signifacant at a p-value of $p < .05$.





Statistical Data	Anterior/Posterior	Medial/Lateral
R-value	-.4682	.2128
R^2 value	.2192	.0543
P-value (p<.05)	.353131	.849591

DISCUSSION

Though a non-linear trend may be present, results are not significant and it is not possible to make a firm conclusion on these relationships with the data collected. A larger sample size would facilitate a better representation of potential patterns.

CONCLUSION

Some correlations exist, but data was not significant.

CLINICAL APPLICATIONS

If a pattern could be determined with future studies demonstrating more natural walking gait kinematics, it may have implications regarding shoe type selection and risk injury.

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THE USE OF KINESIO TAPE ON INFLUENCING GAIT VELOCITY OF ABLE-BODIED INDIVIDUALS

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INTRODUCTION

A common conception in gait is that the natural combination of joint movements , muscle activity, and energy use leads to a customary walking speed, stride length and step rate (Perry & Burnfield, 2010). The parameters are often used to assess pathological gait and can easily be effected by small deviations from the normal. One very common deviation from optimal is a pronated foot. This type of deviation can be found in persons with disability and those without. In the fitness world, Kinesio Tape is a very popular "quick fix" for muscle pains by pulling the muscles in different directions to optimally stretch the muscles. This style of pulling the muscles in the optimal direction is new in the world of orthotics but is starting to gain momentum. The hypothesis of this study is applying Kinesio Tape to the medial arch of able-bodied bare feet will significantly alter the normal walking speed compared to barefoot walking speed without any taping.

METHOD

Subjects: All able-bodied. Five men, 5 women. Mean age of 25.2 with a standard deviation of 2.98.

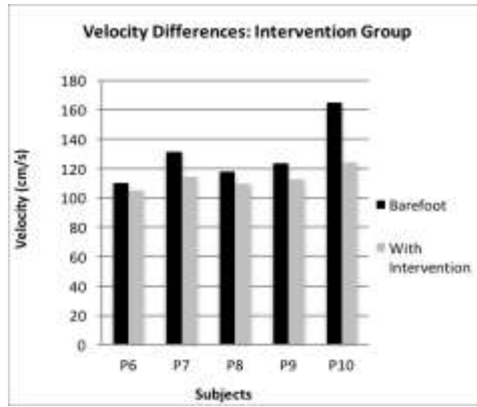
Apparatus: KT Tape, Protokinetics Zeno Walkway, PKMAS software.

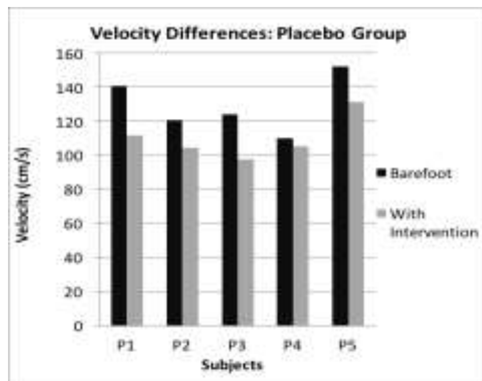
Procedures: Kinesio Tape was applied to half of the 10 applicants with a stretch and half without a stretch on left the medial arch, done by the author.

Data Analysis: A paired correlated T test was used to determine the significance value for both the intervention and the placebo data.

RESULTS

The results demonstrated that when participants had the Kinesio Tape stretch on their medial arch they walked significantly slower than barefoot walking without the Kinesio Tape. The group who received a placebo intervention did not walk significantly slower than their baseline barefoot walking.





DISCUSSION

This result provides a good base for further research into providing patients with quick, easy and a cheap way to improve their gait. Further research could show a route for patients to reduce the energy used during ambulation.

CONCLUSION

This study demonstrates that more research needs to be performed on the benefits of Kinesio Tape in ambulation.

CLINICAL APPLICATIONS

By positively effecting a patients gait we can reduce the energy consumed during ambulation which would have a positive effect on the person's health.

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March 1-4, 2017

Unilateral Transfemoral Amputee VO_2 Response to Graded Exercise Compared to Exercise Prescription Estimations

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Faculty Advisor: Frank J. Fedel, MS, CES

INTRODUCTION

In current practice, amputee rehabilitation focuses primarily on restoring functional capacity postamputation. There is a heavy emphasis placed on the ability to stand and walk with a prosthesis (Velzen *et al*., 2006), but little focus is placed on physical fitness beyond that needed to perform activities of daily living.

