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Subject-specific responses to an adaptive ankle prosthesis during incline walking

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ABSTRACT

Individuals with lower-limb amputation often have difficulty walking on slopes, in part due to limitations of conventional prosthetic feet. Conventional prostheses have fixed ankle set-point angles and cannot fully replicate able-bodied ankle dynamics. Microprocessor-controlled ankles have been developed to help overcome these limitations. The objective of this study was to characterize how the slope adaptation feature of a microprocessor-controlled ankle affected individual prosthesis user gait biomechanics during sloped walking. Previous studies on similar microprocessor-controlled ankles have focused on group-level results (inter-subject mean), but did not report individual subject results. Our study builds upon prior work and provides new insight by presenting subject-specific results and investigating to what extent individual responses agree with the group-level results. We performed gait analysis on seven individuals with unilateral transtibial amputation while they walked on a 7.5° incline with a recently redesigned microprocessor-controlled ankle that adjusts ankle set-point angle to the slope. We computed gait kinematics and kinetics, and compared how users walked with vs. without this set-point adjustment. The microprocessor-controlled ankle increased minimum toe clearance for all subjects. Despite the microprocessor-controlled ankle behaving similarly for each user, we observed marked differences in individual responses. For instance, two users switched from a forefoot landing pattern with the microprocessor-controlled ankle locked at neutral angle to rearfoot landing when the microprocessor-controlled ankle adapted to the slope, while two maintained a forefoot and three maintained a rearfoot landing pattern across conditions. Changes in knee angle and moment were also subject-specific. Individual user responses were often not well represented by inter-subject mean. Although the prevailing experimental paradigm in prosthetic gait analysis studies is to focus on group-level analysis, our findings call attention to the high inter-subject variability which may necessitate alternative experimental approaches to assess prosthetic interventions.

1. Introduction

Healthy individuals adjust to sloped terrains via characteristic changes in gait kinematics and kinetics (Franz et al., 2012; Hansen et al., 2004a; Kuster et al., 1995; Lay et al., 2006; Leroux et al., 1999; McIntosh et al., 2006; Redfern and DiPasquale, 1997). For example, healthy individuals typically dorsiflex their ankle more during stance and generate more positive ankle work when walking uphill than during level ground walking (McIntosh et al., 2006). Individuals with lower-limb amputation, however, are often incapable of making similar adjustments with their prosthetic side (Vickers et al., 2008; Vrieling et al., 2008), due in part to the limitations of conventional prosthetic feet. Most conventional prosthetic feet are passive (cannot generate net-positive work) and have a fixed ankle set-point angle (Agrawal et al., 2015; Edelstein, 1988), which limits prosthetic ankle articulation during common daily activities like incline walking (Vickers et al., 2008). Limitations of conventional prosthetic feet can have detrimental effects on individuals with lower-limb amputation. For instance, reduced speed, cadence, prosthetic-side single-support time and knee moment have been attributed to the limited range of motion of conventional prostheses (Vickers et al., 2008; Vrieling et al., 2008). Other studies have reported reduced toe clearance of the prosthetic side relative to the intact side which

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may increase trip and fall risk (De Asha and Buckley, 2015). Prosthesis users have also been observed to exhibit an increased amplitude and duration of muscle activity during sloped walking (Vickers et al., 2008) which may accelerate the rate of fatigue.

Adaptive prosthetic ankles have been developed in recent years in an effort to address limitations of conventional passive prosthetic feet. Various adaptive prostheses are commercially available and have been designed to restore some degree of healthy ankle behavior (e.g., dorsi-/plantar-flexion range of motion (Endolite Elan and Fillauer Raize), powered push-off (Ottobock Empower)). Among these adaptive ankles are quasi-passive devices, such as the Össur ProprioFoot, which uses a microprocessor and low-power motor to adjust the set-point of the ankle angle when the device is unloaded (i.e., during swing phase) to better conform to sloped terrains (Koniuk, 2002). For example, during incline walking the ProprioFoot increases the ankle dorsiflexion angle (Fradet et al., 2010), as is observed in healthy ankle behavior (Hansen et al., 2004b). A few previous studies on individuals with unilateral transtibial amputation have investigated the biomechanical effects of the ProprioFoot on sloped terrains. Fradet et al. (2010) found that on average the increased dorsiflexion of the ProprioFoot led to increased peak prosthetic-side knee flexion (by $\sim$8°) and increased peak knee flexion moment (by $\sim$0.2 Nm/kg) in early stance (0–40% gait cycle) during 7.5° incline walking (N = 16), compared against the ProprioFoot without the set-point adjustment. Otherwise, they observed minimal changes in prosthetic-side and intact-side kinematics and kinetics during both incline and decline walking. Agrawal et al. (2015) found that the ProprioFoot improved inter-limb work symmetry for K2-level (Gailey et al., 2002) prosthesis users during decline walking as compared against a K1 (solid ankle cushioned heel prosthesis) foot (N = 10). Statistically significant differences were not found for incline walking, nor for K3-level prosthesis users. Darter and Wilken (2014) found that the ProprioFoot reduced metabolic energy expenditure during decline walking relative to users' daily-use prostheses (N = 6). However, metabolic differences were not statistically significant when comparing the ProprioFoot with vs. without the set-point angle adjustment.

