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Transtibial Amputation Prosthetic Comparisons

Adaptation and Prosthesis Effects on Stride-to-Stride Fluctuations in Amputee Gait

Abstract

Twenty-four individuals with transtibial amputation were recruited to a randomized, crossover design study to examine stride-to-stride fluctuations of lower limb joint flexion/extension time series using the largest Lyapunov exponent (λ). Each individual wore a "more appropriate" and a "less appropriate" prosthesis design based on the subject's previous functional classification for a three week adaptation period. Results showed decreased λ for the sound ankle compared to the prosthetic ankle ($F_{1,23} = 13.897$, $p = 0.001$) and a decreased λ for the "more appropriate" prosthesis ($F_{1,23} = 4.849$, $p = 0.038$). There was also a significant effect for the time point in the adaptation period ($F_{2,46} = 3.164$, $p = 0.050$). Through the adaptation period, a freezing and subsequent freeing of dynamic degrees of freedom was seen as the λ at the ankle decreased at the midpoint of the adaptation period compared to the initial prosthesis fitting ($p = 0.032$), but then increased at the end compared to the midpoint ($p = 0.042$). No differences were seen between the initial fitting and the end of the adaptation for λ ($p = 0.577$). It is concluded that the λ may be a feasible clinical tool for measuring prosthesis functionality and adaptation to a new prosthesis is a process through which the motor control develops mastery of redundant degrees of freedom present in the system.

Introduction

Lower limb amputation presents a major change to the patient's neuromuscular system. The loss of peripheral structures and neural endpoints creates an obstacle for the individual as they potentially learn to walk again following prosthetic rehabilitation. The neuromuscular system must learn new strategies in order to fully integrate a foreign device into its natural movement pattern. Consider prior to amputation, during the common task of walking, the neuromuscular system had developed a movement strategy that encompassed an active, biological leg. Following amputation, major components of the anatomy that led to the solution that the neuromuscular system had settled on are no longer present, thereby leaving the neuromuscular system to learn a new solution if the person is to walk again with a prosthesis. The need for the neuromuscular system to learn a new solution is not unique to limb loss, but occurs under many different pathologies affecting the neuromusculoskeletal system [1].

Contrary to other pathologies that affect the neuromuscular system's previous solution to the multiple variables involved in the task of walking, individuals with a prosthesis will find their motor control being challenged to re-learn every time a new prosthesis is introduced. A new prosthesis will change the variables that the neuromuscular system is accounting for in order to resolve upon the appropriate solution. Importantly, the movement solution that results will manifest within the subtle stride-to-stride fluctuations that are naturally occurring over multiple strides [1]. Perhaps not surprising then, previous work has indeed found altered stride-to-stride fluctuations when walking for individuals with a unilateral, transtibial prosthesis compared to their healthy counterparts [2]. More specifically, Wurdeman et al.[2] reported an increased largest Lyapunov exponent (λ) for motion about the prosthetic ankle as well as the sound leg hip and knee. The λ is a measure of stride-to-stride fluctuations that examines the rate dependent divergence of nearby points within an attractor, representing how quickly a point will vary from stride-to-stride [2–6].

Consistent with any learning task where certain things are naturally easier to learn than others, some prostheses will present variables that will make it easier for the neuromuscular system to determine a solution. On the other hand, other prostheses may present too many variables or the variables presented by the new prosthesis may be too different from those that were naturally occurring or accounted for in a previous prosthesis. Either of these scenarios could lead to a poor solution by the neuromuscular system as it attempts to accomplish the task of walking. A poor solution may be the reason that when presented with a new prosthesis, which altered the stride-to-stride fluctuations during walking, individuals with an amputation exhibited a prosthesis preference that was strongly correlated to the λ such that they preferred the device that resulted in a reduced λ [4].