Aerobic endurance is one of the five components of physical fitness, and is commonly used to improve functional outcomes in a variety of pathologies such as cardiovascular disease. Aerobic endurance is primarily improved through lower-intensity endurance training, with intensity levels determined by ACSM guidelines (ACSM, 2013).

A common gauge of aerobic intensity is metabolic rate, which is measured by oxygen consumption, or VO_2. With endurance training, individuals will see a decrease in VO_2 values at the same work rate. The literature indicates that decreased exercise VO_2 values correlate with improved functional status (Waters & Mulroy, 1999). However, since amputees have a higher energy cost of ambulation (Goktepe *et al*, 2010), established guidelines may be inadequate.

The purpose of this study was to evaluate the applicability of current exercise prescription (ExRx) guidelines designed for the general population to healthy transfemoral (TF) amputees.

METHOD

Subjects: 3 established (>15 years with prosthesis) nondysvascular transfemoral amputees (K3/K4) ages 30-41 with no comorbidities. All wore their usual ischial containment sockets and microprocessor-controlled knees. None used assistive devices.

Apparatus: Physical Activity Readiness Questionnaire (PAR-Q), treadmill, Polar heart rate monitor, PARVO Medics TrueOne 2400 metabolic cart.

Procedures: The PAR-Q was used to determine risk level for clinical exercise testing. Subjects' heart rates, respiratory rates, and rates of oxygen consumption were measured using the PARVO during administration of the Ebbeling treadmill protocol, a two-stage clinical submaximal VO_2 test (Table 1). Resting and recovery HR and BP were taken manually, while exercise HR was recorded using the Polar monitor.

Data Analysis: Calculation of mean of steady-state relative VO_2 data during warm-up and exercise stages. Estimated relative VO_2 data was calculated using ACSM metabolic equations for treadmill use.

RESULTS

Relative VO_2 values for the amputee subjects were 3-4 mL/kg/min greater than what was expected based on normative data from nonpathologic populations. However, VO_2 response from 0% incline to 5% incline (ΔVO_2) increased 1.46 mL/kg/min, approximately 30% less than the estimated ΔVO_2.

	Warmup VO2 (mL/kg/min	Exercise VO2 (mL/kg/min)	Δ VO2 (mL/kg/min)
Estimated	8.9	13.7	4.8
Measured	13.27	16.62	3.34

Table 1. Estimated and measured (mean value) oxygen consumption at warm-up (2.0mph and 0.0% grade) and exercise (2.0mph and 5.0% grade) workloads

DISCUSSION

The subjects tested all showed higher metabolic demands than would be expected of non-amputees. This is likely due to the decreased gait efficiency caused by compensatory mechanisms such as vaulting or hip-hiking (Villa *et al*, 2015). However, ΔVO_2 values from the warmup to the exercise stage were mitigated. This could be due to several factors, including supplemental support from using handrails or excessive toe clearance with no incline. It should be noted that a small sample size could skew the results. Further research is necessary to validate these results.

CONCLUSION

These data indicate that transfemoral amputees have altered metabolic responses to elevation changes during ambulation when compared to predicted values for non-disabled non-amputees. The mitigated ΔVO_2 response indicates that the alteration might not simply be a baseline shift. Current ACSM exercise prescription guideline equations for metabolic cost estimation may be inaccurate for this population.

CLINICAL APPLICATIONS

Exercise prescription is commonly used as a rehabilitation technique for many disabilities. The creation of appropriate guidelines of exercise prescription for amputees has the potential to improve clinical care with a population-specific formula.

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UPPER EXTREMITY PROSTHETIC TRAINING WITH THE USE OF A COMPUTER ASSISTED REHABILITATION ENVIRONMENT (CAREN)

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The University of South Florida, Department of Chemical and Biomedical Engineering[1], and Mechanical Engineering[2]

INTRODUCTION

Approximately 10 million people live with a limb loss worldwide, with around 30% being an upper extremity amputee (LeBlanc, 2008). The sudden loss of a hand or arm causes the loss of fine, coordinated movements, reduced joint range of motion (ROM), proprioceptive feedback and aesthetic appearance, all which can be improved with the use of a prosthesis (Michael, 2004). An effective prosthetic training and rehabilitation regime is important in returning the patient to the highest level of independence and functioning possible. The present study describes a virtual reality (VR) environment system to facilitate an effective training and rehabilitation process for amputees.

METHOD

Subjects: The study included two male and two female subjects without an amputation, and one male and two female subjects with a unilateral transradial amputation who regularly used a myoelectric prosthesis. Subjects had a mean (SD) age of 29.3 years (±12.2), weight of 71.0 kg (±13.4), and height of 1701.7 mm (±98.5).

