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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 ≥ 25 mm displacement and $\leq 75\%$ energy loss were usually placed in the *Stiff* category; those feet with ≥ 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

Table 1
Demographic data of study participants at the time of study entry. Some participants entered the study with a prescribed foot that was not included in any of the categories defined in this study. These feet are identified as "Other" in the table.

Partici-pant	*Age* (yrs)	*Weight* (kg)	*Height* (m)	*Gender*	*K level-prosthetist rating*	*Galileo K level*	*Amputa-tion side*	*Community test original foot*	*Community test foot 1* (*Stiff, Intermediate, Compliant*)	*Community test foot 2* (*Stiff, Intermediate, Compliant*)
P01	41	110	1.96	M	3	3.7	L	Other	*Stiff*	*Stiff*
P02	55	73	1.70	M	2	3.1	R	*Compliant*	*Intermediate*	*Compliant*
P03	74	75	1.78	M	3	3.3	R	*Stiff*	*Stiff*	*Intermediate*
P04	68	70	1.68	F	2	3.0	R	*Compliant*	*Compliant*	*Compliant*
P05	49	75	1.75	M	4	4.2	R	Other	*Stiff*	*Stiff*
P06	39	111	1.91	M	4	3.9	R	*Compliant*	*Stiff*	*Intermediate*
P07	65	91	1.83	M	3	3.3	L	Other	*Compliant*	*Compliant*
P08	58	86	1.78	M	3	3.5	L	Other	*Stiff*	*Compliant*
P09	69	57	1.57	M	2	2.9	L	Other	–	–
P10	53	99	1.88	M	3	4.0	L	*Compliant*	*Intermediate*	*Compliant*
P11	66	78	1.73	M	3	3.4	L	*Compliant*	*Compliant*	*Stiff*
P12	47	61	1.70	M	4	4.6	L	*Compliant*	*Stiff*	*Intermediate*
Mean	57	82	1.77		3	3.6				
SD	11.5	18	0.11		0.7	0.5				
Range	41–74	57–111	1.57–1.96		2–4	2.9–4.6				

Table 2
Kinetic variables from sagittal moment data, and temporal gait data for three categories of prosthetic feet.

Variable	*Stiff* Mean ± SD	*Intermediate* Mean ± SD	*Compliant* Mean ± SD	*P* value
Max (Nm)	69.7 ± 5.3	60.7 ± 3.4	59.1 ± 2.9	0.0011*
Min (Nm)	– 16.6 ± 3.4	– 15.9 ± 2.3	– 14.9 ± 2.0	NS
45% (Nm)	24.3 ± 2.6	17.6 ± 3.4	20.2 ± 2.8	NS
Stance time (s)	0.67 ± 0.08	0.69 ± 0.09	0.70 ± 0.09	NS
Cadence (steps/min)	116 ± 12	111 ± 10	114 ± 16	NS

* *Stiff* category feet had significantly higher *Max* moments during laboratory testing compared with *Intermediate* and *Compliant* category feet. NS = non–significant.

Fig. 1. Each prosthetic foot tested was built to the same height to facilitate quick swapping during laboratory kinetic testing. Feet were covered with black socks zip-tied to the pylon to obscure the foot make and model from the investigators, the participants and the statistician.

et al., 1999). Briefly, Galileo utilized steps per minute data collected with a StepWatch activity monitor to determine the most active minute each day; the ratio of minutes with low (< 15 steps/min): medium (15–40 steps/min): high (> 40 steps/min) step rates; and the daily energy expenditure based on total daily steps and body mass [EEtotal (kcal) = 2.033 kcal kg^{-1} × weight (kg) + 0.368 kcal × steps − 86.1 kcal; (Foster et al., 2005)]. 25% of the Galileo score is based on the prosthetist's rating of K level and 75% of the score is based on real world steps per minute data on the participant. Combined, these algorithms are used to calculate the Galileo functional level score. The Galileo functional level score is similar to the medicare functional classification level (MFCL) K levels, but includes increased resolution to one decimal point (e.g. 2.3 or 3.6).

Ratings for the modified mobility section of the Prosthetics Evaluation Questionnaire (PEQm) (Legro et al., 1998) were collected from the participants on each foot tested following the seven day community wear test. This questionnaire (see Appendix A) asked about the participant's perception of their level of activity during the past week on the foot being tested, the length of time it took to adapt to the foot used during the past week, and a 5-point satisfaction scale about the comfort, appearance, weight, stability, energy required to walk, and overall satisfaction while wearing the foot. The PEQm also asked for ratings of the user's perception of the specific foot's performance across different environmental challenges (slopes, uneven surfaces, turning, stairs, etc.; see Appendix A).