Yet, what is unknown, is the behavior that will result when individuals with amputation are asked to learn to use a new device. Adaptation to a prosthesis is the period of time through which learning and ultimately a movement solution is discovered. The gravity of such a learning period is such that it is often cited as a limitation in many prosthetics studies [7–14]. A better understanding of how individuals modify their behavior (i.e. changes in stride-to-stride fluctuations) throughout the adaptation period could provide understanding of what could be expected in terms of outcomes. Even more importantly, an understanding of adaptation provides insight into the process by which the neuromuscular system is able to resolve all the potential movement strategies into a single, optimal solution [15,16]. Such insight could potentially help guide future rehabilitation strategies to optimize outcomes.

Therefore, the purpose of this study was to examine the effects of an adaptation period on stride-to-stride fluctuations in both the sound leg and prosthetic leg following receipt of a new prosthesis. It was hypothesized as the individual's neuromuscular system learns to fully integrate the prosthesis into the person's movement, there will be a decrease in stride-to-stride fluctuations as the movement converges on a solution more similar to healthy, non-amputees [2]. Furthermore, if a new prosthesis presents variables that allow the individual's neuromuscular system to settle into its natural movement solution this will intuitively result in decreased stride-to-stride fluctuations (i.e. more similar to their healthy counterparts [2]). On the other hand, if the new device presents variables that are very foreign to those that the neuromuscular system would naturally incorporate into its innate movement strategy, then increased stride-to-stride fluctuations would be expected (i.e. less similar to their healthy counterparts [2]). Therefore, it was also hypothesized that a more appropriate prosthesis design would result in decreased stride-to-stride fluctuations compared to a less appropriate prosthesis design.

Methods

Participants

Twenty-four individuals (19 males, 5 females) with unilateral, transtibial amputation were recruited for this study (Table 1). The study was approved by the University of Nebraska Medical Center IRB "Nonlinear Analysis of Amputee Gait", 021-11-EP, and by the Nebraska/Western Iowa Veterans Affairs Medical Center IRB "Nonlinear Analysis of Amputee Gait", 00793. All participants provided written informed consent as approved by the overseeing Institutional Review Boards. Inclusion criteria included: 1) ability to ambulate non-stop for three minutes, 2) able to commit to a 6 week protocol, and 3) have had their current prosthesis longer than thirty days. Exclusion criteria included: 1) presence of any ulcers on either the residual limb or contralateral limb, 2) inability to provide informed consent due to cognitive condition, 3) exoskeletal type prosthesis or non-removable cosmetic cover (prevents exchanging of components without destroying person's prosthesis), 4) presence of any major neuromuscular or musculoskeletal conditions affecting gait (i.e. stroke, Parkinson's disease, multiple sclerosis), 5) previously classified by physician as K1 or K0 level ambulatory [17], or 6) a poor fitting current prosthesis.

Procedures

Subjects participated in a 6 week, randomized-crossover design adaptation protocol. This encompassed two separate 3 week adaptation periods [18]. All prosthesis modifications and data collections occurred within the University's gait laboratory. At the initial visit, the subject's foot/ankle/pylon were removed distal to the socket in preparation for a different prosthesis. For the duration of the study, subjects wore the socket that their own prosthetist had created for them as well as utilizing their own current method of suspension. Once the foot/ankle/pylon were removed, an alternate foot/ankle/pylon were assembled and attached. The alternate prosthesis design was classified as either "more appropriate" or "less appropriate" based on the prosthesis activity level and the subject's previously determined activity/functional level. In other words, if a subject was classified as a K3 ambulator, then the prosthesis setup utilizing the K3 level foot (high activity) would be considered "more appropriate", whereas the prosthesis setup with the K2 level foot (low activity) would be deemed "less appropriate". The prosthesis was then aligned by a certified prosthetist. Once the prosthesis was properly aligned, the initial gait analysis was performed. Subjects then wore the device home and returned in 1.5 weeks to complete another data collection. After 3 weeks of wearing the alternate prosthesis, subjects again returned for a final data collection with the initial alternate prosthesis. Following the data collection with the initial alternate prosthesis, the foot/ankle/pylon sections were again removed and again an alternate foot/ankle/pylon were assembled and attached. The second alternate prosthesis setup was different from the initial setup; if the first prosthesis was "more appropriate", then the second prosthesis was the "less appropriate" or vice versa. Order for prosthesis type was randomized across subjects. The prosthesis was again re-aligned based on its current setup by a certified prosthetist. The wear and data collection procedures were then repeated similar to the initial prosthesis. This resulted in three data collections per prosthesis per subject.

