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Biomechanical characteristics, patient preference and activity level with different prosthetic feet: A randomized double blind trial with laboratory and community testing

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ABSTRACT

Providing appropriate prosthetic feet to those with limb loss is a complex and subjective process influenced by professional judgment and payer guidelines. This study used a small load cell (Europa™) at the base of the socket to measure the sagittal moments during walking with three objective categories of prosthetic feet in eleven individuals with transtibial limb loss with MFCL K2, K3 and K4 functional levels. Forefoot stiffness and hysteresis characteristics defined the three foot categories: *Stiff*, *Intermediate*, and *Compliant*. Prosthetic feet were randomly assigned and blinded from participants and investigators. After laboratory testing, participants completed one week community wear tests followed by a modified prosthetics evaluation questionnaire to determine if a specific category of prosthetic feet was preferred. The *Compliant* category of prosthetic feet was preferred by the participants ($P=0.025$) over the *Stiff* and *Intermediate* prosthetic feet, and the *Compliant* and *Intermediate* feet had 15% lower maximum sagittal moments during walking in the laboratory ($P=0.0011$) compared to the *Stiff* feet. The activity level of the participants did not change significantly with any of the wear tests in the community, suggesting that each foot was evaluated over a similar number of steps, but did not inherently increase activity. This is the first randomized double blind study in which prosthetic users have expressed a preference for a specific biomechanical characteristic of prosthetic feet: those with lower peak sagittal moments were preferred, and specifically preferred on slopes, stairs, uneven terrain, and during turns and maneuvering during real world use.

1. Introduction

There are a large number of prosthetic feet currently available for individuals with limb loss. Choosing an appropriate foot for a specific individual is a complex process dominated by guidelines from payers that are based on the functional level of the prosthetic user. The choice is also influenced by the professional judgment of the prosthetist and prescribing physician, and by user preference. There have been limited systematic reports on prosthetic foot designs and their mechanical characteristics (heel impact damping, keel deformation under load, etc.) (AOPA, 2010; Rihs and Polizzi, 2001), but the data to link mechanical characteristics to appropriate functional level or to user preference is incomplete, presenting a hindrance to evidence-based practice in the field. Prosthetic foot performance has been the focus of many publications (Curtze et al., 2009; Geil, 2002; Geil et al., 1999; Geil et al., 2000; Gitter et al., 1991; Jensen and Treichl, 2007; Klodd et al., 2010; Lehmann et al., 1993a; Lehmann et al., 1993b; Postema et al., 1997a; 1997b; Zmitrewicz et al., 2006), and a consensus conference (Cummings et al., 2005), but objective data to inform clinical decision-making in choosing an appropriate prosthetic foot remains elusive. In keeping with payer guidelines, those prosthetic users with high functional levels

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generally receive more expensive and technologically advanced carbon fiber "energy-storing" prosthetic feet, with more basic and less expensive feet (solid ankle cushioned heel – SACH) provided to prosthetic users with lower functional levels. This prescriptive paradigm appears to be shifting and has recently been violated with enough regularity that it has come to the attention of the US Inspector General of Health and Human Services (Levinson, 2011). Levinson charges questionable billing practices by providers of prosthetic feet, citing a 27% increase in the cost of lower limb prostheses billed to Medicare/Medicaid between 2005 ($517 million) and 2009 ($655 million) while the number of individuals receiving these prostheses decreased by 2% to 74,000 during the same period (Levinson, 2011). Most of this increased cost is for expensive carbon fiber prosthetic feet being provided to low functional level individuals with limb loss (Levinson, 2011). Although these concerns are specific to the US health care system, providing the appropriate prosthetic device to individuals with differing functional performance requirements is a key concept in controlling costs for health care systems in other countries.

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 prosthetic users' gait (Ventura et al., 2011; Versluys et al., 2009; Zmitrewicz et al., 2007; Zmitrewicz et al., 2006). The results for evaluating the walking efficiency (metabolic cost) of different types of prosthetic feet have been equivocal (Lehmann et al., 1993a; 1993b; Perry and Shanfield, 1993; Waters et al., 1976). The increase in the sagittal ankle power generation in pre-swing (A2) demonstrated for some "energy storing" prosthetic feet is preceded by an equal and inexorable absorption of sagittal ankle power in stance phase. There remains some skepticism that these small differences in forefoot compliance are quantifiable using current technology, including the biomechanical models used for computerized gait analysis systems (Geil, 2002; Geil et al., 1999, 2000), or are perceptible to prosthetic users. Previous work has failed to find any relationship between biomechanical measures and prosthetic foot preference (Hafner et al., 2002).

This study used a randomized double blind design with both laboratory and real world testing to determine if a specific category of prosthetic feet were preferred by those with transtibial limb loss.

2. Methods

Twelve transtibial amputees gave informed consent to participate in this Ethics Committee-approved trial. Participant recruitment was open to vascular and traumatic amputees with stable socket fit. Inclusion criteria included: unilateral trans-tibial amputees; over the age of 21; at least one year post-amputation; had a stable gait pattern and; were fluent in English. Exclusion criteria for the study were underlying conditions that could impact performance and gait (e.g. chronic obstructive pulmonary disease or symptomatic cardiovascular disease). Participant characteristics are detailed in Table 1.

This study collected data in three complementary domains that were deemed important to establishing a difference in prosthetic feet: the biomechanical domain, the activity domain, and the perceptual domain. The aim was to determine if a reported preference was related to a biomechanical characteristic of the foot when worn by the participant, and if this resulted in an increase in activity in the participant's community (Table 3).