The prosthetic feet tested were placed into three categories prior to hypothesis testing: *Stiff*, *Intermediate*, *Compliant* (see Table 3). The participants, the research prosthetist, and the investigators were blinded to the foot being tested in the community. The clinical prosthetist and principal investigator were not blinded and did not participate in data collection or hypothesis testing. The codes for the prosthetic foot types were kept in a locked cabinet and the principal investigator had the only key.

This research protocol was designed to manage the participant burden and safety such that the number of feet tested increased as the participant's activity level increased, and the data matrix was unbalanced for number of feet tested by each participant, and the number of feet in each category. Therefore, linear mixed effects regressions were used to determine if the kinetic variables extracted from the sagittal moment curves (*Min, 45%, Max*) differed among the three prosthetic foot categories (*Stiff*, *Intermediate*, *Compliant*). The kinetic measure was the dependent variable, foot category was the independent fixed effect modeled as 2 dummy variables (with the *Stiff* prosthetic foot category as the reference) and random effects for error due to participant, error due to foot type within participant and error due to trial within foot type/session. Significance was assessed using the likelihood ratio test. If a significant association was found, post-hoc pairwise comparisons were carried out with significance set at $P = 0.05/3 = 0.017$, using Bonferroni's correction for multiple testing. The statistical analysis for the kinetic measure was carried out using R 2.13 (Bates et al., 2011a), and the lme4 package (Bates et al., 2011b) to do the linear mixed effects modeling.

For the PEQm data, a Wilcoxon signed-rank test was used (Excel 2010, Microsoft, Redmond WA) to evaluate the participants' preference for the *Stiff* vs. *Intermediate* vs. *Compliant* feet.

For the activity data, the Galileo functional level score was compared between foot categories using a repeated measures ANOVA in StatView (SAS, Cary, NC). In addition, simple linear regression was used to determine the relationship between the clinical prosthetist's rating of the participants MFCL K level and the Galileo functional level score collected in the participants' original prescribed foot.

This study design has three different and complimentary domains: The biomechanical domain, the patient preference domain and the activity domain. The primary hypothesis in the biomechanical domain was that *Stiff* feet > *Intermediate* feet > *Compliant* feet for the peak sagittal moments (*Max*) during gait. The secondary hypotheses in the biomechanical domain were that *Stiff* feet > *Intermediate* feet > *Compliant* feet for the minimum sagittal moment in early stance (*Min*) and the value at 45% of stance (*45%*). The hypothesis in patient preference domain was that users would prefer feet in the *Stiff* category. The hypothesis in the activity domain was that activity level would increase significantly during community testing with *Stiff* category prosthetic feet.

Table 3
Modified PEQ (PEQm) questionnaire results for three categories of prosthetic feet and eleven participants, who rated the feet on a 5-point satisfaction scale (higher is better) after one week of community wear testing while blinded to foot type. Some participants wore originally prescribed feet that were not included in the three defined categories (see Table 1). Wilcoxon signed-rank test showed that *Compliant* prosthetic feet were preferred compared to *Stiff* or *Intermediate* prosthetic feet (Wilcoxon signed-rank $P < 0.025$). Bold font shows the highest average rating among feet for each characteristic.