Previous adaptive prosthesis studies (Agrawal et al., 2015; Darter and Wilken, 2014; Fradet et al., 2010) have primarily analyzed and reported results from a group-level perspective (i.e., computing inter-subject means and standard deviations, paired t-tests and repeated measures analysis of variance); however, group-level behaviors may not reliably reflect the behaviors of individuals within the group (Fisher et al., 2018). Prosthesis users are well known to be a heterogeneous population, even within a given K-level. It is not uncommon for multiple prosthesis users to adapt in different ways to the same intervention, or for some users to benefit while others do not (e.g., (Caputo and Collins, 2014)). This variability may be due to inherent differences amongst prosthesis users (e.g., cause, level and type of amputation) and/or clinical adjustments, such as prosthesis alignment, which can be highly variable (Zahedi et al., 1986). With a large enough sample size, these covariates could be factored into an analysis (e.g., stratification, multivariate models, or logistic regression (Pourhoseingholi et al., 2012)) to help explain the effects of these covariates on biomechanical outcomes. However, most instrumented gait analysis studies on prosthesis interventions are conducted on small sample sizes (10.2 ± 5.5 subjects (Van et al., 2004)). It is not uncommon for the number of covariates (confounding variables) to exceed the number of subjects tested, thus these population-based analyses are generally not adequate to account for covariates in gait analysis studies. In light of these limitations and challenges, the objective of this study was to characterize how individual prosthesis users alter their gait biomechanics during sloped walking with an adaptive ankle prosthesis, versus walking with the same ankle when the adaptive feature was turned off (i.e., ankle fixed in the nominal prosthetist alignment). This comparison allows us to directly evaluate the effects of the ankle adaptation without introducing additional confounds due to differences in size, mass, shape, or stiffness across prostheses. This study provides a unique and novel contribution to the literature, and builds upon prior work, by presenting subject-specific outcomes in order (i) to better elucidate how individuals adapt their gait pattern to an increase in ankle dorsiflexion set-point angle provided by a recently redesigned microprocessor-controlled ankle, and (ii) to investigate to what extent these individual adaptations are reflected by group-level responses.

2. Methods

2.1. Participants and intervention

Eight individuals with unilateral transtibial amputation were recruited for this study. However, one prosthesis user was omitted from the analysis because he was not comfortable walking on slopes when the microprocessor-controlled ankle (MPA) was locked at a neutral angle. The seven participants analyzed (6 male, 1 female, height 1.76 ± 0.07 m, mass 89.0 ± 14.1 kg, age 41.4 ± 13.4 yrs.) were either K3- or K4-level ambulators, each at least 6 months post amputation surgery (Table 1, for participant details). All participants provided written informed consent, according to Vanderbilt Institutional Review Board procedures. Participants were fitted with an adaptive MPA by a trained prosthetist, and were educated on the functions of the device. The prosthesis tested in this work was a premarket MPA developed and fabricated by Össur; it is the next generation of the ProprioFoot, which has various software and hardware updates relative to its predecessor (Fig. 1, A). Specifically, this device has an updated foot blade design based on the Pro-Flex LP (Össur), which may affect the stiffness and elastic energy storage/return properties of the prosthesis (Childers and Takahashi, 2018), whereas the previous generation ProprioFoot's foot blade was based on the Vari-Flex LP (Össur). This MPA provided two behaviors not found in conventional prosthetic feet. First, the MPA changed the set-point angle proportionally to the ground slope. It was programmed to dorsiflex the ankle to 75% of the incline slope angle (estimated via onboard sensors). Second, to facilitate toe clearance, the MPA dorsiflexed the ankle during early leg swing, then plantarflexed the ankle later

Table 1
Prosthesis user information. User 3 is female, the rest are males. All users have unilateral transtibial amputation.

User	Height (m)	Mass (kg)	Age (yrs.)	K-level	Daily-use	Suspension	Cause	Yrs. Amp.	Side	Shoes
1	1.8	94	48	K4	All-Pro	Sleeve & Liner	Trauma	6	L	Athletic
2	1.75	95	31	K4	All-Pro	1-way valve	Trauma	14	L	Athletic
3	1.63	63	31	K4	Elation	Seal-in	Stroke	1	L	Casual
4	1.85	83	50	K4	All-Pro	Sleeve & Liner	Trauma	10	L	Athletic
5	1.72	83	42	K4	Re-Flex Shock	Pin-lock	Trauma	7	R	Casual
6	1.8	105	63	K3	Rush 87	Sleeve & Liner	Trauma	2	L	Athletic
7	1.75	100	25	K3	Pro-Flex XC	Passive Suction	Trauma	1	R	Athletic

Fig. 1. Premarket microprocessor-controlled prosthetic ankle (MPA) developed by Össur (left) and sagittal view of the placement of passive reflective markers on the MPA and socket (right). Foot marker placement was intended to mirror markers on the intact foot (medial epicondyle, medial malleolus, and 1st metatarsal not shown).

in swing to return to the ankle set-point angle (in preparation for stance phase). After the fitting, prosthesis users wore the MPA for at least two weeks of at-home acclimation before returning for instrumented gait analysis testing.

