BIOMECHANICAL CHARACTERISTICS OF PROSTHETIC FEET: RANDOMIZED DOUBLE BLIND USER TESTING

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INTRODUCTION
There is a wide range of prosthetic feet currently available. Those prosthetic users with high functional levels generally receive more technologically advanced “energy-storing” prosthetic feet, with more basic feet provided to prosthetic users with lower functional levels. The ability of the forefoot region of the prosthetic foot to behave like a spring and store and return energy during the gait cycle is one characteristic that is supposed to improve the energy efficiency of prosthetic users’ gait. There remains some skepticism that these small differences in forefoot compliance are detectable using current computerized gait analysis systems or are perceptible to prosthetic users. Previous work has failed to find any relationship between biomechanical measures and prosthetic foot preference1. This study used a double-blind randomized design with both laboratory and real world testing to determine the minimal clinically important difference (MCID) in three categories of prosthetic feet.

METHOD
Twelve transtibial amputees gave informed consent to participate in this Ethics Committee-approved trial. The participant’s functional level was determined objectively by assessing their steps per minute data over a 7-day period (Galileo, Orthocare Innovations)2. Each participant’s prosthesis was fitted with a load cell at the socket base (Europa, Orthocare Innovations)3.4. Participants were also fit with a quick-swap set-up on their limb and 3 to 6 prosthetic feet were crafted with the exact same build height, size and alignment. Each foot was covered with a black sock zip-tied to the pylon to obscure the make and model of the foot. Between 3 and 6 prosthetic feet were tested in random order; more feet were tested by participants with higher functional levels (K3-4). Sagittal and coronal moments were collected via Bluetooth as the participant walked along a 12m walkway in a gait laboratory. After 40 steps were recorded (~2 min), the next foot was fit to their prosthesis. Each participant then wore a foot for a week-long wear test in the community, one within a functionally appropriate range of choice, and at least one above and below the usual prescriptive paradigm; higher functional level participants tested more feet in the community. Peak sagittal moments in late stance were extracted from the laboratory data, activity data was collected during the wear test, and modified PEQ scores were collected on each foot following real-world use. Feet were placed into three categories based on an objective scale of compliance and “energy return”: A-Stiff, B-Intermediate, C-Compliant. The participants, the prosthetist, and the researchers were blinded to the foot being tested. Blinding was removed for some investigators, but only after hypothesis testing was complete.

RESULTS
Participants reported a preference for C-Compliant feet (Wilcoxon sign-rank P < 0.025) that had the lowest peak sagittal moments in late stance phase (ANOVA P <0.011). They specifically scored this category of prosthetic foot as being superior over uneven terrain and for maneuvering over stairs, ramps, curbs and similar barriers. The activity for the participants did not change significantly for any metric for any foot category (ANOVA P=0.38).

DISCUSSION
Despite the low number of participants in this study, it appears that over a wide range of K2, K3 and K4 transtibial amputees, feet with lower peak moments during straight ahead walking were preferred for real-world mobility, especially over uneven terrain. This study provides some evidence that amputees can detect specific biomechanical characteristics of prosthetic feet, one definition of the MCID. In this case the mean reduction was 11-14% of the peak sagittal moment for preferred feet. The randomized double-blind design of this study lessens the confounding influence of marketing hype and visual appeal that can affect foot preference.

CONCLUSION
Prosthetic users could not detect stiffness differences following laboratory tests, but expressed a preference for more compliant feet after one week wear tests in the community.

CLINICAL APPLICATIONS
In this small sample, K2, K3 and K4 ambulators all appeared to prefer prosthetic feet with greater forefoot compliance and lower peak moments in late stance. This suggests that K2 ambulators might benefit from carbon fiber feet, if the feet were flexible.

REFERENCES

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