Apparatus: All subjects participated in a 2-hour session, on a Computer Assisted Rehabilitation Environment (CAREN). The CAREN is a multimodal system consisting of 10 motion-capture cameras, a 6-DOF hydraulic base, an instrumented treadmill, and a 180-degree projection screen.

Procedures: A series of ROM, activities of daily living (ADL), and return to duty (RTD) tasks were tested with and without the VR visualization. The session with the VR included a real-time model, which directly corresponded to the motion of the subject, and an avatar performing the optimal motions developed with average normal joint positions and ROMs (Norkin, 2009).

Figure 1. Real-time and optimal model avatar visualization with an amputee subject on the CAREN system.

Data Analysis: The user's motion and joint angle measurements were recorded and calculated throughout all tasks and compared to one another. Observations throughout the tasks were also considered, and patient feedback was collected through a post-testing survey.

RESULTS

The results of this study suggest that the use of the VR allowed for improved positioning, motivation, and overall a better performance. The patient feedback revealed that subjects found the tasks more enjoyable and felt more motivated to perform with proper movement with VR. This allowed subjects to quickly adjust and perform the movements alike the optimal motion shown.

The interim results demonstrated differences in joint angles with and without VR. Looking at one amputee subject, greater pelvic tilt was demonstrated when preforming the unilateral lift without VR (Figure 2). This shows that with VR, subjects were able to adjust their positioning to be closer to the optimal of little to no pelvic tilt.

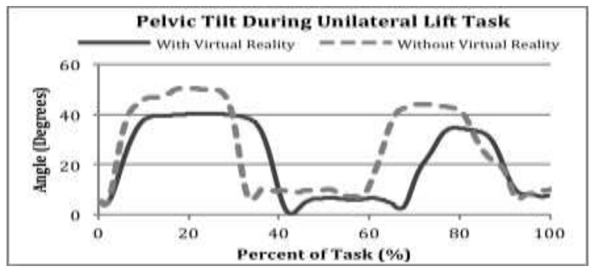

Figure 2. Pelvic tilt of one amputee subject during the unilateral lift task, with and without the use of the virtual reality visual feedback.

DISCUSSION

The visual feedback provided by VR, allowed for the subjects to adjust and correct their motion to perform tasks without compensating with other joint movements. The visual feedback, along with the quantitative data collected, allowed for the patient and operator to know where improvements must be made while providing an accurate assessment of the patient's developments.

CONCLUSION

The provisional and anecdotal results suggest that the use of VR enhances upper limb prosthetic training and rehabilitation with the thought that a more extensive biomechanical analysis will further support the findings.

CLINICAL APPLICATIONS

The results from this study intend to introduce a way to significantly improve prosthetic training and rehabilitation, while providing useful guidelines and recommendations for an adaptable system for clinics or at home use. This will be clinically significant to training and rehabilitation programs by introducing an adaptable way to increase effectiveness and greatly impact the future of prosthetic users.

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Visual Impairment and Stride Length

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INTRODUCTION

For people living with visual impairments, ambulating safely can be an issue. Many obstacles may not be fully seen which can possess a danger to individuals. This study aimed to look at how a visual impairment affects a person's stride length. It is hypothesized that ambulating with a visual impairment would decrease a person's stride length.

METHOD

Subjects: Six females and four males aged 25.6 ± 2.84 years old with no clinical pathologies were included in this study.

Apparatus: The Zeno walkway mat and Protokinetics PKMAS software program were used to analyzed the data.

Procedures: Participants walked down the walkway at self selected walking speed, then with their eyes closed at their own self selected walking pace.

Data Analysis: The PKMAS software was utilized for data analyzation of steps.

RESULTS

The results support larger stride length for people when ambulating with a visual impairment. This negates our original hypothesis that stride length would shorten.

DISCUSSION

The results of this study contradict previous studies that displayed a shorter step length. This may be due to the data analyzation process with how steps were processed or eliminated. This is a concern that would need to be adjusted in a follow up study.

CONCLUSION

The results of our study negate the hypothesis that a visual impairment will shorten stride length, and this may be due to limitations that provided inaccurate results.

CLINICAL APPLICATIONS

Although the results of this study may not be fully accurate, the clinical applications behind the idea of it are very relevant. People with a visual impairment cannot always see obstacles in front of them, so if it is possible to understand how these impairments will affect them, we can do our best to provide them a safe environment to ambulate in.

