



The effects of prosthetic ankle stiffness on ankle and knee kinematics, prosthetic limb loading, and net metabolic cost of trans-tibial amputee gait

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ARTICLE INFO

Article history:

Received 2 May 2013

Accepted 18 October 2013

ABSTRACT

Background: Previous studies of commercially-available trans-tibial prosthetic components have been unable to provide clear insight into the relationships between prosthetic mechanical properties and user performance (i.e., gait quality and energy expenditure), the understanding of which is key to improving prosthesis design and prescription. Many of these studies have been limited by not characterising the mechanical properties of the tested prostheses and/or only considered level walking at self-selected speeds. The aim of this study was to conduct a systematic investigation of the effects of ankle rotational stiffness on trans-tibial amputee gait during various walking conditions reflective of those encountered during daily ambulation.

Methods: Ankle and knee kinematics, prosthetic limb normal ground reaction forces, and net metabolic cost were measured in five traumatic unilateral trans-tibial amputees during treadmill walking on the level, a 5% incline and a 5% decline whilst using an experimental articulated prosthetic foot with four different rotational stiffness setups and without changes in alignment between conditions.

Findings: Overall, lower dorsiflexion stiffness resulted in greater prosthetic side dorsiflexion motion and sound side knee flexion, reduced normal ground reaction force during the loading phase of prosthetic stance and reduced net metabolic cost.

Interpretation: Few differences were observed with changes in plantarflexion stiffness, most likely due to the foot achieving early foot flat. Low dorsiflexion stiffness generally improved gait performance seemingly due to easier tibial progression during stance. However, observed differences were small, suggesting that a wider range of walking and stiffness conditions would be useful to fully explore these effects in future studies.

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1. Introduction

Amputees exhibit energy inefficient gait (Perry and Burnfield, 2010; Waters et al., 1976), and their mobility is often restricted by discomfort of the residual limb and the functional limitations of the prosthesis (Ephraim et al., 2005; Kelly et al., 1998; Klute et al., 2001; Postema et al., 1997b). Therefore, it has been a long standing goal to understand how prostheses may be designed to improve these aspects of amputee performance. However, although it is reasonable to assume that the walking performance of trans-tibial prosthesis users is affected by the mechanical properties of passive prosthetic components (Hafner et al., 2002; Klute et al., 2001; Major et al., 2012), these relationships remain poorly defined. This is perhaps not surprising, given that, until recently, most in-vivo investigations have compared commercial prostheses in terms of their effects on biomechanical and/or physiological

performance (Hafner et al., 2002; Hofstad et al., 2004; Klute et al., 2001; Twiste and Rithalia, 2003; van der Linde et al., 2004) but did not characterise the amputee-independent mechanical properties of the different prostheses (Major et al., 2011, 2012). Such an approach only provides information on relative performance but no insight into the mechanical properties of a prosthesis that may lead to improved amputee performance (Major et al., 2012).

One way of addressing this issue is to use standardised methods for measuring the mechanical properties of commercial devices in conjunction with their in-vivo evaluation (e.g., Lehmann et al., 1993a,b; Miller and Childress, 1997; Postema et al., 1997a, vd Water et al., 1998). A more recent approach has been to utilize custom-built experimental prostheses that allow for systematic variation of certain mechanical properties whilst holding others constant, such as roll-over shape arc length (Hansen et al., 2006), forefoot flexibility (Klodd et al., 2010a,b), and foot-ankle compliance (Fey et al., 2011). The latter (more recent) approach, which we term “parameterised testing”, is preferred, as the tested properties are not limited to those provided by commercial devices. More importantly, in-vivo studies, involving experimental

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prostheses for parameterised testing, allow relationships to be explored between specific mechanical properties and aspects of user performance. Previous studies have offered initial insight into the effects of prosthetic foot compliance on unilateral trans-tibial amputee gait performance, such as relationships between increased foot flexibility and increased prosthetic dorsiflexion motion (Fey et al., 2011; Klodd et al., 2010a) and decreased first and second peak normal ground reaction force on the sound and prosthetic limb, respectively (Fey et al., 2011). However, these studies have not investigated the effects of changing the ankle stiffness of an articulated foot-ankle prosthesis, have been limited to level ground walking, and have been restricted in the number of steps analysed due to their methods of data collection (use of floor-mounted force plates to measure ground reaction forces).

Therefore, the aim of this study was to conduct a controlled investigation of the relationships between the rotational stiffness properties of a novel articulated prosthetic Custom-built Foot-Ankle Mechanism (CFAM) and the gait performance of the user during different walking conditions reflective of those encountered during daily ambulation (i.e., level, uphill, and downhill). The reason for using a CFAM, rather than commercial prostheses, was to enable a systematic testing of a range of ankle stiffness without simultaneously altering other properties, as it is known that the alteration of prosthetic components and alignment affects prosthesis mechanical properties in a complex and interactive manner (Major et al., 2011). This preliminary study focused on several gait performance variables related to gait efficiency (i.e., metabolic energy expenditure), prosthetic limb loading, and the ability of the sound limb to attenuate force through knee flexion during early stance (Perry and Burnfield, 2010). A better understanding of these relationships will help optimize clinical prescription guidelines and the development of improved prosthesis designs.