The same procedure was utilized for all data collections. Subjects performed 2 separate walking trials on a treadmill. Each trial was 3 minutes non-stop at their self-selected preferred walking speed with at least 1 minute rest between trials to avoid fatigue. The walking speed was determined at the initial visit with the same speed subsequently utilized for all walking trials. Subjects were permitted to use the hand rail if needed for balance but were instructed not to place weight through their arm. Subjects wore a tight fitting uniform during all walking trials. Twenty-seven retro-reflective markers were placed on various anatomical locations on the lower limbs [2,4,19] such that each segment had a minimum of three non-collinear markers to allow three dimensional relative joint angle calculations. On the prosthetic limb, markers were placed on analogous locations as the sound limb. Marker motion was recorded in three dimensions with a 12 camera motion capture system at 60 Hertz (Motion Analysis Corp., Santa Rosa, CA, USA). Lower limb joint angle flexion/extension time series for each joint of the sound and prosthetic limbs were then calculated from the raw marker position data (Visual 3D, Germantown, MD, USA).

Analysis

Stride-to-stride fluctuations were calculated using λ. The λ is a measure of how quickly similar points in state space diverge along their respective trajectories [2–4]. In terms of gait, it represents how quickly an independent point in the gait cycle fluctuates from other similar points in the gait cycle occurring during a different stride. If the walking pattern were perfectly periodic, then two points occurring at the same point in the gait cycle would then have similar successive points. In gaits that have more stride-to-stride fluctuations, the two points occurring at the same point in the gait cycle would then have very different successive points due to large fluctuations. The λ is chosen specifically for its ability to detect stride-to-stride fluctuations that are overlying a strongly periodic movement. Joints flex and extend repeatedly with every stride during controlled walking. This repeated motion is not

Table 1. Subject demographics. Note all participants were MFCL K3 or K4 level ambulators.

Age (yrs)	Height (cm)	Mass (kg)	Time Since Amputation (yrs)	Self-selected speed (m/s)	Residual limb length (cm)	Cause of amputation
53.3 (11.6)	177.6 (7.9)	100.8 (18.4)	8.7 (9.9)	0.85 (0.39)	15.7 (3.6)	14 trauma, 7 vascular/diabetes, 1 cancer, 2 infection

Mean (SD).
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perfectly similar with every cycle, but the motion is similar enough such that other measures (e.g. detrended fluctuation analysis, sample entropy, approximate entropy, etc.) potentially examining stride-to-stride fluctuations in the joint motions may algorithmically have their end calculation dominated by this strong, underlying periodicity. The method for the calculation of the λ is outlined in greater detail in previous studies [2,4]. For the adaptation portion of the study, all joint angle flexion/extension time series were subsequently cropped to 110 strides with the lone exception of 1 subject that was only able to attain 70 strides in all data collections. Trials were cropped to 110 strides as this was the maximum amount that the individual who took the least strides was able to achieve with the lone exception of the individual that took 70. This individual's walking trials were therefore cropped to 70 strides. The large discrepancy between this individual and the other 23 subjects was the reason for not cropping all trials to 70 strides. Furthermore, the study utilized a within subject design and thus a similar number of strides are being compared for each subject. The embedding dimension and time lag for each time series were calculated using the false nearest neighbor and average mutual information algorithms, respectively [2,20,21]. All time series were consequently embedded with the average dimension of 7. The λ was then calculated for each joint of the sound and prosthetic legs. Of note, only the first treadmill trial was used for analysis unless during the data collection or in post-processing problems were noted (e.g. subject's foot clipped the side of the treadmill or large marker dropouts during trial resulting in excessive interpolating of marker position data). In these cases the second trial was utilized for analysis. Calculation of λ requires several input parameters which were set to the following: time evolution equal to 3 [2,4,22], max angle to replacement point equal to 0.3 radians [2,4,22], minimum scale length of 0.0001 [2,4,22], and maximum scale length of 0.1 times the maximum diameter of the attractor (maximum distance to selection of new nearest neighbor) [2,4,22]. Main effects for leg (prosthetic vs. sound), prosthesis (more vs. less appropriate), and adaptation (visit 1 vs. visit 2 vs. visit 3) at the hip, knee, and ankle were tested through a 2×2×3 fully repeated ANOVA ($\alpha = 0.05$) with Fisher's LSD for post-hoc. An analysis of trend was performed for adaptation effects through the course of the 3 weeks. All statistical analyses were done using SPSS (SPSS 16.0. Chicago, IL, USA).