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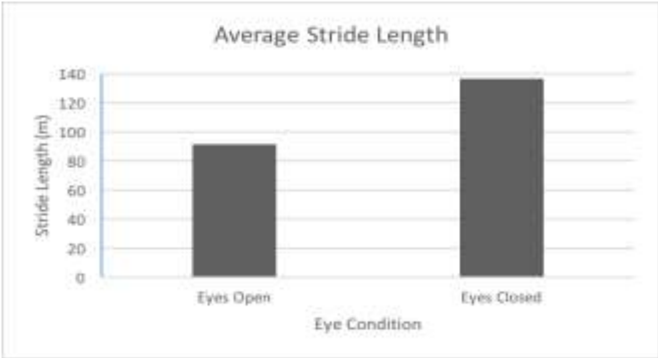

During walking in women's safety shoes

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INTRODUCTION

Although workers in Japan are required to wear safety footwear, there is concern about occupational accidents that occur when wearing safety shoes. This study aimed to analyze the effect of wearing hard-soled safety shoes on spatiotemporal gait characteristics using a kinematic approach.

METHOD

Subjects: Seventeen female college students (mean (standard deviation); age 19.3 (0.9) years, weight 50.2 (5.0) kg, height 157.7(4.3) cm, body mass index 20.2(1.8) kg/m2, foot length 230.1(9.7) mm)

Apparatus: 1. the 5-m gait analysis system (Walkway 7.60; Nitta Corporation, Osaka, Japan). 2. Surface electromyogram (EMG) recording system (BioLog DL-2000; S&ME Inc., Tokyo, Japan)

Procedures: A 5-m gait trial and a surface electromyography trial were conducted while the women walked in either safety shoes or sports shoes. Muscles: Vastus lateralis (VL), Biceps femoris (BF), Tibialis anterior (TA), Lateral head of the gastrocnemius muscle (LG)

Statistical analysis: The Wilcoxon rank-sum test. The threshold for statistical significance was set at $P < 0.05$

RESULTS

When walking in the safety shoes, women exhibited a shorter step length compared to when walking in the sports shoes. There was no significant difference in cadence, step velocity, or foot angle between the different shoes. (Table 1) The muscle activity rates for the VL, BF and TA when walking in the safety shoes were significantly higher than those when walking in the sports shoes. Although not significant, the muscle activity of the LG when walking in the safety shoes tended to be higher than when walking in the sports shoes (100.9% vs 100%, P = 0.11). (Table 2)

	Safety Shoes	Sports Shoes	P-value*
Cadence	109.6(12.1)	108.7(8.3)	0.25
Step Length	68.4(6.3)	67.8(6.1)	0.049
Step Velocity	124.5(18.0)	123.7(17.4)	0.26
Foot Angle	0.09(2.6)	0.03(2.7)	0.37

Table 1. Stride characteristics.

(A)

	Safety Shoes （mV/sec）	Sports Shoes （mV/sec）
VL	130.3(143.1)	98.2(110)
BF	141.1(154.9)	126.6(139.6)
TA	373.2(239.2)	344.9(199.3)
LG	522(116.2)	502.5(81.5)

(B**)**

	Safety Shoes (%)	Sports Shoes (%)	P-value*
VL	129.5(47.1)	100	0.008
BF	114.3(20.7)	100	0.007
TA	105.8(10.8)	100	0.002
LG	103.3(7.7)	100	0.11

Table 2. Muscle activity in the left lower extremity. Mean values are shown (with standard deviation in parentheses). A: muscle activity (mV/sec), B: muscle activity (%) when wearing safety shoes; with activity

DISCUSSION

The safety shoes were associated with a slight reduction in step length and a slight increase in the muscle activity in the lower extremities.

CONCLUSION

A greater anterior driving force from the terminal stance phase to the pre-swing phase may be needed when wearing safety shoes to prevent fatigue of the lower extremities.

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CYCLING WITH A TRANS-TIBIAL AMPUTATION: MOTOR ADAPTATIONS TO POSTERIOR-ANTERIOR CLEAT POSITION

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INTRODUCTION

Cycling, as a form of recreation and exercise, is growing in popularity for individuals with a trans-tibial amputation (AMP-TTA). Alignment of the body relative to the bicycle, i.e. bicycle fit, can alter how a person is able to propel the bicycle and yet little is known on the relationship between bicycle fit, prosthetic alignment, and cycling performance. In particular, the anterior/posterior relationship of the socket relative to the cleat should alter how loads can be transmitted to the pedal. This relationship has shown to effect ankle moment and muscle activation in cyclists with two intact limbs (Ericson et al., 1985). Therefore, this should also affect how someone can control the prosthesis and ultimately cycling performance when pedaling with a uni-lateral transtibial amputation. In this study, we analysed the relationship between posterior translation of the cleat relative to the socket during cycling and the response in the amputated limb using joint moments and muscular activity changes. We hypothesize that by translating the cleat of AMP-TTA individuals posteriorly on the individual's shoe, we can influence the superior hip extensors, namely the gluteus maximus.