Each participant's Medicare Functional Classification Level (MFCL K level) was determined subjectively by the clinical prosthetist, and objectively by assessing their steps per minute data over a 7-day period (Galileo, Orthocare Innovations, Mountlake Terrace, WA) (Orendurff et al., 2012). The results of the clinical prosthetist's rating of MFCL K level, and Galileo functional level score were blinded from the participants and all researchers, except the principal investigator and an experienced clinical prosthetist who chose the feet that each participant would test. Each participant's prosthesis was fit with a load cell at the socket base (Europa, Orthocare Innovations, Mountlake Terrace, WA) (Kobayashi et al., 2013a, 2014) by a clinical prosthetist (who was not blinded to condition [foot], but did not participate in data collection). Using different lengths of pylon, each foot was built to the exact same height, size and bench alignment (see Fig. 1) for each participant by the clinical prosthetist so that different test feet could be quickly changed in the laboratory. Static alignment was performed to the satisfaction of the clinical prosthetist and participant for each foot. Then, each foot was covered with a black sock zip-tied to the pylon to obscure the make and model of the foot (see Figs. 1 and 2) and the foot identifying codes were kept in a locked cabinet. A total of 12 different prosthetic feet were tested in three categories, but no individual tested all 12 feet.

The three prosthetic foot categories (*Stiff, Intermediate, Compliant*) were primarily based on mechanical testing of forefoot displacement and hysteresis (AOPA, 2010), but also included additional criteria detailed below. The mechanical testing is described in detail in a previous publication (AOPA, 2010), but briefly, feet were placed in 20° of plantarflexion in a mechanical test machine, loaded on the forefoot from 0 to 1230N at 200 N/s. The load was then removed at 200 N/s until zero. The displacement of the forefoot was measured and the trapezoid method was used to calculate the area between the load and unload curves (hysteresis). For this study feet with $\geq$25 mm displacement and $\leq$75% energy loss were usually placed in the *Stiff* category; those feet with $\geq$25 mm displacement and $\geq$75% energy loss were usually placed in the *Compliant* category; and those feet with $<$25 mm displacement were usually placed in the *Intermediate* category. In addition to this objective scale based on the mechanical tests, foot category determination also included expert clinical opinion, and in cases of disagreement between the two, the manufacturer's description of the intended MFCL K level of the user for that specific foot to define the categories. *Stiff* category feet are designed to be prescribed to prosthetic users with a $\geq$MFCL K3 level; *Compliant* and *Intermediate* category feet are designed to be prescribed to prosthetic users with $<$MFCL K3 level.

The participants arrived at the gait analysis laboratory and a research prosthetist brought the blinded prosthetic feet selected for that individual. Between 2 and 7 prosthetic feet were tested in random order (codes drawn from a hat); in order to ameliorate participant burden, more feet were tested by participants with higher MFCL K levels and fewer feet were tested by participants with lower MFCL K levels. The research prosthetist performed dynamic alignment for each foot and did on several occasions remove the zip-tie and lower the black sock to reach the set screws on the foot. The zip-tie was replaced after dynamic alignment to the satisfaction of the research prosthetist.

Sagittal and coronal moments were collected at 100 Hz via Bluetooth (Europa, Orthocare Innovations, Mountlake Terrace, WA) as the participant walked along a 12 m walkway in a gait laboratory. This device has been described in detail in previous publications (Boone et al., 2012; Boone et al., 2013; Kobayashi et al., 2012, Kobayashi et al., 2013a, 2013b, 2014), but briefly the load cell measures moments in the sagittal and coronal planes during gait within the prosthetic limb system. The sagittal moment pattern has a similar appearance to the sagittal ankle moment curve calculated from inverse dynamics (Segal et al., 2012; Ventura et al., 2011), but is measured directly within the limb system. The data are presented in a similar convention as internal muscle moments from inverse dynamics: negative moments tend to plantarflex the foot and positive moments tend to dorsiflex the foot. As in previous studies using Europa, the moment data was plotted across stance phase for all steps. After 40 level steps were recorded ($\sim$3 min), the next foot was fit to their prosthesis by the research prosthetist who was blinded to foot type (see Fig. 2).

After the participant completed testing all their assigned feet in the laboratory, a subset of two of these feet were selected, each for a week-long community wear test by the participant. The choice of feet for the participant to test in the community was made by the clinical prosthetist and based on their judgment of a foot that had higher ESR characteristics and one that had lower ESR characteristics than the participant's original prescribed foot. Feet judged to be too risky for the participant were not chosen due to ethical factors associated with the clinical impression of the level of risk to the participant. This is less objective than the categories based on published evidence of stiffness and hysteresis, but is closer to typical clinical practice for a prosthetist. In total, the participant completed one week of community wear testing in their originally prescribed foot, one week each in one of the chosen test feet. The participants wore the same shoes while testing different feet in the laboratory. In the community participants were free to wear different shoes as needed. All investigators collecting and analyzing data, all participants and the statistician remained blinded to foot type throughout the research protocol.

Based on the results from previous publications (Boone et al., 2013) the maximum sagittal moment value in stance phase (*Max*) was extracted with the Europa software and was the primary biomechanical outcome measure. Two secondary outcome measures were extracted from the sagittal moment data collected in the laboratory on each foot tested including the minimum sagittal moment in early stance (*Min*), the value at 45% of stance phase (*45%*) (Boone et al., 2013). Stance time and cadence values were also calculated to determine if gait speed was similar for all feet tested in the laboratory.

Activity data (Galileo, Orthocare Innovations, Mountlake Terrace, WA) was collected during the seven day community wear test for all feet tested, including a baseline in the participant's original prescribed foot before entering the study. The Galileo algorithm utilizes steps per minute data collected with a StepWatch activity monitor (Motus Health, Washington DC), which has been shown to provide steps per minute data for those with limb loss with better than 99.6% accuracy (Coleman