2.2. Procedure

Prosthesis users performed level (0°) and sloped (incline/decline 7.5° (Fradet et al., 2010)) walking on a treadmill at a fixed speed (0.8 m/s for 6 users, and 0.9 m/s for user 6 who felt more comfortable at this speed), and also stair ascent and descent. Prosthesis users performed walking conditions in the following order: (i) the MPA with the ankle adaptation feature turned on (hereafter referred to as the MPA condition), (ii) the MPA with the adaptation feature turned off and the ankle fixed at a neutral angle (i.e., the alignment set by the prosthetist during fitting, hereafter referred to as the MPA-unadapted condition), and (iii) with their daily-use prosthesis (Table 1). Prosthesis users wore their preferred shoes during each testing condition (Table 1). Prosthesis users were not instructed to adopt any particular gait pattern, and were allowed to adapt as they desired. For brevity, and due to the large number of subject-specific results, we only present findings on the incline walking with the MPA vs. MPA-unadapted conditions in this work. These conditions allow us to isolate the effect of changing the ankle set-point angle on slopes without confounds due to the physical differences between the MPA and daily-use prostheses. Ground reaction force data were collected under each foot at 1000 Hz using a split-belt force-instrumented treadmill (Bertec, Columbus, OH, USA), and lower-body kinematics were recorded at 200 Hz via a synchronized 10-camera motion capture system (Vicon, Oxford, UK). Passive reflective markers were placed bilaterally over the anterior/posterior superior iliac spines, medial/lateral femoral epicondyles and malleoli, calcaneus, 1st and 5th metatarsal, and navicular bone. Clusters of four markers were placed bilaterally on the thigh and shank for segment tracking. Six markers were placed on the prosthetic socket (cluster of four on the body of the socket and two near the medial/lateral femoral epicondyles), and six were placed on the prosthetic-side shoe (estimated location of medial/lateral malleoli, calcaneus, 1st and 5th metatarsal heads and navicular bone, Fig. 1, B).

2.3. Data analysis

Joint angles, moments and powers were calculated over the stride, via inverse dynamics (Visual3D, C-Motion, Germantown, USA). Of note, ankle-foot power was calculated using an inverse dynamics estimate that considers contributions from all sources distal to the shank (or distal to the prosthetic socket for the prosthetic side) to avoid errors resulting from rigid-body assumptions of the ankle-foot (Takahashi et al., 2012; Zelik and Honert, 2018). Toe height during swing phase was estimated using a geometric model based on reflective markers placed on the foot, similar to previously published techniques (Begg et al., 2007). All data were divided into strides and processed for each participant and condition (yielding a mean of 25 strides ±9 strides per trial). Note that for the MPA condition, only strides after the foot had adapted to the slope were used in the average. Data were normalized to 100% stride cycle, and then averaged across strides prior to reporting. Prior to analysis, ground reaction force and motion capture data were filtered with a zero-lag 3rd order low-pass Butterworth filter at 15 and 6 Hz, respectively. Inter-subject comparisons between the MPA and MPA-unadapted conditions were performed with a non-parametric Wilcoxon signed-rank test ($\alpha = 0.05$).

2.4. Outcome metrics

In this work, we focus on a few select metrics. First, we report prosthetic-side sagittal ankle angle in order to confirm proper MPA function (i.e., that the MPA dorsiflexed to accommodate the sloped terrain, and also dorsiflexed during swing phase to aid toe clearance). Next, we report a few key outcome metrics that capture changes in participant gait biomechanics. These metrics include prosthetic-side (i) minimum toe clearance (MTC) during swing phase, (ii) fore-aft center-of-pressure, which provided an objective means of differentiating a rearfoot vs. forefoot landing pattern, and (iii) sagittal knee angle and moment, which were reported in prior work (Fradet et al., 2010) and may be important towards understanding changes in knee behaviors such as knee joint loading (Sanderson and Martin, 1997).

A few additional results are presented in the main text to assist readers in contextualizing and interpreting results and/or generating their own hypotheses based on the subject-specific results provided. First, we computed inter-subject mean outcomes, similar to prior ProprioFoot studies (e.g., (Alimusaj et al., 2009; Fradet et al., 2010)). The inter-subject mean curves provide a reference to visualize if and when individuals adopted gait strategies that are consistent or inconsistent with the group mean. In order to remove the variability in kinetic measurements due to physical differences between subjects, data were non-dimensionalized using base units of mass, gravity and leg length prior to computing the inter-subject averages (Pinzone et al., 2016). Second, we included data from the participants' daily-use prosthesis, which provides a reference for how each individual walks in daily life. Third, six healthy controls (4 female, 2 male, height 1.78 m ± 0.1 m, mass 69 kg ± 10.6 kg, age 21 years ± 1.8 years) were tested with the same protocol. To help account for differences in size and weight, control data were non-dimensionalized. We then computed kinematic and kinetic outcome measure means and standard deviations. Finally, we re-dimensionalized these mean control outcomes using the mean mass and leg length of the analyzed unilateral transtibial amputation group.