METHOD

Eight TTA (34.1 ± 8.7 yrs, 1.83 ± 0.08 m, 83.8 ± 14.9 kg) and a group of nine intact subjects (34.7 ± 8.8 yrs, 1.82 ± 0.05 m, 82.4 ± 11.7 kg) provided written informed consent to participate in for this IRB approved study. Subjects pedaled at a constant cadence and torque of 90 rpm and 15Nm respectively. A Helen Hayes marker set in combination with a six infrared camera system (Peak Motion Systems) recorded lower limb kinematics at 60 Hz. Dual piezoelectric element force pedals (Broker & Gregor 1990) recorded pedal reaction forces at 300 hz. Muscular activity was recorded at 1000 Hz using surface electromyography (Noraxon 1400). Control or anterior position of the cleat was in the center of the foot in the coronal plane and aligned with the subject's first metatarsal head on his or her sound limb in the sagittal plane, the posterior position was 40% the distance between the ankle joint and the anterior position. Data was recorded for thirty seconds after two minutes of cycling at each condition. Ten consecutive crank cycles were time normalized to 100 datapoints and averaged together per subject and condition. Moments at the joints were calculated using inverse dynamics based on pedaling kinetics and limb kinematics (Broker & Gregor, 1990). Amputated (AMP-TTA) side hip extension moment, gluteus maximus EMG activity, and work asymmetry variables in the anterior and posterior cleat positions were compared using a paired T-Test.

RESULTS

Results showed an increase in average hip joint extension moment from -37.4 (±9.9) to -47.3 (±12.1) (P=0.01) between the cleat in the forward and posterior positions. Gluteus maximus activity in the posterior position increased from 0.30 (±0.04) to 0.85 (±0.97)(P=0.15). Work asymmetry of the AMP-TTA group was dropped from 24.5 (±10.1) to 20.5 (±11.3)(P=0.56) when the posterior cleat position was used.

DISCUSSION

Hip extension moments for AMP-TTA were significantly increased during posterior cleat position trials when compared to the forward location. Work asymmetry during the pedaling cycle did decrease, although the results did not show a significant difference between the control or the posterior locations.

CONCLUSION

Our most significant finding was that we were able to significantly increase the extension moment at the hip of the AMP-TTA group by translating the pedal posteriorly relative to the socket. This suggests a hip based strategy was used by the subjects and incorporated larger muscle groups, such as the gluteus maximum. By understanding the biomechanical principals involved in adapting to posterior-anterior translation of the pedal interface of cyclists with a trans-tibial amputation, we can better assist these individuals in the areas of rehabilitation and recreation. In addition, by decreasing the amount of work asymmetries between the sound and amputated side, we can increase the performance of the intact limb by allowing operation at a lower output for a given load (Childers et al., 2011).

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STUDY ON RELATIONSHIP BETWEEN MOBILITY OF METATARSALS AND DEFORMABILITY OF FOREFOOT

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INTRODUCTION

Total foot care salons for feet, shoes, and walking are visited by women concerned about shoe trouble. Women concerned with shoe trouble often visit total foot care salons. Properties such as the stiffness or flexibility of feet are taken into consideration at these salons when deciding on foot care that will directly contact a customer's feet. Differences in the flexibility of feet are thought to be due to large differences in intermetatarsal mobility. Feet in which forefoot deformation is seen are unlikely to fit well in ready-to-wear shoes, so shoe fitting accuracy is also demanded from the perspective of foot care. With pumps in particular, the need for semi-custom shoes that can be closely fit should be considered.

In shoe-last fabrication, deformation characteristics of the foot circumference are important in addition to foot dimensions. With pumps in particular, the degree of constriction on the foot circumference is an important reduction ratio. However, there are large individual differences in the amount of forefoot deformation, and even with semi-custom shoes, the shoe shape is difficult to determine.

If the forefoot deformation characteristics could be understood by numerically expressing the mobility between each of the metatarsals, it may allow prediction of the amount of forefoot deformation and be an indicator for use in determining shoe shape.

The purpose of this study was to help improve the fit of semi-custom made shoes by measuring intermetatarsal mobility and investigating the relationship with forefoot characteristics.