2. Methods

2.1. Participants

Ethical approval was obtained from the local government health and university institutional review boards. Participant inclusion criteria included: unilateral trans-tibial amputation as a result of trauma; no known neurological or other musculoskeletal pathologies; at least one year of prosthesis use prior to data collection; and able to walk without a mobility aid (other than the prosthesis).

2.2. Custom prosthesis and experimental protocol

The CFAM was part of a custom prosthesis and designed and fabricated to allow for independent modulation of plantarflexion and dorsiflexion rotational stiffness of a single-axis ankle joint (Fig. 1),

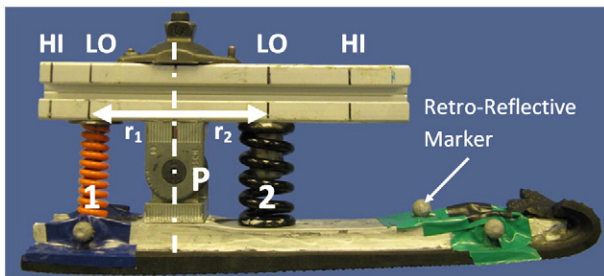


Fig. 1. An image of the CFAM. The plantarflexion stiffness ($K_{rot,1}$) and dorsiflexion stiffness ($K_{rot,2}$) are defined as: $K_{rot,i} = K_{lin,i} \times r_i^2$ for $i = 1$ and 2 , where $K_{lin,i}$ is the linear stiffness of the respective springs (1 and 2) and r_i is the distance of the spring from the central pivot (P). The springs can be translated along the upper rail. Vertical black lines on the upper rail indicate spring positions for high and low plantar and dorsiflexion stiffness to the left and right of the vertical dashed line, respectively. Adjustment of the spring positions without modifying prosthetic alignment is accomplished by separating the upper from the lower rail at the central pivot.

without concurrently changing other mechanical properties or requiring alteration of prosthesis alignment relative to the proximal limb (design specifications can be found in Major, 2010). The plantarflexion and dorsiflexion rotational stiffness of three common, commercially-available, prosthetic foot designs (i.e., SACH foot, Seattle Foot, and Flex Foot) were estimated from published heel and forefoot force-displacement curves (Lehmann et al., 1993b), and the lowest (LO) and highest (HI) stiffness values were identified (Major, 2010). The LO rotational stiffness values were 9,420 and 39,430 N-cm/rad for plantarflexion and dorsiflexion, respectively, and the HI values were 20,280 and 139,570 N-cm/rad for plantarflexion and dorsiflexion, respectively. In short, these rotational stiffness values were estimated by 1) applying a linear best fit approximation to the force-displacement curves to identify linear stiffness; and 2) multiplying the linear stiffness by the squared value of the distance between the point of load application and the effective ankle position. Consequently, these LO and HI plantarflexion and dorsiflexion stiffness settings led to four CFAM setup testing conditions in this study:

- LOLO = LO dorsiflexion & LO plantarflexion;
- LOHI = LO dorsiflexion & HI plantarflexion;
- HILO = HI dorsiflexion & LO plantarflexion;
- HIHI = HI dorsiflexion & HI plantarflexion.

In order to minimize confounding variables contributing to its stiffness properties, the CFAM was intended to be worn without a foot shell or shoe, and therefore has treaded rubber sole material on its plantar surface for increased friction whilst walking. For use in the experiment, a total surface bearing test socket (Icecast, Össur, Reykjavik, Iceland) was fabricated for each participant, and this included an Iceross silicon liner (Össur, Reykjavik, Iceland) and shuttle-lock pin suspension. A 3-axis load-cell (Model 51E20A, JR3, Woodland, CA, USA) was integrated between the socket and a rigid aluminium pylon that was attached to the proximal aspect of the CFAM.

Participants made three visits to the laboratory, where walking trials were conducted on a multiple speed/grade treadmill (Vision Fitness, Lake Mills, WI, USA). During the first visit: informed consent was obtained; a cast was taken of the residual limb for fabrication of the new socket; descriptive measurements were collected; participants walked with their own prosthesis on the treadmill for 10 min at a “comfortable and safe” walking speed to familiarize themselves with treadmill walking without using handrails; and this speed was noted as “self-selected speed” for subsequent use in the experiment.

During the second and third visit, participants were fitted with the custom prosthesis, and clinical alignment was performed with the CFAM in the most compliant condition (LOLO) for the purpose of standardization. As standard clinical alignment is based on a prosthetist's knowledge and skills, and influenced by prosthetic foot geometry and stiffness (Hansen et al., 2003), no subsequent alignment adjustments were made for the different conditions to eliminate this as a confounding variable and hence ensure that only stiffness was being systematically adjusted. Each participant wore their own shoe on the sound foot and this shoe was the same for both visits.