3. Results

For all individuals, the MPA adjusted to the incline slope and provided dorsiflexion during swing phase (Fig. 2), as expected. The MPA increased dorsiflexion by 6.6° ± 1.5° relative to the MPA-unadapted. During leg swing, the MPA provided 4.5° ± 0.5° of additional dorsiflexion at 80% of the gait cycle (Fig. 2). This resulted in an increase in minimum toe clearance (MTC) for all par-

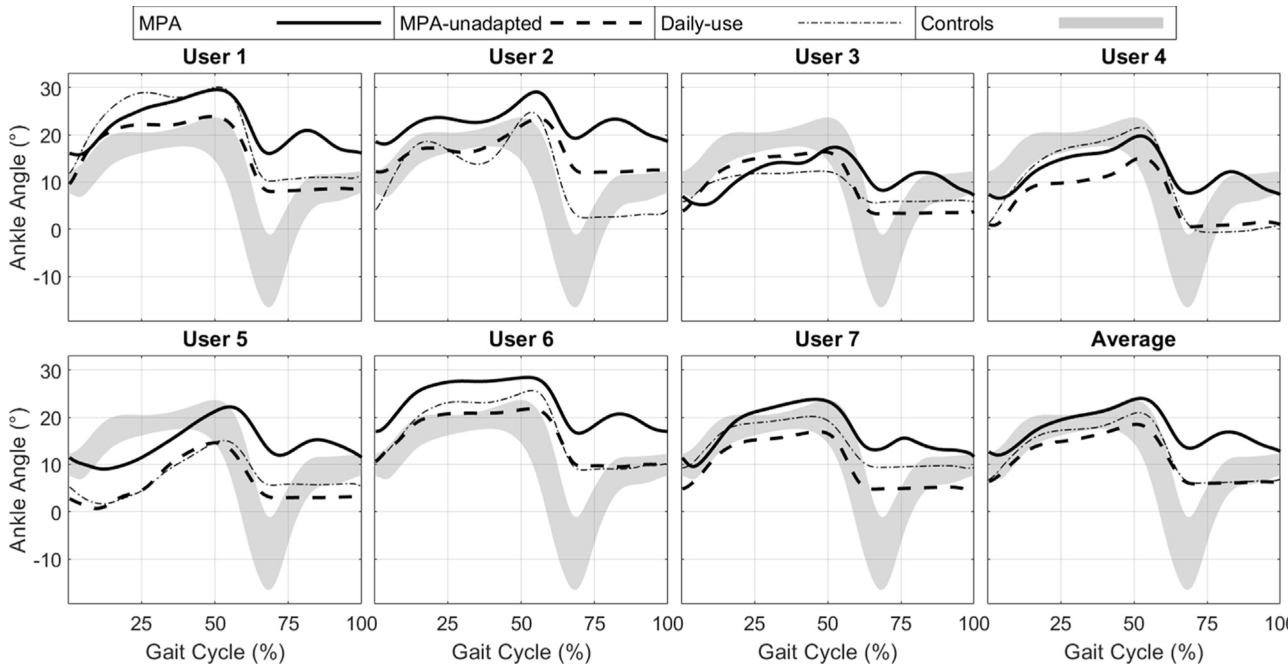

Fig. 2. Prosthetic-side sagittal ankle angle for each prosthesis user as well as the seven-subject average during incline walking for the MPA (solid), MPA-unadapted (dashed), and daily-use prosthesis (dash-dot) conditions. Positive values indicate dorsiflexion. Shaded gray region represents control mean ± one standard deviation. Ankle angle is defined as the angle between the shank and the foot and was calculated via motion capture markers on the foot and shank segments.

ticipants (mean 2.0 cm ± 0.4 cm more clearance, $p = 0.0156$) relative to the MPA-unadapted.

Participants exhibited two distinct incline walking strategies on their prosthetic side: (i) rearfoot landing, which was qualitatively similar to the behavior of the healthy controls and is characterized by a posterior-to-anterior (i.e., heel-to-toe) progression of the center-of-pressure (CoP, presented in the reference frame of the foot) and (ii) forefoot landing, which is characterized by an anterior bias of the CoP during the first 40% of the gait cycle. Rearfoot vs. forefoot landing were characterized using the CoP, and confirmed visually using video footage of the trial. However, the landing pattern used for a given condition (MPA vs. MPA-unadapted) was highly user-specific. Three users adopted a rearfoot landing pattern on the MPA-unadapted and maintained that pattern on the MPA. Out of the four users who adopted a forefoot pattern on the MPA-unadapted, two transitioned to a rearfoot pattern on the MPA while two maintained the forefoot pattern (Fig. 3).