METHOD

The subjects were customers (88 women, 176 feet; age range 19–74 years) who received foot care in the authors' salon. Their foot length and width were measured with a foot gauge while bearing weight (standing). Based on the measurement results, the foot width ratio was calculated from (foot width while bearing weight / foot length while bearing weight) × 100.

A measuring device was made following the method of Greisberg et al., and the mobility between each of the metatarsals (1st–2nd, 2nd–3rd, 3rd–4th, 4th–5th) was measured.

The side angle of the hallux was obtained from a foot contour line drawn on paper by using a scriber and the hallux valgus angle was calculated from the hallux side angle. Correlations were investigated between the total mobility between all of the metatarsals and the foot width ratio (total of 176 feet), and the mobility between the 1st and 2nd metatarsals and the foot width ratio (total of 31 feet with hallux valgus angles ≥ 15°). Statistical analysis was done using Spearman's correlation.

RESULTS

88women 176feet	n=176	A(n=145)	B(n=31)
Standing foot length (mm)	231.4	231.8	229.4
Standing foot width(mm)	95.0	94.6	96.9
The foot width ratio(%)	41.1	40.2	42.3
The hallux side angle(°)	12.1	10.1	21.3
The hallux valgus angle(°)	10.8	9.2	18.4
The mobility between M1-M2(mm)	8.5	8.3	9.3
The mobility between M2-M3(mm)	8.9	8.8	9.3
The mobility between M3-M4(mm)	9.1	9.0	9.5
The mobility between M4-M5(mm)	8.5	8.4	9.1
The mobility between all metatarsals(mm)	35	34.5	37.1

A:Hallux valgus angle<15°   B:Hallux valgus angle≧15°

The results of statistical analysis showed moderate correlations of r = 0.39 between the foot width ratio and the total mobility between all metatarsals, and moderate correlations of r = 0.44 between the foot width ratio and the mobility between the 1st and 2nd metatarsals of the 31 feet with hallux valgus angles ≥ 15°calculated from the hallux side angle.

DISCUSSION

In a study by Motozuka et al., the strength of the connection between the 1st and 2nd metatarsals was weak. Thus, it is conjectured that the hallux angle increased with large spread between the 1st and 2nd metatarsals and decreased side arch.

In this study, a correlation was seen between the foot width ratio and the mobility between the 1st and 2nd metatarsals in subjects with hallux valgus deformation, and it was shown statistically that forefoot deformation characteristics can be predicted from the mobility between the 1st and 2nd metatarsals. Therefore, information on intermetatarsal mobility enables prediction of forefoot deformation characteristics.

CONCLUSION

Foot width and the metatarsal between mobility were measured. Mobility between the metatarsal with hallux valgus angle ≧15 ° is large. Prone to forefoot deformation. It could be inferred.

CLINICAL APPLICATIONS

A result of this study can be applied to foot check when select of shoes.

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COMPARISON OF ELECTROMYOGRAPHY (EMG) AND GAIT IN TRANSITION FROM LOCKED KNEE-ANKLE-FOOT-ORTHOSIS (KAFO) TO PRE-STRIDE™ STANCE CONTROL ORTHOSIS (SCO): A CASE STUDY

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INTRODUCTION

Energy efficiency measured through muscle fatigue in KAFOs has not been investigated in detail. The clinical relevance of stance-control KAFOs and their effects on the quality of life has yet to be documented with a validated outcome measure. The purpose of this study was to systematically quantify any differences in EMG signals and gait mechanics as well as qualitative orthosis function for one subject diagnosed with post-polio wearing a custom, conventional locked KAFO and an immediate-fit stance control KAFO.

METHOD

One participant met enrollment criteria, was officially enrolled, and completed the entire study protocol. The study control was the subject's normal gait with their locked KAFO. The subject completed two sessions of data collection. Each session consisted of 10 walking trials on a 10-foot long walkway for each testing condition. Prior to the first SCO trial, the subject completed a familiarization session during which he was instructed on use and activation of the PreStride™ SCO device. For each of the 10 walking trials, data was collected using a Vicon 3D motion capture system, GaitRite portable gait analysis system, and a wireless electromyography (EMG) system. Two representative trials were chosen for data analysis from each session.

RESULTS

Vicon data supported use of the KAFO over the SCO. Hip and knee joint angles were measured closer to normal values with the KAFO. In both orthoses, the subject never reached full hip or knee extension. The subject demonstrated a more normal stance to swing ratio in the KAFO. The anterior tibialis muscle activation was also increased in the KAFO condition. However, the SCO trials showed an increased right calf, hamstrings and quadriceps muscle group activation. The spatiotemporal values derived from the GaitRite system were closer to expected normal values in the KAFO. Single and double limb support was more normalized with the KAFO. The OPUS survey demonstrated that the subject has a good outlook on his condition and quality of life. He appears to be limited more physically than emotionally.