Following alignment, participants sat quietly for 3 min to record their resting metabolic energy expenditure. They then performed 10 min of free-walking around the laboratory to familiarize themselves with the custom prosthesis. After that, retro-reflective markers were attached to the participants' lower extremities for optical motion capture. Then, the four CFAM setups were tested during four walking conditions:

- SSWS = self-selected speed on the level;
- FWS = fast walking speed (150% of self-selected) on the level;
- INC = self-selected walking speed on a 5% incline;
- DEC = self-selected walking speed on a 5% decline.

The order of testing the four CFAM setups was randomised, whereby two setups were tested during the second visit and the other two during the third visit. At the start of each walking trial, participants walked on

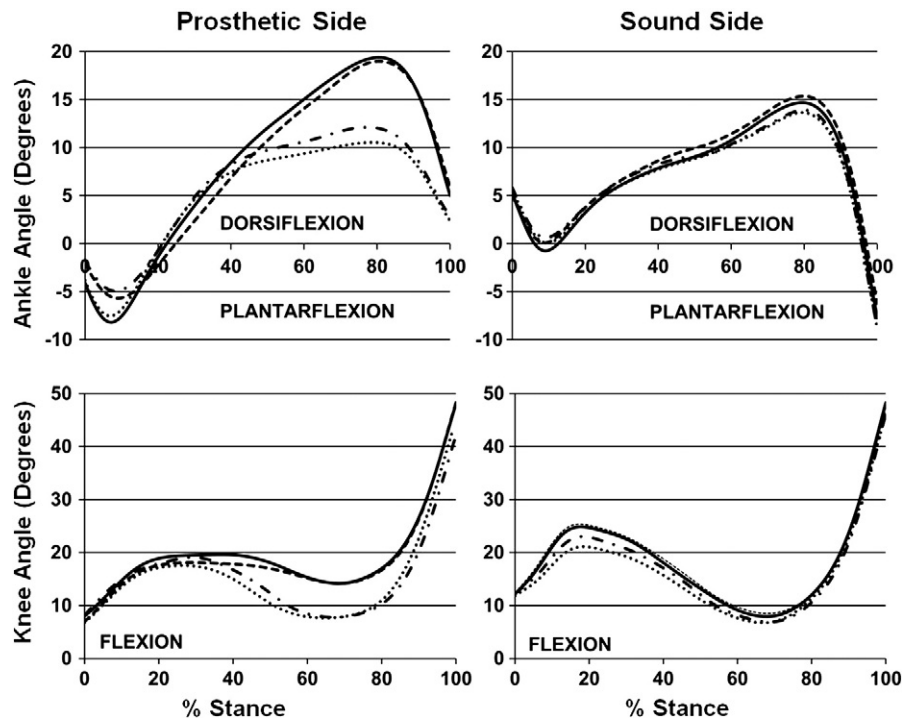


Fig. 2. Average ankle and knee joint kinematics during stance for the four CFAM setups and all subjects for the FWS condition (0% and 100% approximating initial contact and toe-off, respectively); solid line = LOLO, dash line = LOHI, dotted line = HILO, dash-dot line = HIHL.

the treadmill whilst holding the handrails and speed was simultaneously increased to their self-selected speed. The participants released the handrails when comfortable and then walked for 5 min, which was deemed to be an acceptably short period in terms of keeping the total testing time to a minimum. The first walking conditions to be tested were SSWS and then FWS (both on the level) for each CFAM setup, and these conditions were tested in sequence and continuously, as this is an established protocol used in a similar within-subject study on lower extremity prostheses (Schmalz et al., 2002). Then, the two graded walking conditions were tested in randomised order. To avoid fatigue, 20 min of seated rest were provided between CFAM setups and as much rest as requested was provided between the three sets of tests at different slopes (i.e., level, incline, and decline).

2.3. Data collection and analysis

Kinematic data were collected by an eight camera motion capture system (Vicon, Oxford, UK) at 100 Hz using retro-reflective markers. These were mounted 1) in clusters of four on plates attached to the participants' thighs, sound shank, and prosthetic socket; and 2) individually (rather than in clusters) on the sound foot (three on the forefoot and one on the heel) and CFAM (two on the anterior end of the foot plate and two on the posterior end of the foot plate (see Fig. 1)). Lower extremity joint centres and angular displacements (for the sound and prosthetic ankles and both knee joints) were estimated in Visual 3D software (C-Motion, Germantown, MD, USA) using a custom model and the Calibrated Anatomical Systems Technique (Cappozzo et al., 1995). Knee and sound side ankle joint centres were estimated during a static trial prior to each testing session (Cappozzo et al., 1995), and so was the CFAM ankle joint centre, which was assumed to be at the centre of its single-axis joint. Joint angles were considered as neutral (i.e., 0°) during upright standing when the shank is upright (i.e., near perpendicular to the plantar surface of the foot) and the knee is in full extension. Kinetic data (i.e., normal ground reaction forces) of the prosthetic limb were collected with the load-cell, and were transformed

from their local reference frame to the global reference frame that was always aligned with the treadmill walking surface regardless of the slope (i.e., resulting inferior–superior ground reaction forces were normal to the treadmill belt). A Butterworth low-pass filter was applied to the kinetic and kinematic data using custom software in Matlab (Mathworks, Natick, MA, USA) with cut-off frequencies of 25 Hz and 6 Hz, respectively. To normalize data to stance time, initial contact and toe-off events were estimated from the kinematic data (O'Connor et al., 2007) using custom software in Matlab. The loading phase of stance was defined as 0–50% of the stance time.

