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

Kaluf, B.D.[1], Leland, R.B.[2], Bridges, W. C.[3], Shoemaker, E.[1], Martin, T.R.[1], DiGioia, C.[1]
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 (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 (a=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 (a=0.05)

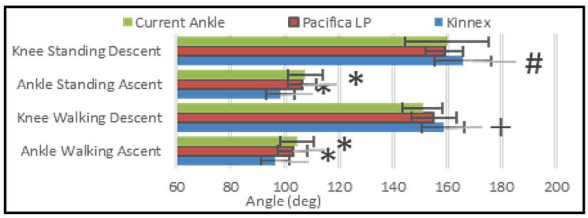

Figure 2. Ankle and Knee angles on the prosthesis side when using different ankle-foot configurations. (*) denotes Kinnex and Pacifica LP significantly different than Current Ankle, (+) denotes Kinnex significantly different than Current Ankle, (#) denotes Kinnex significantly different than Pacifica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

REFERENCES

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American Academy of Orthotists & Prosthetists
43rd Academy Annual Meeting & Scientific Symposium
March 1-4, 2017

CLINICAL STUDY REVIEW

Kinnex Comparative Pilot Study

FREEDOM KINNEX™ MICROPROCESSOR ANKLE/FOOT SYSTEM

Introduction

- This Pilot study compared Kinnex MPC Ankle/Foot System to Pacifica LP in 4 individuals with unilateral transtibial amputations.

Method

- 26 variables were measured using 13 different outcome measure tests to study patient gait while walking and standing on level ground and slopes, and during sit to stand.

Results

The pilot study found significant benefits from the Kinnex in the following areas:

- **HAI ramp descent:** Evidence proves that Kinnex improves walking down ramps
- **Ankle angle walking and standing ramp ascent:** Evidence indicates that Kinnex helps accommodate upslope angle to allow for full foot loading for increased stability compared to toe-only loading while walking and standing on an incline.
- **Knee angle walking and standing ramp descent:** Evidence confirms that Kinnex can accommodate downslope to allow patients to lower themselves in a more controlled manner with a more symmetric gait by allowing the knee to be in a more extended and stable position while standing and walking down slopes.
- The study also showed positive trends of improved balance, mobility and socket comfort with Kinnex.

Full study including 30 subjects will be completed summer of 2017