Results

At the ankle, there were significant main effects for leg, prosthesis, and visit (Figure 1). The sound leg ankle had significantly reduced λ compared to the prosthetic ankle ($F_{1,23} = 13.897$, $p = 0.001$) with an observed power of 0.946. The "more appropriate" prosthesis resulted in reduced λ when compared to the "less appropriate" prosthesis design ($F_{1,23} = 4.849$, $p = 0.038$) with an observed power of 0.559. For visit there was also a significant effect ($F_{2,46} = 3.164$, $p = 0.050$) with an observed power of 0.578. Post-hoc analysis showed the initial visit (i.e. initial fitting) to have a significantly increased λ compared to the second visit (i.e. middle of 3 week period; $p = 0.032$), and the final visit (i.e. end of adaptation period) had a significantly increased λ compared to the second visit ($p = 0.042$). The λ values for the initial and final visits were not statistically different ($p = 0.577$). This yielded a significant U-shaped quadratic trend across the adaptation period ($p = 0.013$). There were no significant interactions.

At the knee, there was no significant effect for leg (sound vs. prosthetic; $F_{1,23} = 0.149$, $p = 0.703$; Figure 2). There was also no significant effect for prosthesis ("more appropriate" vs "less appropriate"; $F_{1,23} = 0.387$, $p = 0.540$), or for visit ($F_{2,46} = 2.402$, $p = 0.102$). There were no significant interactions.

Similar to the knee, the hip showed no effect for leg ($F_{1,23} = 0.187$, $p = 0.669$) or for visit ($F_{2,46} = 0.681$, $p = 0.511$). This was not the case, however, for prosthesis. Counter to the ankle, the "more appropriate" prosthesis design had an increased λ compared to the "less appropriate" design ($F_{1,23} = 5.300$, $p = 0.031$; Figure 3), with an observed power of 0.597. There were no significant interactions.

Discussion

The primary significant findings occurred at the ankle. This is not entirely surprising given previous work showing a significantly increased λ at the prosthetic ankle compared to the sound ankle and compared to healthy control ankles [2]. In addition, it was only the λ at the prosthetic ankle that was previously found to be strongly correlated with the patient's prosthesis preference [4]. Our results with a larger sample size comparing the λ between the prosthetic ankle and the sound leg ankle agree with previous work by Wurdeman et al. [2]. More specifically, the motion about the prosthetic ankle has increased stride-to-stride fluctuations compared to the sound ankle. This would seem to continue to highlight the motion of the prosthetic ankle as a primary signal of the effectiveness of the person's motor control. It has previously been stated that the λ for the motion about the prosthetic ankle represents the union of the biological system (i.e. amputee) and the mechanical system (i.e. prosthesis) in an effort to work cooperatively as a single amputee-prosthesis locomoting system [4]. This is believed to be the case for the prosthetic ankle in the transtibial amputee as it is the sole joint that is directly influenced by the biological system (remnant shank) and the mechanical system (prosthetic foot) [4]. Improved cooperation between the person and the prosthesis would then likely decrease stride-to-stride fluctuations to be more similar to the sound leg, possibly resulting in improved patient satisfaction [4]. It would be tolerable to speculate that the prosthesis then that results in improved control is permitting increased coordination of all dynamical degrees of freedom [15,23].