Prosthetic-side knee angle and moment trends were also user-specific. For three users, stance-phase knee-flexion was decreased with the MPA vs. MPA-unadapted (Fig. 4). Three users showed the opposite trend, i.e., greater stance-phase knee-flexion with the MPA vs. MPA-unadapted, while one user exhibited minimal changes to knee angle between the conditions. Six of seven users showed increased prosthetic-side knee-extension moments with the MPA relative to the MPA-unadapted (Fig. 5). The remaining user showed a reduction in prosthetic-side knee-extension moment with the MPA relative to the MPA-unadapted. There were also various other differences between users in terms of peak knee moment magnitude and time-varying waveform over the stride (Fig. 5). Comprehensive subject-specific kinematics and kinetics are presented in the Appendix for reference.

4. Discussion

Despite the same intervention (increased dorsiflexion with the MPA during incline walking), changes in gait biomechanics across users were highly variable. Some users switched from a forefoot landing pattern on the MPA-unadapted to a rearfoot landing pattern when the MPA adapted to the slope, some exhibited a forefoot landing pattern regardless of the MPA ankle adaptation, and yet others exhibited a rearfoot landing pattern regardless of ankle adaptation (Fig. 3). Rearfoot landing is more consistent with how healthy controls walked up the incline (Fig. 3, shaded gray), and thus might be considered beneficial from a gait appearance or psychosocial standpoint (Breakey, 1997). Changes in knee kinematics and kinetics were also subject-specific (Figs. 4–5). For instance, some users exhibited more knee flexion in early stance with the MPA, whereas others exhibited less, and one individual showed negligible change (Fig. 4).

As a result of high inter-subject variability, group-level biomechanical results (e.g., inter-subject means) did not reflect the behavior of each individual. For example, the 7-subject mean CoP curve suggests that users transitioned from a forefoot landing pattern on the MPA-unadapted to a rearfoot landing pattern with the MPA (Fig. 3, Average). At best, this mean curve only partially reflects the gait of a subset of users and largely misrepresents the remaining users, highlighting the importance of individualized analysis. Furthermore, the mean knee angle curve suggests that the MPA condition had little effect on user knee flexion. In post-processing we performed a group-level statistical analysis and found that the peak at ∼10% gait cycle was not significantly different across users (Fig. 4, $p = 0.468$). Nonetheless, the majority (six of seven) of individual subjects exhibited changes >5° in knee flexion. One subset of individuals exhibited more knee flexion with the MPA, whereas another exhibited less knee flexion, such that averaging effectively canceled out these inverse effects in the average results. To summarize and report large amounts of biomechanical data from gait analysis studies, prior prosthesis studies – including our own – have primarily presented group-level results (e.g., (Agrawal et al., 2015; Darter and Wilken, 2014; Fradet et al., 2010; Zelik et al., 2011)), but this may inadvertently mask trends and important behaviors exhibited at an individual level. This highlights a contemporary challenge with prosthesis research (Caputo and Collins, 2014), and more generally with human sub-