Real-time metabolic energy expenditure during walking and quiet sitting was measured using a MetaMax 3B breath-by-breath indirect calorimetry device (Cortex Biophysik, Leipzig, Germany) that required participants to wear a silicon mask. The final 30 s of each five minute walking trial (without handrails) were used for kinetic and kinematic data analysis, because it was estimated that, by this stage at the latest, the participants achieved steady-state treadmill walking and hence a repeatable gait pattern (Owings and Grabiner, 2003; Zeni and Higginson, 2010). Resting metabolic energy was estimated as the average of the final 2 min of the 3 min of seated rest, and active (walking) metabolic energy as the final minute of the 5 min of treadmill walking. Metabolic energy was normalized by participant mass. A net metabolic cost (ml O₂/kg/m) was calculated by subtracting the resting energy from the active energy and dividing this by walking speed.

2.4. Statistical analysis

Given that the Shapiro–Wilk test revealed that the majority of data sets were not normally distributed ($\alpha = 0.05$) and would preclude any parametric analysis, within-subject kinematic, kinetic data and metabolic cost differences between CFAM setups were statistically analysed with the (non-parametric repeated-measures) Friedman test and the Dunn–Bonferroni posthoc adjustment for multiple comparisons (Dunn, 1964) using SPSS (version 20, IBM, Armonk, NY, USA). Effects of CFAM setup on these gait parameters were analysed for each walking

Table 1

Effects of CFAM setup on peak prosthetic plantarflexion (degrees). For pairwise comparisons 'A vs B' a positive difference (Δ medians) means that A produced more plantarflexion than B. Posthoc results are listed for each pairwise comparison. The *P*-value and test statistic (χ^2) for the Friedman tests are reported, as well as the *P*-value and test statistic (*z*) for each pairwise comparison when the Friedman *P*-value is at or below the critical alpha (0.008). N/A indicates not applicable.

	SSWS		FWS		INC		DEC	
	Friedman (<i>P</i> = 0.440, χ^2 = 2.700)		Friedman (<i>P</i> = 0.098, χ^2 = 6.300)		Friedman (<i>P</i> = 0.308, χ^2 = 3.600)		Friedman (<i>P</i> = 0.272, χ^2 = 3.900)	
	Δ medians	<i>p</i> , <i>z</i>	Δ medians	<i>p</i> , <i>z</i>	Δ medians	<i>p</i> , <i>z</i>	Δ medians	<i>p</i> , <i>z</i>
LOLO vs HILO	−0.6	N/A	0.1	N/A	2.1	N/A	2.2	N/A
LOHI vs HIHI	0.4	N/A	0.9	N/A	0.6	N/A	0.5	N/A
LOLO vs LOHI	2.5	N/A	2.0	N/A	2.2	N/A	3.0	N/A
HILO vs HIHI	3.5	N/A	2.9	N/A	0.7	N/A	1.4	N/A
LOLO vs HIHI	2.9	N/A	3.0	N/A	2.8	N/A	3.6	N/A
LOHI vs HILO	−3.1	N/A	−1.9	N/A	−0.1	N/A	−0.9	N/A

condition separately. For the purpose of presentation, the median values across all CFAM setups for each walking condition were calculated. A Bonferroni adjustment was used to control for the family-wise error rate, which reduced the pre-defined critical α to 0.008.

3. Results

Following participant recruitment, five males (mean (SD): 48 (8) years, 1.83 (0.3) m, 88 (8) kg) gave consent to be tested. Participants' clinically-prescribed prostheses included a SACH (solid-ankle cushion heel; Otto Bock, Duderstadt, Germany), Elite (Endolite, Basingstoke, UK), Quantum (Hanger, Austin, TX, USA), Ceterus (Össur, Reykjavik, Iceland), and Trias (Otto Bock, Duderstadt, Germany) foot.

During the tests, one participant grasped the handrails whilst walking with the HIHI setup for all walking conditions, hence these data were excluded from analysis. The same participant was able to increase walking speed to only 133% of SSWS as opposed to 150% for all other participants (FWS), but these data were nevertheless included, as they were, after all, based on a considerable faster speed. Additionally, force data are missing for one participant when using the LOLO and HILO setup due to a hardware fault. The median walking speed for the SSWS and FWS conditions were 0.7 m/s (interquartile range: 0.7–0.8 m/s) and 1.1 (interquartile range: 1.1–1.3 m/s).