Examining the effect of appropriateness of the prosthesis, we note the "more appropriate" prosthesis setup did allow for a decreased λ, or reduced stride-to-stride fluctuations at the ankle.

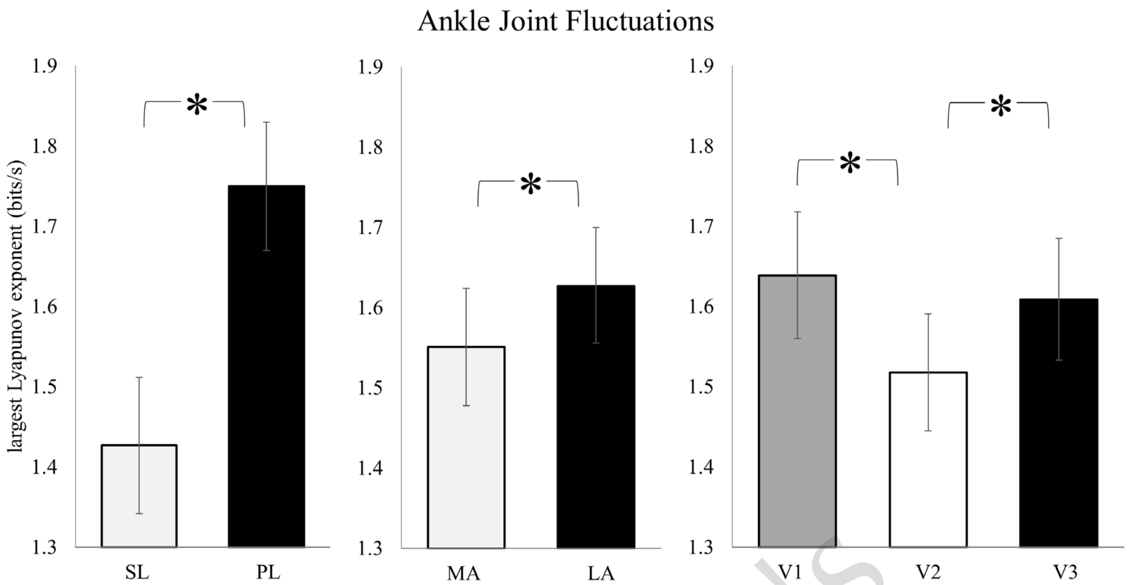

Figure 1. Stride-to-stride fluctuations for the ankle were significantly decreased for the sound leg compared to the prosthetic leg. The "more appropriate" prosthesis design also yielded decreased stride-to-stride fluctuations compared to the "less appropriate" prosthesis. Through the adaptation, a significant U-shaped quadratic trend was present, with significantly increased stride-to-stride fluctuations at the initial visit and final visit compared to the middle of the adaptation period. (mean ± SEM) SL: sound leg; PL: prosthetic leg; MA: "more appropriate" prosthesis; LA: "less appropriate" prosthesis; V1: initial visit; V2: second visit; V3: final visit. *Sig. at $p<0.05$.
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This is consistent with the notion that the most appropriate prosthesis is likely to yield dynamics preferred by the patient [4]. Furthermore, this finding agrees with the idea above that the most appropriate prosthesis will allow a patient to achieve stride-to-stride fluctuations that are most similar to the sound leg. In light of this finding, it is difficult not to conclude that effective lower limb loss rehabilitation will reduce stride-to-stride fluctuations as the individual is able to have high coordination of dynamic degrees of freedom [23]. On the other hand, when the device is less appropriate for the individual, these coordinative strategies are not likely to form and therefore there is a higher number of dynamic degrees of freedom needing to be controlled, required increased control and likely an increased risk of negative outcomes. From a dynamical systems perspective, it may be fitting to think of receiving a prosthesis as similar to receiving an organ transplant; a larger system must integrate a vital component into its normal dynamics. Bogaert et al. [24] found when looking at cardiac dynamics no difference between heart transplant recipients and