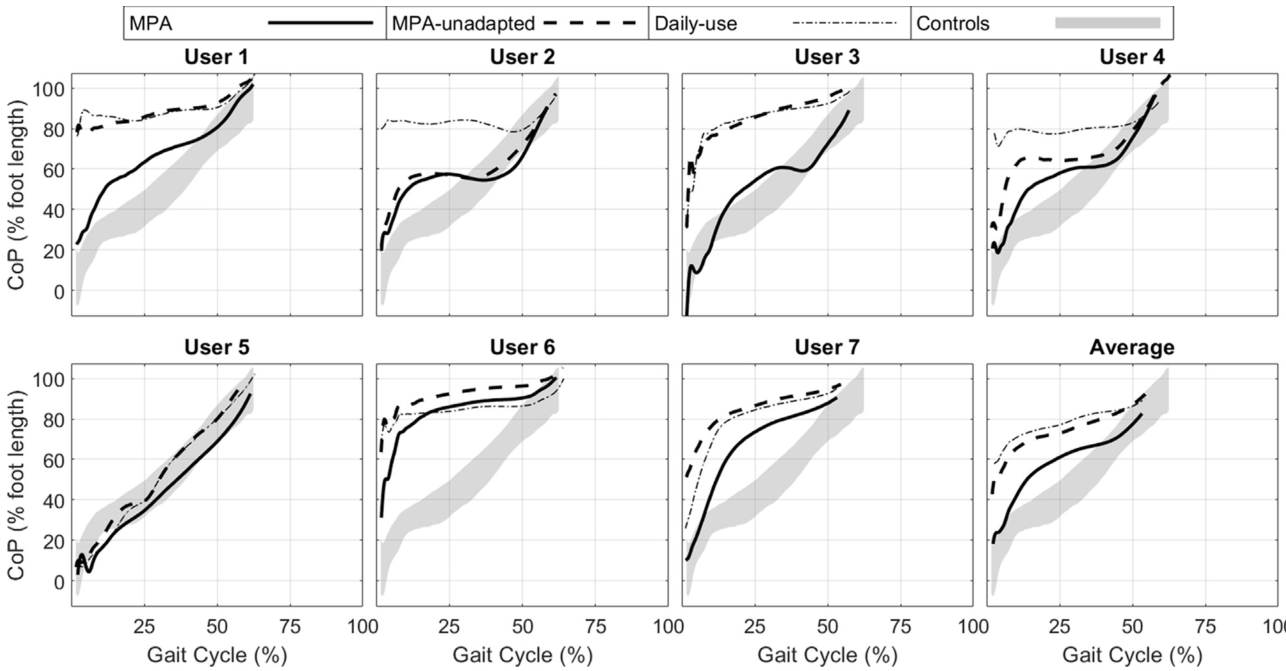

Fig. 3. Anterior/posterior position of the prosthetic-side center-of-pressure (CoP) in the foot reference frame (where 0% and 100% correspond to the rearfoot and forefoot, respectively) during incline walking for each prosthesis user as well as the seven-subject average for the MPA (solid), MPA-unadapted (dashed), and daily-use (dash-dot) conditions. CoP provides a means of visualizing whether users adopted a rearfoot landing pattern (similar to control subjects, shaded gray) vs. a forefoot landing pattern (larger CoP value in early stance indicates CoP is under forefoot). CoP measurements were truncated for vertical ground reaction forces less than 30 N to minimize noise for plotting purposes. Users 1 and 3 transitioned from a forefoot landing pattern with the MPA-unadapted to a rearfoot pattern with the MPA, whereas users 2, 4 and 5 exhibited a rearfoot landing pattern for both conditions. Users 6 and 7 exhibited forefoot landing for both conditions. Shaded gray region represents control mean ± one standard deviation.

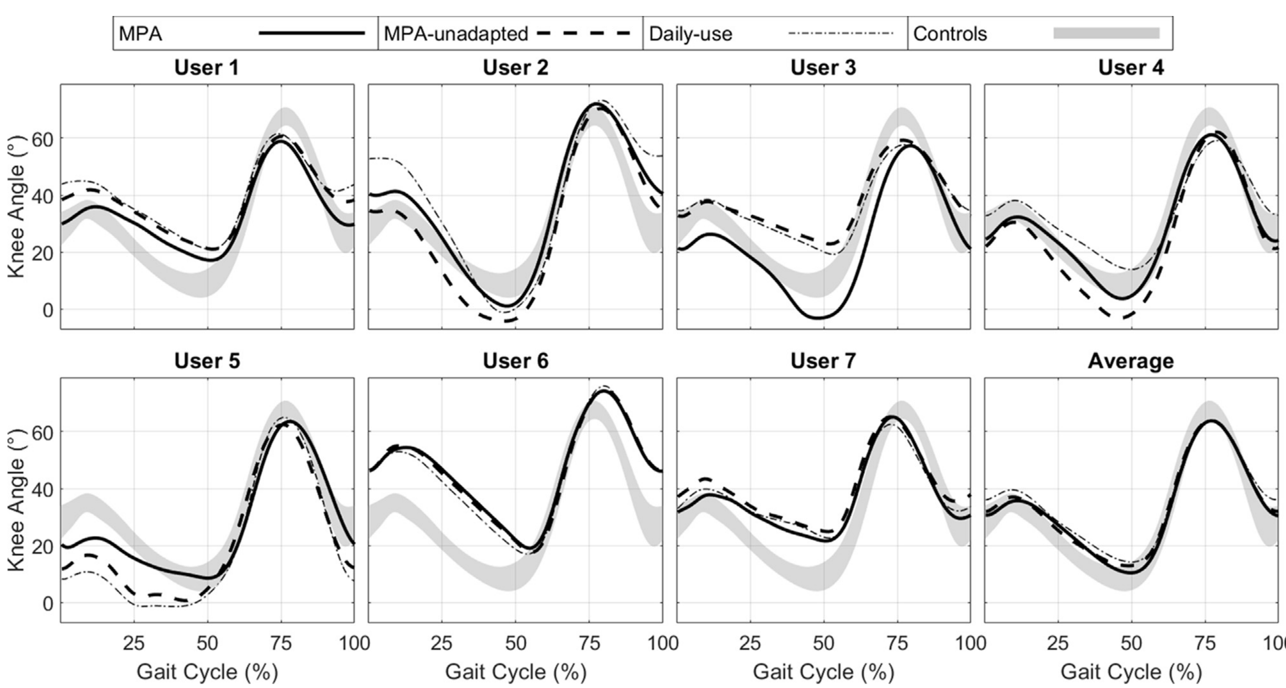

Fig. 4. Prosthetic-side sagittal knee angle for each prosthesis user, as well as the seven-subject average during incline walking with the MPA (solid), MPA-unadapted (dashed), and daily-use (dash-dot) conditions. Positive values indicate knee flexion. Six of seven users exhibited changes >5° in their maximum knee flexion in early stance (∼10–15% of gait cycle); however, these changes were not consistent among subjects. A subset of users (1, 3 and 7) exhibited reduced knee flexion with the MPA vs. MPA-unadapted, whereas another subset (2, 4, 5) exhibited increased knee flexion. Shaded gray region represents control mean ± one standard deviation.

ject research (Fisher et al., 2018; Yandell and Zelik, 2016), namely that group mean results may not reflect the behaviors of individuals.