PEQm Question	*Stiff feet*	*Intermediate feet*	*Compliant feet*
Number of participants testing feet	$n = 10$	$n = 5$	$n = 14$
Number of prosthetic feet in category	$n = 5$	$n = 2$	$n = 4$
Comfort	3.5 ± 1.3	3.8 ± 0.8	**4.0 ± 1.1**
Appearance (with sock on)	**4.4 ± 0.7**	3.6 ± 1.7	3.9 ± 1.2
Weight	**4.4 ± 0.8**	4.2 ± 0.8	4.3 ± 0.6
How you look when you walk	**3.8 ± 1.5**	**3.8 ± 0.8**	3.6 ± 1.1
Stability	3.6 ± 1.8	3.4 ± 1.1	**3.8 ± 0.9**
The energy it took to walk	3.4 ± 1.7	3.6 ± 0.5	**3.8 ± 1.3**
Ability to wear a range of shoes	**4.3 ± 0.8**	3.0 ± 1.7	3.6 ± 1.2
Overall satisfaction	3.4 ± 1.3	3.4 ± 1.1	**4.1 ± 1.1**
Walking on level surface	3.9 ± 1.4	3.8 ± 0.8	**4.1 ± 1.1**
Walking on uneven terrain (grass, gravel)	3.2 ± 1.8	3.0 ± 1.0	**3.7 ± 1.1**
Walking up stairs	3.6 ± 1.5	3.4 ± 1.1	**4.1 ± 0.9**
Walking down stairs	3.5 ± 1.4	3.2 ± 1.1	**4.1 ± 0.9**
Walking up a hill or sloped surfaces	3.6 ± 1.3	3.6 ± 0.9	**3.7 ± 0.9**
Walking down a hill or sloped surface	3.4 ± 1.3	3.4 ± 0.9	**3.7 ± 1.0**
Walking in bad weather	3.4 ± 1.3	3.7 ± 0.6	**3.9 ± 0.8**
Negotiating turns or corners	3.7 ± 2.6	4.0 ± 1.0	**4.4 ± 0.7**
Participating in sports	2.6 ± 1.5	3.0 ± 0.0	**3.2 ± 1.3**

Bold font indicates best score for each criterion.

3. Results

Eleven participants completed all phases of the study. One participant passed away before completing all community testing of feet due to health issues unrelated to the study. Despite attempting to recruit participants across a full range of functional levels (based on clinical impression of the gait ability of the individuals in the recruitment pool), all participants were MFCL K 2 or higher measured by the clinical prosthetist in their original prescribed foot. The ratings of MFCL K level made by the clinical prosthetist and Galileo at baseline are shown in Table 1.

Contrary to our hypothesis, on the PEQm participants reported a preference for *Compliant* feet (Wilcoxon signed-rank $P < 0.025$; see Table 3). They specifically scored this category of prosthetic feet as being consistently superior over uneven terrain and for maneuvering on stairs, ramps, slopes and similar barriers. Other factors rated by the participants such as stability, energy to walk, and comfort showed variable, but statistically significant preferences for the *Compliant* category feet (see Table 3).

The Galileo functional activity level (Orendurff et al., 2012) for the participants did not change significantly for any metric for any foot category ($P = 0.38$), indicating that for each foot worn in the seven-day community test, a similar number of steps – at similar step rates for similar durations – were performed (see Fig. 4).

The prosthetic feet in the *Stiff* category had the highest maximum sagittal moments (*Max*) in late stance phase during the laboratory gait testing compared to *Intermediate* and *Compliant* category feet ($P < 0.0011$; see Fig. 3 & Table 2). Other areas of the curve that were of interest, the minimum sagittal moment in early stance (*Min*), and the value at 45% of stance (*45%*) did not show statistically significant differences ($P > 0.43$). Cadence and stance time variables did not show statistically significant differences