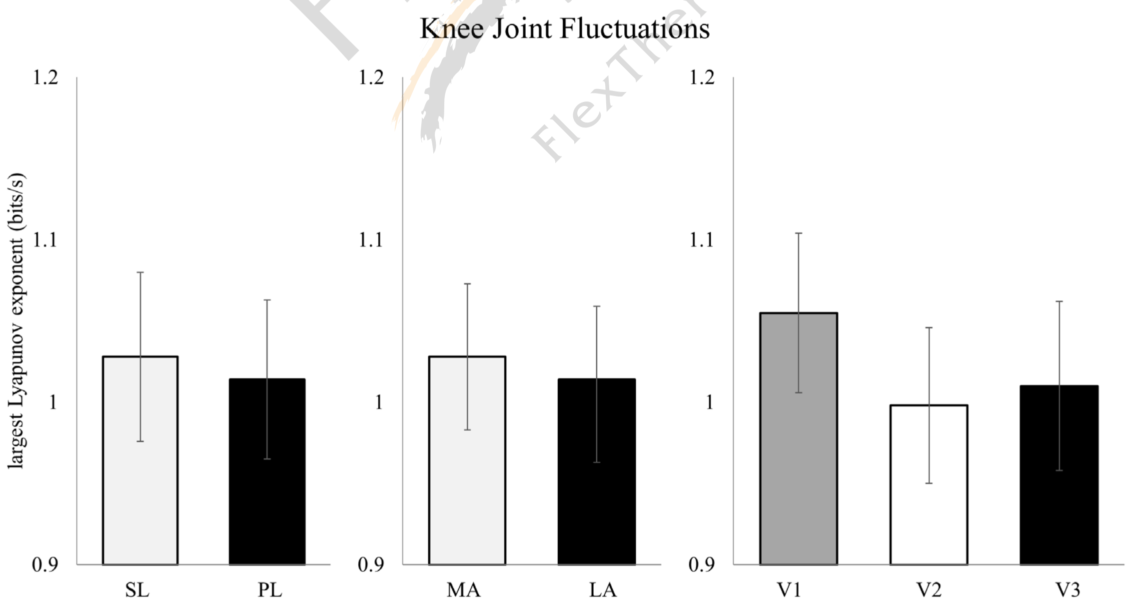

Figure 2. Differences in stride-to-stride fluctuations for the knee were not significant for the effect of leg, prosthesis, or time point in the adaptation period. (mean ± SEM) SL: sound leg; PL: prosthetic leg; MA: "more appropriate" prosthesis; LA: "less appropriate" prosthesis; V1: initial visit; V2: second visit; V3: final visit. *Sig. at $p<0.05$.
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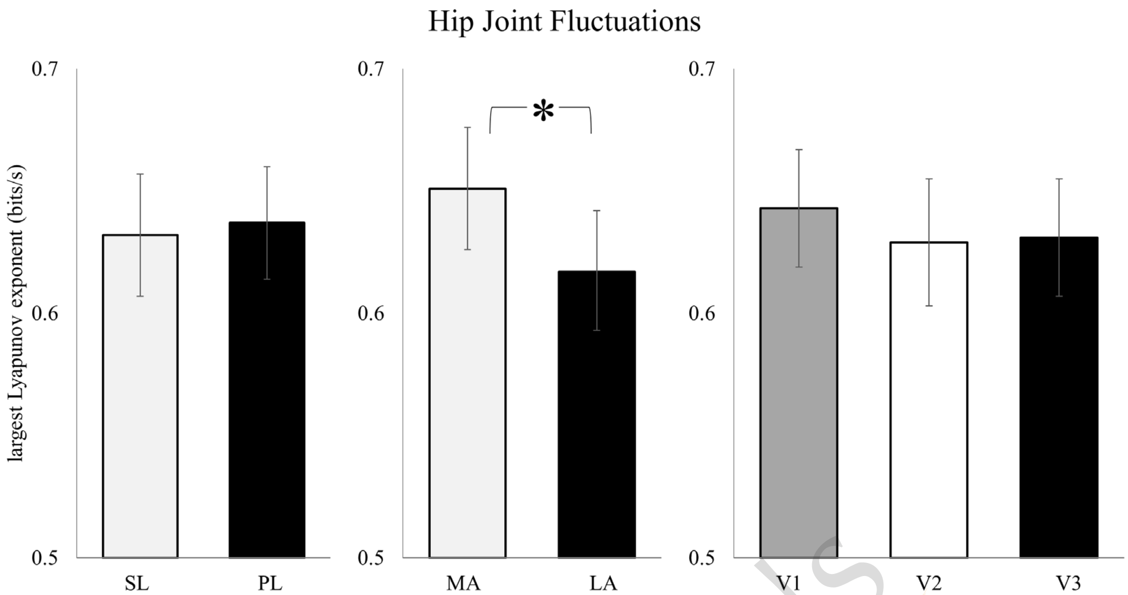

Figure 3. Stride-to-stride fluctuations for the hip were not significantly different for the effect of leg or for changes across the adaptation period. The ''more appropriate'' prosthesis design did however result in increased fluctuations at the knee compared to the ''less appropriate'' design. (mean ± SEM) SL: sound leg; PL: prosthetic leg; MA: ''more appropriate'' prosthesis; LA: ''less appropriate'' prosthesis; V1: initial visit; V2: second visit; V3: final visit. *Sig. at $p<0.05$.
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healthy controls. But, Izrailtyan et al. [25] found a shift in the cardiac dynamics amongst those heart transplant recipients that were in the early stages of rejecting the transplanted organ. These two studies seem to highlight that a body can integrate a foreign device/organ into its natural behavior and have near similar dynamics, but when the systems are not cooperating this will reflect in the measured dynamics (e.g. heart beat activity or stride-to-stride fluctuations). Thus, if the prosthetist and limb loss rehabilitation team can properly and effectively prescribe a prosthesis, the outcome will be reduced stride-to-stride fluctuations.