For illustration purposes, Fig. 2 shows average ankle and knee joint kinematic data for the four CFAM setups and all subjects during the FWS walking condition. Overall, compared to HI stiffness, LO dorsiflexion stiffness increased peak CFAM dorsiflexion (median of 19° versus 11°) and LO plantarflexion stiffness increased peak CFAM plantarflexion (median of 6° versus 4°). Tables 1 to 6 present a comprehensive set of results for peak prosthetic ankle plantarflexion, peak prosthetic ankle dorsiflexion, peak sound side ankle dorsiflexion during late stance, peak sound side knee flexion during stance, prosthetic peak normal ground reaction force (NGRF) during the loading phase of stance (normalized to % body weight (BW)), and net metabolic cost,

respectively. The changes in median values are presented for each comparison of CFAM setups, with the posthoc statistic values of Friedman tests only for *P*-values at or below the critical alpha (0.008). The first two rows show the effects of altering dorsiflexion stiffness (LOLO vs HILO and LOHI vs HIHI) and the third and fourth rows show the effects of altering plantarflexion stiffness (LOLO vs LOHI and HILO vs HIHI). Row 5 compares the most compliant vs the most stiff feet (LOLO vs HIHI) and row 6 compares the effect of changing the fore-aft distribution of stiffness (LOHI vs HILO). Table 7 shows the grouped medians and inter-quartile range for the four walking conditions across all CFAM setup testing conditions and the four CFAM setups across all walking conditions.

4. Discussion

4.1. Lower extremity kinematics

As expected, LO plantarflexion and LO dorsiflexion CFAM stiffness consistently produced greater range-of-motion of the prosthetic ankle (Fig. 2, Tables 1 and 2). The LO plantarflexion stiffness setting increased peak prosthetic plantarflexion, better approximating the values typically observed in able-bodied stance during level walking (7°). However, LO dorsiflexion stiffness produced peak prosthetic dorsiflexion that exceeded typical values in able-bodied stance during level walking (10°) (Perry and Burnfield, 2010).

In the majority of walking conditions, HI plantarflexion stiffness increased the peak dorsiflexion of the sound side ankle joint during late stance, but the median reduction across all participants and all conditions was minimal (Table 7) and probably not clinically significant, although this obviously needs exploring further and over prolonged periods of time to establish long-term side effects.

Overall, the majority of compensatory changes in sound side kinematics were seen at the knee joint. As compared to LO stiffness, HI dorsiflexion stiffness produced a reduction in sound side peak knee

Table 2

Effects of CFAM setup on peak prosthetic dorsiflexion (degrees). For pairwise comparisons 'A vs B' a positive difference (Δ medians) means that A produced more dorsiflexion than B. Posthoc results are listed for each pairwise comparison. The *P*-value and test statistic (χ^2) for the Friedman tests are reported, as well as the *P*-value and test statistic (*z*) for each pairwise comparison when the Friedman *P*-value is at or below the critical alpha (0.008). N/A indicates not applicable.

	SSWS		FWS		INC		DEC	
	Friedman (<i>P</i> = 0.006, χ^2 = 12.600)		Friedman (<i>P</i> = 0.006, χ^2 = 12.600)		Friedman (<i>P</i> = 0.019, χ^2 = 9.900)		Friedman (<i>P</i> = 0.004, χ^2 = 13.080)	
	Δ medians	<i>p</i> , <i>z</i>	Δ medians	<i>p</i> , <i>z</i>	Δ medians	<i>p</i> , <i>z</i>	Δ medians	<i>p</i> , <i>z</i>
LOLO vs HILO	9.7	0.020, 2.400	9.3	0.020, 2.400	9.3	N/A	9.3	0.086, 2.000
LOHI vs HIHI	6.5	0.331, 1.750	7.1	0.331, 1.750	7.3	N/A	6.2	0.171, 2.000
LOLO vs LOHI	2.2	1.000, 0.200	2.1	1.000, 0.200	2.6	N/A	2.6	1.000, −0.600
HILO vs HIHI	−1.0	1.000, −0.500	−0.1	1.000, −0.500	0.6	N/A	−0.4	1.000, −0.500
LOLO vs HIHI	8.7	0.331, 1.750	9.2	0.331, 1.750	10.0	N/A	8.8	0.602, 1.500
LOHI vs HILO	7.5	0.042, 2.200	7.2	0.042, 2.200	6.7	N/A	−6.6	0.009, 2.600

Table 3

Effects of CFAM setup testing condition on peak sound side ankle dorsiflexion (degrees). For pairwise comparisons 'A vs B' a positive difference (Δ medians) means that A produced more dorsiflexion than B. Posthoc results are listed for each pairwise comparison. The *P*-value and test statistic (χ^2) for the Friedman tests are reported, as well as the *P*-value and test statistic (*z*) for each pairwise comparison when the Friedman *P*-value is at or below the critical alpha (0.008). N/A indicates not applicable.

