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

Kaluf, B.D.[1], DiGioia, C.[1], Shoemaker, E.[1], Martin, T.R.[1], Leland, R.B.[2], Bridges, W.C.[3], Duncan, A.
Ability Prosthetics and Orthotics, Inc.[1], Eastern Michigan University[2], Clemson University[3]

Introduction

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

Methods

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

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

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

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

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

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

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

Results

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

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

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

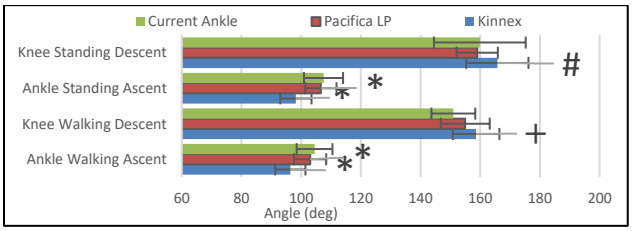

Figure 2. Ankle and Knee angles on the prosthesis side when using different ankle-foot configurations. (*) denotes Kinnex and Pacifica LP significantly different than Current Ankle, (+) denotes Kinnex significantly different than Current Ankle, (#) denotes Kinnex significantly different than Pacifica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

Discussion

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

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

Conclusion

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

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

References

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