DISCUSSION

The overall effectiveness of the SCO was reduced in part because of instability experienced with the selectively unlocked mechanical knee joint, as well as the allowed motion in the ankle joints. Additional time for gait training beyond the protocol may have improved results. The KAFO yielded more symmetric gait with improved spatiotemporal values. It is essential that further research incorporate additional SCO gait training and an extended accommodation phase. Additional trials, subjects, and data collection are necessary to determine energy expenditure differences between the SCO and KAFO.

CONCLUSION

While results indicated the locked KAFO provide more normal gait parameters for the subject, the SCO has potential to add therapeutic benefits by increasing muscle activity of lower extremity muscles for patients with similar presentations to this subject in a controlled therapy setting.

CLINICAL APPLICATIONS

The utilization of an immediate-fit stance control orthosis allowed increases in muscle activation of the lower limb of the subject in this case study; however, spatiotemporal gait parameters were closer to normal in the locked KAFO.

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The Contribution of Vestibular Sensory Integration to Mobility in People with Unilateral Transtibial Amputation

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INTRODUCTION

The vestibular system provides critical information regarding the position of the body in space. The ability to receive and process that information is known as Vestibular Sensory integration (VSI). People with lower limb amputation have a significant loss of afferent somatosensory information due to loss of proprioceptors within the limb; therefore utilizing the information from the visual and vestibular system becomes more critical during static and dynamic activities. Previous work has shown a relationship between VSI and performance-based mobility,[1] but this relationship has not been explored in the limb loss population. The purpose of this study is to determine the relationship of VSI on mobility in unilateral transtibial amputees (TTA).

METHOD

Subjects: A convenience sample of 26 healthy community ambulators with unilateral TTA were recruited to participate in a study conducted at the 2015 Amputee Coalition National Conference in Tucson, Arizona.
Procedures: The participants answered questions regarding history of vestibular symptoms. Visual acuity and sound protective sensation were assessed and the Modified Test of Sensory Interaction and Balance (mCTSIB) was performed. Mobility was assessed using the PLUS-M™ 12-Item Short Form (v 1.0) and the Timed Up and Go (TUG) test.
Data Analysis: Statistical analysis was performed using SPSS version 22 (SPSS Inc., Chicago, USA). Chi-Square, Odds Ratio, and T-Test were performed to determine differences between the normal sensory integration (NSI) and impaired VSI cohorts (IVSI), as classified by mCTSIB performance.as classified by mCTSIB performance.

RESULTS

Based on pass/fail performance on the mCTSIB subjects were classified into cohorts: two subjects (8%) were classified as having visual dependence, six subjects (23%) were identified as IVSI, and eighteen (69%) were classified as NSI. The IVSI cohort were significantly different from the normal cohort with a greater percentage having diabetes (p=.024) and history of vertigo (p=.05), greater waist circumference (p=.004), and decreased sound limb sensation (p=.024). Participants with either diabetes or impaired sound limb sensation were 8.75 times more likely to have IVSI (CI 1.2, 63.4).

	IVSI (n= 6)	**NSI** (n= 18)	**p**
TUG (sec)	**11.0** ± 2.5	**9.3** ± 2.0	0.04*
PLUS-M™ (T-score)	**53.9** ± 7.8	**59.1** ± 9.2	0.03*

Table 1. Mobility differences in cohorts with impaired vestibular integration (IVSI) and normal sensory integration (NSI). Mean values + standard deviation shown. *T-test significant at p <.05 level.

Mobility was significantly lower in participants with IVSI (Table 1). The IVSI cohort performed the TUG a mean of 1.7 seconds slower than the NSI cohort. The PLUS-M™ t-scores for the IVSI cohort (percentile rank = 63.9%) was a mean of 5.2 points lower than the NSI subjects (percentile rank =83.2%).

DISCUSSION

This is the first study to examine the contributions of vestibular sensory integration to mobility in those with lower limb amputation. Those participants with IVSI presented with greater co-morbidity, greater central adiposity, impaired intact foot sensation, and poorer self-perceived mobility and daily mobility compared to the NSI cohort.
The TTA subjects that participated in this study were active community ambulators that performed the TUG faster than previously reported.[2] Screening for VSI can differentiate mobility performance in the active lower limb amputees.

CONCLUSION

These results suggest that a strong relationship exists between IVSI and mobility limitation in people with unilateral transtibial amputation, particularly if sensation deficits and/or diabetes are comorbidities.