	SSWS		FWS		INC		DEC	
	Friedman (<i>P</i> = 0.753, χ^2 = 1.200)		Friedman (<i>P</i> = 0.753, χ^2 = 1.200)		Friedman (<i>P</i> = 0.825, χ^2 = 0.900)		Friedman (<i>P</i> = 0.045, χ^2 = 8.040)	
	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>
LOLO vs HILO	1.7	N/A	0.7	N/A	0.1	N/A	2.4	N/A
LOHI vs HIHI	−2.3	N/A	−0.9	N/A	−2.0	N/A	−1.2	N/A
LOLO vs LOHI	−0.3	N/A	−1.6	N/A	−1.1	N/A	0.7	N/A
HILO vs HIHI	−4.3	N/A	−3.2	N/A	−3.3	N/A	−2.9	N/A
LOLO vs HIHI	−2.6	N/A	−2.6	N/A	−3.1	N/A	−0.5	N/A
LOHI vs HILO	2.0	N/A	2.3	N/A	1.3	N/A	1.7	N/A

flexion with a median reduction of 4° (Table 4, rows 1 and 2), resulting in 20° flexion, which is also the value seen in typical able-bodied gait during level walking (Perry and Burnfield, 2010). Results suggest that a reduction in CFAM ankle dorsiflexion resulting from HI dorsiflexion stiffness encouraged a more extended sound knee during early to midstance. This may have detrimental effects on the sound limb's ability to minimize potentially harmful joint stress, taking into account the capacity of knee flexion to attenuate forces and absorb energy through early stance (Winter, 2009). Particularly for unilateral trans-tibial amputees, this may be critical because joint stress due to compensatory gait mechanisms has been linked to greater prevalence of joint degeneration of the sound side knee joint compared to the prosthetic side knee joint (Burke et al., 1978; Norvell et al., 2005; Royer and Koenig, 2005).

4.2. Prosthetic side loading

No consistent differences in the peak NGRF under the prosthetic side during the loading phase of stance were observed between LO and HI plantarflexion stiffness. This may be the result of the small differences in plantarflexion (i.e. shock absorbing) motion between stiffness setups as the plantar surface of the foot quickly reached foot flat during loading (Fig. 2). In turn, results show that LO dorsiflexion stiffness, as compared to HI, generally reduced the NGRF, (Table 5, rows 1 and 2) with a median reduction of 3.6% BW. Similarly, a within-subject study that tested various prosthetic feet observed that the foot with the greatest dorsiflexion stiffness produced the greatest peak NGRF during loading (Lehmann et al., 1993b). Overall, higher dorsiflexion stiffness elevates the loading forces on the prosthetic side, and although these were not excessive for the set of walking conditions in this study, they could however be more harmful for the prosthetic limb at increased walking speeds.

Table 4

Effects of CFAM setup testing condition on peak sound side knee flexion (degrees). For pairwise comparisons 'A vs B' a positive difference (Δ medians) means that A produced more flexion than B. Posthoc results are listed for each pairwise comparison. The *P*-value and test statistic (χ^2) for the Friedman tests are reported, as well as the *P*-value and test statistic (*z*) for each pairwise comparison when the Friedman *P*-value is at or below the critical alpha (0.008). N/A indicates not applicable.

	SSWS		FWS		INC		DEC	
	Friedman (<i>P</i> = 0.118, χ^2 = 5.880)		Friedman (<i>P</i> = 0.019, χ^2 = 9.900)		Friedman (<i>P</i> = 0.019, χ^2 = 9.900)		Friedman (<i>P</i> = 0.006, χ^2 = 12.600)	
	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>
LOLO vs HILO	1.5	N/A	3.5	N/A	5.2	N/A	3.4	0.165, 1.800
LOHI vs HIHI	3.5	N/A	3.8	N/A	4.2	N/A	4.6	0.171, 2.000
LOLO vs LOHI	−2.7	N/A	−1.0	N/A	2.2	N/A	−1.3	1.000, −0.600
HILO vs HIHI	−0.7	N/A	−0.8	N/A	1.1	N/A	0.1	1.000, −0.500
LOLO vs HIHI	0.8	N/A	2.8	N/A	6.3	N/A	3.3	0.602, 1.500
LOHI vs HILO	4.2	N/A	4.5	N/A	3.0	N/A	4.7	0.020, 2.400

4.3. Net metabolic cost

For LO dorsiflexion stiffness, as compared to HI, the results show a reduction in net metabolic cost (Table 6, rows 1 and 2) with a modest median decrease of 0.015 ml-O₂/kg/m. Although any reduction in metabolic cost is presumably beneficial (taking into consideration amputees' increased energy consumption compared to non-amputees (Perry and Burnfield, 2010)), this 8% reduction may not be clinically significant. The vast majority of previous research on metabolic differences in unilateral trans-tibial amputee gait when comparing various different prosthetic foot designs have also reported similar modest findings (Hofstad et al., 2004; van der Linde et al., 2004). A similar study that observed systematic changes in forefoot flexibility also reported small differences in oxygen cost (Klodd et al., 2010b). The results from this research and that of previous studies suggest that metabolic cost may not be a sufficiently sensitive (and hence appropriate) parameter for comparing the overall performance of different passive prosthetic foot-ankle mechanisms for active unilateral trans-tibial amputees, such as the participants in this study. Future prosthetic designs should perhaps be optimized to maximize functional balance during daily activities, particularly given amputees' increased fall risk compared to able-bodied individuals (Miller et al., 2001).