Observed discrepancies between inter-subject mean and individual responses call attention to prevailing experimental protocols that involve testing prosthesis users on one or more

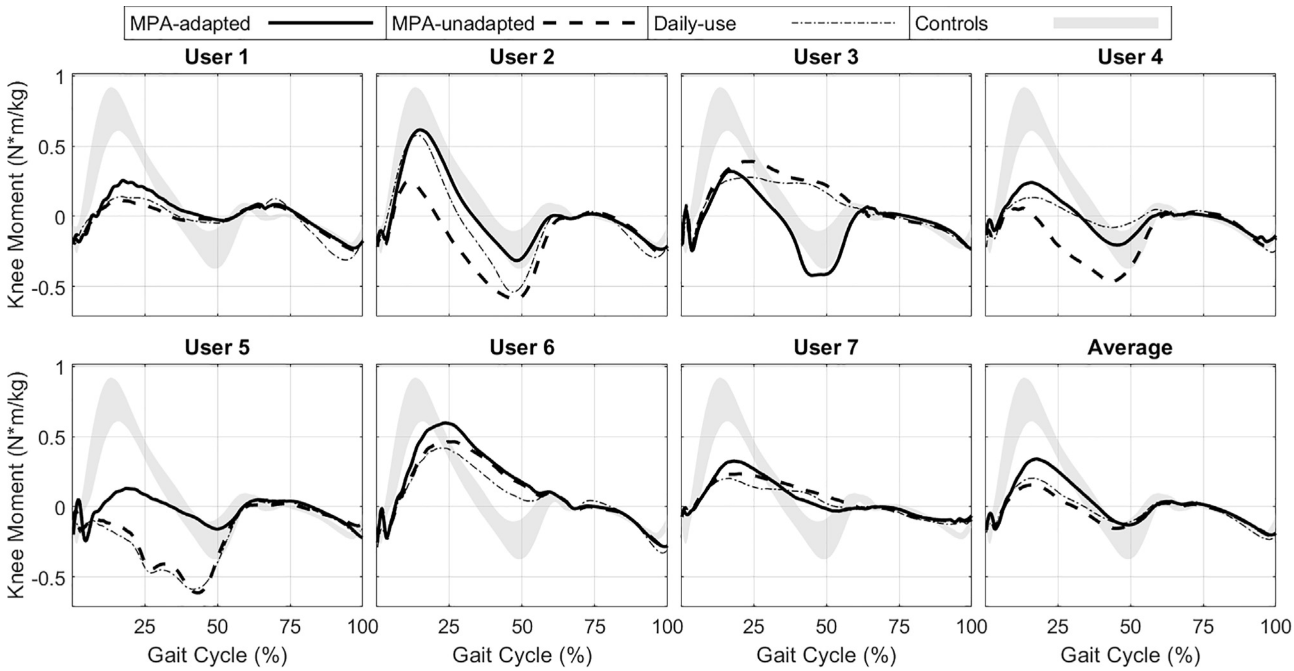

Fig. 5. Prosthetic-side sagittal knee moment for each prosthesis user, as well as the seven-subject average during incline walking with the MPA (solid), MPA-unadapted (dashed), and daily-use (dash-dot) conditions. Positive values indicate knee extension moments. Six of seven users exhibited an increase in stance-phase knee extension moments when walking on the MPA vs. MPA-unadapted; however, there was substantial variability in waveforms between users. Shaded gray region represents control mean ± one standard deviation.

interventions, and then performing group-level statistical analyses to identify significant effects. One of the most common ways to evaluate prosthetic interventions involves controlled experiments (e.g., with parallel or cross-over design) to evaluate whether an intervention improves a given outcome for a group of prosthesis users. Group-level analyses may be appropriate when responses are known to be consistent across a given population (Fisher et al., 2018), and useful for certain practical purposes (e.g., to inform whether an intervention is beneficial enough, on average, to be covered by insurance). There are many circumstances when generalizability across prosthesis users is not expected (e.g., due to variability in residual limb length or pain, type of amputation surgery, fitness level, height, weight, age, etc.). Also, research on new prosthetic devices are often carried out on relatively small (and often statistically underpowered) sample sizes, due in part to constraints related to time, cost and access to study participants. Thus, typical sample sizes used in prosthetic gait analysis studies often preclude the use of statistical methods that help account for confounding variables between subjects. Furthermore, especially for new devices, the sub-population who will benefit may not be known a priori. As a result, it is common that some subset of users exhibits an intended outcome, while others may not. Finally, it is not clear that obtaining group-level statistical significance is always of critical importance for evaluating prosthetic interventions. Particularly for new interventions, and interventions designed for highly heterogeneous populations, it may be more important to determine if a subset of users can derive a substantial (e.g., clinically meaningful) benefit from the device and/or to determine the range of potential behavioral responses. From a clinical perspective, an intervention need not be beneficial for all individuals within a group, nor demonstrate statistically significant improvements on average across a group, in order to be beneficial for a single user or subset of users. A key question moving forward is whether group-level analysis should continue to be the *de facto* standard for evaluating prosthetic interventions (as it currently seems to be), particularly given the number of existing and emerging technologies and the practical constraints on testing large samples of prosthesis users using instrumented gait analysis. The field may benefit from supplementing conventional group-level analyses with alternative approaches such as single-subject study designs (Backman and Harris, 1999; Shultz and Goldfarb, 2018) or from various improvements in data presentation (Weissgerber et al., 2016a, 2016b), such as depicting subject-specific data points within plots, enumerating the number of participants who exhibited a key outcome or trend, reporting subject-specific results in supplementary material, or publicly archiving subject-specific data to empower other researchers to explore subject-specific responses ("Show the dots in plots," 2017).