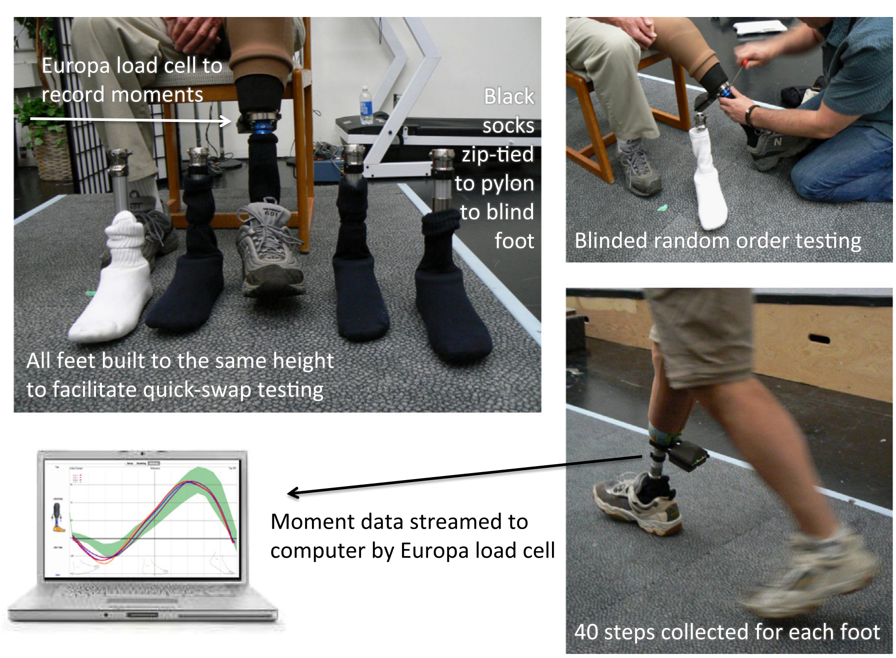

Fig. 2. Laboratory testing of each blinded foot required 40 steps recorded in each blinded foot built for each participant. Sagittal and coronal moment data measured by a Europa™ load cell (Orthocare Innovations, Mountlake Terrace, WA) was sent by Bluetooth to a computer and plotted across stance phase. (Prosthetic foot with white sock is the participant's original prescribed prosthetic foot at study entry; feet tested in this study have black sock covers.)

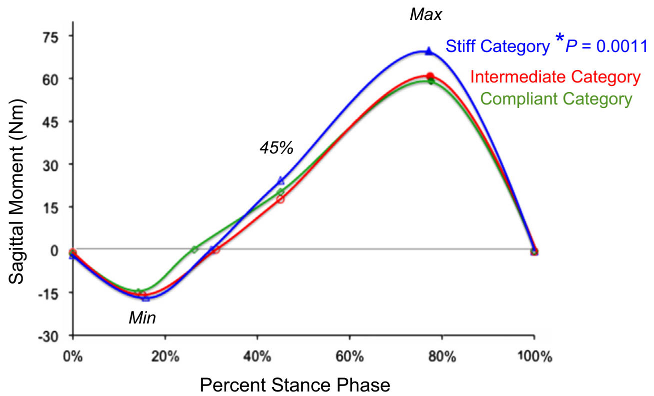

Fig. 3. Sagittal moment data across stance phase for three categories of prosthetic feet: *Stiff*, *Intermediate* and *Compliant* (based on forefoot displacement under load and hysteresis) (AOPA, 2010). Hypothesis testing was performed for the *Min*, *45%* and *Max* sagittal moment using a mixed effect linear regression with paired comparisons post-hoc.

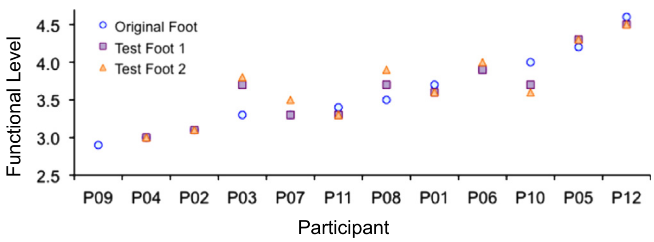

Fig. 4. Functional activity level calculated for each participant using Galileo™ (Orthocare Innovations, Mountlake Terrace, WA) during week-long community wear tests in their originally prescribed prosthetic foot and two blinded prosthetic feet (test foot 1 and test foot 2). See Table 1 for the specific category of feet tested by each participant in the community.

across different foot categories suggesting that participants walked at similar speeds in the laboratory while testing feet ($P > 0.59$ in all cases) (Table 2).

4. Discussion

This study utilized three complimentary domains to evaluate prosthetic feet: the biomechanical domain, the activity domain and the perceptual domain, in a randomized double blind design. Despite the low number of participants who completed this study ($n = 11$) and contrary to the hypothesis, it appears that over a range of functional level prosthetic users, *Compliant* feet were preferred over other categories. As hypothesized, *Stiff* feet had significantly larger maximum sagittal moments during walking compared to *Compliant* and *Intermediate* feet. However, *Intermediate* feet were hypothesized to have higher maximum sagittal moments than *Compliant* feet, rather than equal maximum sagittal moments, and this was unexpected.

Contrary to the hypothesis in the activity domain, the mean Galileo functional levels in the community did not show significant increases in any of the prosthetic feet tested over the week-long wear tests. This suggests that although the participants indicated a preference for *Compliant* category prosthetic feet, participants did not spontaneously increase their activity level when changing prosthetic feet. Together, these results suggest that prosthetic foot preference was based on perceived performance characteristics during community ambulation but may not have been based on perceptions of increased activity level in the community since there was no detectible change in activity level. The *Compliant* category of feet produced consistently higher preference scores on PEQm questions related to walking on: level surfaces; up and down slopes and stairs; in bad weather; while negotiating turns; and while participating in sports. Despite these noted preferences, participants did not increase their activity level or functional classification level of the Galileo score. The PEQm included a question about the participant's perception of their activity level while wearing different feet in the community. Several participants noted on the PEQm that they were especially more or less active during the week testing different feet. However, the Galileo functional level score shows that activity level in their original foot and the two test feet were extremely similar. This suggests that participants were unable to correctly assess their habitual activity level when reflecting back on the previous weeks.