4.4. Limitations

The small sample size of this preliminary study limited its statistical power, which was a result of the recruitment difficulties associated with amputee studies. Also, using a CFAM may be considered to limit the clinical relevance of this study, however, the stiffness settings used here were reflective of commercially available prosthetic feet, and the results obtained from this could therefore be considered as appropriate for a clinical setting. Additionally, clinicians assign foot stiffness and length

Table 5

Effects of CFAM setup testing condition on peak normal ground reaction force during loading phase of stance (% BW). For pairwise comparisons 'A vs B' a positive difference (Δ medians) means that A produced greater force than B. Posthoc results are listed for each pairwise comparison. The *P*-value and test statistic (X^2) for the Friedman tests are reported, as well as the *P*-value and test statistic (*z*) for each pairwise comparison when the Friedman *P*-value is at or below the critical alpha (0.008). N/A indicates not applicable.

	SSWS		FWS		INC		DEC	
	Friedman (<i>P</i> = 0.615, X^2 = 1.800)		Friedman (<i>P</i> = 0.011, X^2 = 11.100)		Friedman (<i>P</i> = 0.896, X^2 = 0.600)		Friedman (<i>P</i> = 0.145, X^2 = 5.400)	
	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>
LOLO vs HILO	−2.3	N/A	−7.0	N/A	−2.6	N/A	−8.3	N/A
LOHI vs HIHI	−2.3	N/A	1.9	N/A	−0.8	N/A	−3.6	N/A
LOLO vs LOHI	−1.0	N/A	−2.8	N/A	0.1	N/A	−2.1	N/A
HILO vs HIHI	−1.0	N/A	6.1	N/A	1.9	N/A	2.6	N/A
LOLO vs HIHI	−3.3	N/A	−0.9	N/A	−0.7	N/A	−5.7	N/A
LOHI vs HILO	−1.3	N/A	−4.2	N/A	−2.7	N/A	−6.2	N/A

as a function of user weight, height, and also activity level (among other considerations), but the foot length and stiffness settings in this study remained for practical reasons the same for each participant and were not body height and weight specific, respectively, and this may have produced participant-specific compensations. However, many of our findings are consistent with previous related research, and this gives us confidence in the results. Further, only one alignment was used for each participant for all tests, irrespective of the stiffness condition. Although this is at odds with standard and subjective clinical alignment of trans-tibial prostheses, this approach was adopted to eliminate alignment as a variable that could have had a confounding influence in this study. Further, the standardised alignment may have affected the results of this study, such as the observed general trend of improved gait dynamics and metabolic cost when walking with the LOLO setting, as this was the setting that all prosthesis conditions were aligned to. Future studies should consider the use of stiffness-specific alignments, as well as standardised alignment as in this study, to further explore the effects of this clinically relevant variable. Furthermore, interpretation of the results should consider that, due to the short accommodation time provided for each new prosthesis setting, this study observed acute prosthetic effects on gait. However, the time required for active unilateral trans-tibial amputees to accommodate to new devices has not yet been definitively determined and hence varies considerably in the literature, ranging from minutes to months (Hafner et al., 2002; Hofstad et al., 2004; Klute et al., 2001; Twiste and Rithalia, 2003; van der Linde et al., 2004). Finally, although the level walking conditions were performed before the slope conditions to keep the testing time at an acceptable level, the study may consequently suffer from task order effects. Future studies may account for these limitations to more clearly understand these effects on in-vivo performance.

5. Conclusions

In summary, results suggest that unilateral trans-tibial amputee gait performance may benefit from prostheses with LO dorsiflexion stiffness.

Table 6

Effects of CFAM setup testing condition on net metabolic cost (ml O₂/kg/m). For pairwise comparisons 'A vs B' a positive difference (Δ medians) means that A required greater metabolic cost than B. Posthoc results are listed for each pairwise comparison. The *P*-value and test statistic (X^2) for the Friedman tests are reported, as well as the *P*-value and test statistic (*z*) for each pairwise comparison when the Friedman *P*-value is at or below the critical alpha (0.008). N/A indicates not applicable.