There were several limitations to this study. First, we analyzed a limited sample, which included seven prosthesis users. This study included only K3-K4 prosthesis users due to the interest and availability of participants who were willing to devote two weeks to acclimating to a new device and several hours to in-lab testing. This challenge of self-selection and subject availability is common amongst prosthesis studies and itself can introduce a bias in the types of individuals tested. Subjects were given more time to acclimate to the MPA condition than to the MPA-unadapted condition. Participants were given at least two weeks to acclimate at home to the MPA, whereas the MPA-unadapted condition was introduced during initial training on the device and during the testing protocol. As such, participants were only given several minutes of walking time on this condition. However, because the ankle was locked at neutral configuration, the expectation was that the MPA-unadapted condition was sufficiently similar to commonly-prescribed prostheses, such that the participants did not need extensive time to acclimate. The order of the prosthesis conditions were not randomized, possibly resulting in ordering effects. We did not enforce the same prosthesis alignment (foot relative to pylon angle) across MPA users. Each user had their MPA aligned by a trained prosthetist using typical standard of care procedures, which includes taking into account each user's comfort and preference. As a result the prosthesis alignment varied between users

Table 2
Subject-specific prosthesis set-point angles (i.e., sagittal plane dorsiflexion angle of the prosthetic foot relative to neutral). A neutral angle of 0° corresponds to the foot being orthogonal to the pylon. For MPA-unadapted this angle corresponds to the standard alignment made by the prosthetist for that individual. For the MPA, larger angles indicate that the ankle is more dorsiflexed (i.e., set-point adjusted to accommodate slope). Angles are reported in degrees. Subjects are ordered from most to least dorsiflexed set-point in MPA-unadapted condition. Ankle angle is defined as the angle between the shank and the foot. The set-point angles for the MPA-unadapted and MPA were calculated as the ankle angle at terminal swing.

	MPA-unadapted		MPA	
User	Set-point angle (°)	Landing pattern	Set-point angle (°)	Landing pattern
2	12	Rearfoot	18	Rearfoot
6	11	Forefoot	17	Forefoot
1	10	Forefoot	16	Rearfoot
7	5	Forefoot	12	Rearfoot
5	4	Forefoot	11	Rearfoot
4	2	Rearfoot	8	Rearfoot
3	4	Rearfoot	7	Rearfoot

(Table 2). However, there was no indication that this subject-specific alignment explained differences observed in terms of rearfoot vs. forefoot landing pattern (Table 2), or more vs. less knee flexion when using the MPA. Note that the subjects' daily-use prosthesis was fit by their standard care provider, and we did not change this alignment prior to testing; as a result the MPA and daily-use prostheses were fit by different prosthetists. However, the daily-use prosthesis condition was only intended as a reference and thus does not affect the main conclusions of the study. The control group tested was not age-, size-, or weight-matched to the prosthesis users; however, as stated in Methods, the data set was non-dimensionalized and re-dimensionalized using the prosthesis users' average mass and leg length values. The results here inform the design of prosthetic feet, and the degree to which an ankle adaptation feature affects the gait of different individuals. The study was not intended to directly inform clinical decision-making for a prosthetist deciding between two different prostheses (e.g. one MPA vs. another non-MPA) on the market, since these feet will also differ in other aspects such as mass, inertia, shape or stiffness.

5. Conclusion

In this work we characterized how seven unilateral transtibial prosthesis users adapted to walking with an MPA that adapted its ankle to inclined slope, relative to the same MPA with ankle unadapted (i.e., fixed in its neutral alignment). Despite the MPA behaving similarly for each user (i.e., dorsiflexing the ankle to help accommodate to the slope), we observed marked differences in user gait patterns (rearfoot vs. forefoot landing) and in gait biomechanics (as evidenced by changes in knee angle and moment). Comprehensive subject-specific kinematics and kinetics are presented in the Appendix for reference. Although the prevailing experimental paradigm in prosthetic gait analysis studies is to focus on group-level (inter-subject mean) analysis, these results call attention to the high inter-subject variability which may necessitate alternative experimental approaches and alternative data visualization strategies to better understand and assess the effects of emerging prosthetic interventions.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jbiomech.2019.07.017.

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