The perception by the user appeared to be that the *Compliant* feet enable more functional gait on typically encountered community challenges in slope and surface, but this may not be the most substantial factor that restricts the individual's activity level.

It is not known why *Compliant* feet were preferred over *Intermediate* feet despite having similar maximum moment values during walking in the laboratory, but might be related to the differences in forefoot power absorption and generation of *Compliant* prosthetic feet at slower walking speeds. There is a possibility that the prosthetic foot categories used in this study are not completely objective, and that clinician judgment may have tainted the mechanically-defined categories. A more specific and rational set of mechanical characteristics to categorize prosthetic feet would be beneficial for outcomes research in prosthetic component prescription. Additional investigation into the power generation characteristics is required to determine if a more sensitive and specific biomechanical measure can better differentiate *Compliant* from *Intermediate* prosthetic feet, or if simply increasing the community testing duration, number of participants and number of feet in the *Intermediate* category would yield more definitive results. There are of course other possibilities, such as socket pressure and perception of comfort in different prosthetic feet, but previous real world activity data has shown that activity levels increase in transtibial prosthetic users if socket comfort improves (Coleman et al., 2004). In the current study, no increase in activity was detected with different feet, suggesting that improvements in comfort of a magnitude that would enable increased levels of activity were not associated with any foot category.

This study provides some evidence that amputees can detect specific biomechanical characteristics of prosthetic feet. There was a ~15% reduction in the maximum sagittal moment during walking for the *Compliant* and *Intermediate* feet compared to the *Stiff* feet. The randomized double-blind design of this study lessens the confounding influence of marketing hype and visual appeal that can affect prosthetic foot preference for the investigator, the prosthetist and the prosthetic user. However, the lack of an accepted set of mechanical characteristics to objectively define the prosthetic foot categories suggests that additional research is needed to achieve the appropriate level of evidence required to guide prosthetic foot prescription choices in the future.

The MFCL K level of the participants was determined by the clinical prosthetist in the clinic, in the participant's originally prescribed foot prior to entering the study protocol. This K level was slightly lower for some individuals than the Galileo calculation from their week-long StepWatch activity monitor data in that same originally prescribed foot. A linear regression produced an $R^2 = 0.77$ when comparing the clinical prosthetist's rating of K level to the Galileo calculated functional level (Table 1) suggesting reasonable agreement between the two methods of determining the K level.

The lack of change in the participants' activity level in any foot category during the week-long community wear tests was also contrary to the hypothesis. However, in retrospect this result is not without precedent. Previous work has shown that microprocessor controlled prosthetic knees do not increase activity levels in transfemoral amputees compared with activity levels using non-microprocessor controlled (hydraulic) knees during community wear tests (Klute et al., 2006). A shock-absorbing pylon also did not increase activity levels in transtibial amputees compared with their activity levels in a rigid pylon (Klute et al., 2006). Many factors influence an individual's activity level, and like any intervention designed to produce a change in behavior, the individual's readiness to change is a more powerful precursor of behavior change (Boudreaux et al., 2003; Pedersen et al., 2009; Phelan et al., 2002; 2006; Taylor et al., 2004) than any enabling technology. The single paper that shows a prosthetic intervention that improves activity was related to socket liner type and comfort during ambulation (Coleman et al., 2004).

In conclusion, this small cohort of prosthetic users with transtibial limb loss preferred *Compliant* feet with lower peak sagittal moments during gait, but did not increase their activity level when using these feet, nor reduce activity when using non-preferred prosthetic feet. A larger multi site randomized double blind trial is warranted to determine if this preliminary result can be replicated over a broader range of participants and with more rigorous categorization of prosthetic feet.

Conflict of interest statement

Michael Orendurff, PhD and Toshiki Kobayashi, PhD are employees of Orthocare Innovations, the developers of the Europa and Galileo systems used in this study. This work was funded by a grant to Silvia Raschke, PhD and British Columbia Institute of Technology by the American Orthotic and Prosthetic Association. AOPA has had no influence upon the design, data collection, analysis, or interpretation of this research study, no involvement in the decision to publish these results, and no involvement in the writing of this manuscript.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.jbiomech.2014.10.002.

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