	SSWS		FWS		INC		DEC	
	Friedman (<i>P</i> = 0.055, X^2 = 7.615)		Friedman (<i>P</i> = 0.326, X^2 = 3.462)		Friedman (<i>P</i> = 0.347, X^2 = 3.308)		Friedman (<i>P</i> = 0.01, X^2 = 11.327)	
	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>	Δ medians	<i>p, z</i>
LOLO vs HILO	−0.006	N/A	−0.007	N/A	−0.014	N/A	−0.026	N/A
LOHI vs HIHI	−0.011	N/A	−0.014	N/A	0.002	N/A	0.009	N/A
LOLO vs LOHI	−0.007	N/A	−0.001	N/A	−0.027	N/A	−0.029	N/A
HILO vs HIHI	−0.012	N/A	−0.008	N/A	−0.011	N/A	0.007	N/A
LOLO vs HIHI	−0.018	N/A	−0.015	N/A	−0.025	N/A	−0.020	N/A
LOHI vs HILO	0.001	N/A	−0.006	N/A	0.013	N/A	0.003	N/A

Despite producing peak sound side knee flexion and prosthetic ankle dorsiflexion that exceeded those found in able-bodied gait, low stiffness tended to reduce prosthetic side NGRF and metabolic cost across level, incline, and decline walking. LO plantarflexion stiffness produced prosthetic plantarflexion motion that better matched the physiological ankle joint but did not noticeably affect prosthetic side NGRF during loading, most likely resulting from early foot flat. Overall, it appears that the ease of tibial progression on the prosthetic side during late stance as afforded with reduced dorsiflexion stiffness may benefit gait quality of unilateral trans-tibial prosthesis users. Consequently, commercial devices of increased dorsiflexion flexibility may be advantageous for these types of patients. Although an encouraging trend in gait performance was observed, the reported gait differences when comparing stiffness setups were small, and this should be considered when interpreting for clinical significance. Future studies would be useful if they tested a wider range of dorsiflexion and plantarflexion stiffness, as well as speeds and surface grades beyond those used in this study to fully explore these effects. Importantly, this study highlights the utility of experimental prostheses to allow for controlled systematic investigations that would not be possible with commercial devices. Such controlled investigations would surely facilitate an improved understanding of the intricate relationship between mechanical properties of passive prostheses and user performance, hence informing prescription guidelines and future designs that aim to maximize safe and efficient ambulation (Major et al., 2012).

Conflict of interest statement

The authors declare that there is no conflict of interest.

Acknowledgements

The authors wish to thank Colin Smith for his assistance in fabrication of components for the experimental prosthesis, and Ruth Nicholson for her assistance in fabrication of the test sockets.

Table 7

Effects of CFAM setup and walking condition on kinematics, kinetics, and metabolic cost [Median (lower quartile, upper quartile)]. Data under the “CFAM Setup” heading are median values across walking conditions and participants for each CFAM condition, and data under the “Walking Condition” heading are median values across CFAM conditions and participants for each walking condition.

Variable	CFAM setup				Walking condition			
	LOLO	LOHI	HILO	HIHI	SSWS	FWS	INC	DEC
Peak prosthetic plantarflexion (degrees)	6.4 (5.7,8.6)	4.7 (3.3,6.2)	6.6 (3.7,7.9)	4.1 (3.1,5.0)	4.7 (3.2,6.2)	6.7 (5.3,8.1)	3.1 (1.9,4.8)	6.5 (5.0,8.0)
Peak prosthetic dorsiflexion (degrees)	20.2 (15.9,21.2)	18.3 (15.7,21.8)	11.1 (8.8,12.3)	11.5 (10.5,12.8)	13.9 (11.6,19.2)	14.3 (12.1,20.2)	13.8 (11.8,19.7)	12.3 (11.2,18.7)
Peak sound side ankle dorsiflexion (degrees)	15.3 (14.3, 16.1)	15.2 (14.6, 17.2)	13.9 (12.4, 16.7)	16.8 (14.1, 18.6)	15.2 (14.0, 17.6)	14.3 (13.2, 15.9)	16.7 (15.1, 18.8)	15.2 (13.9, 16.7)
Peak sound side knee flexion (degrees)	22.7 (19.5, 29.0)	25.4 (21.3, 29.2)	20.1 (16.9, 22.2)	19.4 (18.4, 25.3)	19.2 (18.3, 20.6)	24.8 (20.0, 28.0)	28.9 (26.5, 31.6)	17.6 (16.7, 21.1)
Peak prosthetic side NGRF during loading (% BW)	100.4 (98.2, 101.3)	101.7 (99.5, 104.5)	106.2 (100.9, 109.1)	103.9 (98.5, 106.5)	100.5 (99.5, 102.6)	104.2 (101.8, 106.7)	96.6 (94.2, 100.6)	106.4 (101.7, 110.0)
Net metabolic cost (ml O ₂ /kg/m)	0.162 (0.143, 0.206)	0.173 (0.156, 0.202)	0.184 (0.156, 0.229)	0.181 (0.161, 0.218)	0.183 (0.162, 0.193)	0.167 (0.161, 0.176)	0.246 (0.230, 0.270)	0.135 (0.109, 0.146)

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