CLINICAL APPLICATIONS

Screening tests such as the mCTSIB should be part of the prosthetic rehabilitation standard of care for individuals with lower limb loss. The capacity to identify contributing factors for balance will promote targeted rehabilitation and prosthetic treatments that will maximize mobility and prosthetic performance.

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Reduced Turn Ability, Transfer Ability, and Balance Confidence in Prosthesis Users with History of Falls

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INTRODUCTION

Functional outcome measures commonly used among lower-limb prosthesis users are limited in their ability to capture turning gait and transfer ability. Curved-walking requires unique gait mechanics that can be captured with the Figure-of-8 Walk Test (F8WT). The F8WT has been associated with fall risk (Welch, 2015) and requires participants to turn towards the prosthetic and the sound limb sides. Sit-to-stand asymmetries are prevalent among prosthesis users (Agrawal, 2011) and asymmetrical loading may negatively impact lower limb strength and endurance. Reduced lower extremity strength and endurance may be related to increased fall risk. The 30 second Sit-To-Stand (30-s STS) is used to measure lower extremity functional strength and endurance. The Activities-specific Balance Confidence (ABC) Scale is an established tool linked to fall risk, mobility, and social activity (Miller, 2001). The purposes of this study were to (1) establish test-retest reliability of the F8WT and 30-s STS among prosthetic users, (2) determine if prosthetic users classified as fallers had slower F8WTs, reduced STS transfer ability, and poorer balance confidence when compared to non-fallers, and (3) determine if transfemoral (TF) prosthetic users had slower F8WTs, reduced STS transfer ability, and poorer balance confidence when compared to transtibial (TT) prosthesis users.

METHOD

Subjects: Sixty-eight unilateral lower-limb prosthesis users completed this IRB approved study. Nine participants repeated the F8WT and 30-s STS to determine test-retest reliability. The TF group included one knee disarticulation and one hip disarticulation.

Apparatus: Patient-reported fall history over the past year was assessed with a falls questionnaire. Balance confidence was measured with the ABC Scale.

Procedures: Participants walked a figure-of-8 around 2 cones placed 1.525 m apart and instructions were "complete this course as quickly and smoothly as possible." Time to complete two laps was recorded. Participants then sat in a standardized chair with their arms across their chest and were asked to stand up and sit down as many times as possible in 30 seconds. Total number of sit-to-stands were recorded.

Data Analysis: Test-retest reliability of the F8WT and 30-s STS were examined using intraclass correlation coefficients (ICC(2,1)). Mann-Whitney U tests were conducted to determine differences in outcome measures by fall history (faller/non-fallers) and level of amputation (TT/TF).

RESULTS

F8WT and 30-s STS were reliable with ICC = .856 (95% CI: .489 - .966) and ICC = .848 (95% CI: .416 - .968), respectively. Fallers had greater F8WT times ($p = .022$), less number of sit-to-stands ($p = .044$), and reduced balance confidence ($p \leq .001$) (Table 1). No differences were found for level of amputation.

DISCUSSION

The F8WT, 30-s STS, and balance confidence were significantly different between fallers and non-fallers. These tests are simple and require minimal clinical space. Recent advances in body-worn sensors, which will be used in our future research, may allow for quantification of spatiotemporal and kinematic data during these tests. We will evaluate the relationship between these biomechanical data and falling.

CONCLUSION

The F8WT and 30-S STS are reliable tests for unilateral lower-limb prosthesis users. Lower-limb prosthesis users with a history of falls have worse turning gait performance, reduced sit-to-stand transfer ability, and reduced balance confidence when compared to non-fallers.

CLINICAL APPLICATIONS

With limited clinical space, the F8WT and 30-s STS may provide a means of objectively assessing balance during gait and transfers among clients with unilateral lower-limb amputations. Improved performance of these measures may reduce fall risk.

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Table 1. Median (interquartile range) among fallers/non-fallers and level of amputation

	Fallers (n=37)		Non-fallers (n=32)		p-value	Transtibial (n=36)		Transfemoral (n=33)		p-value
Age (years)	47.0	(22.0)	40.0	(23.8)	.255	49.5	(23.5)	42.0	(23.5)	.198
ABC (%)	86.0	(18.0)	97.0	(5.8)	< .001*	96.0	(18.0)	91.0	(14.5)	.420
STS	11.0	(5.5)	12.5	(3.8)	.044*	12.0	(5.8)	12.0	(4.5)	.299
F8WT (s)	16.8	(4.7)	14.7	(4.9)	.022*	14.9	(5.6)	16.8	(4.8)	.105

* p < .05

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