Finally, we wrongly expected a decrease in stride-to-stride fluctuations to occur through the period of adaptation. The idea that the variability in the stride-to-stride behavior would decrease as the person's neuromuscular system learned to use the device is more consistent with the viewpoint that variability arises from noise in the system, and as the person improves control the noise is reduced, leading to decreased variability from stride-to-stride. Rather, what we measured was a learning process previously formulated by Bernstein [26] and since further described [27-32]. Bernstein described ''the process of mastering redundant degrees of freedom'' in which to ultimately arrive upon the optimal movement control. This requires initially freezing a multitude of the degrees of freedom available to the system [31,32] by creating strong, rigid links. This allows for simplification of the learning task. Then as the task is mastered, there is slow release, or freeing, of the degrees of freedom to increase. The result is a larger movement repertoire allowing for a more flexible and adaptable system [31,32]. Our design was such that we were able to capture the initial period of high variability due to a lack of coordinative structures and poor control at the initial visit. Specifically, our subjects were fitted with a device and after taking only a few steps (~60) to allow for proper alignment, we immediately measured the stride-to-stride fluctuations during the treadmill task. At this point, there was an initially increased λ, or increased stride-to-stride fluctuations. When the individual returned 1.5 weeks later, we seemed to be within the period where several dynamic degrees of freedom were frozen as the individual was learning. As a result, there was a significant reduction in the stride-to-stride fluctuations at the prosthetic ankle. When the individual would return for the final visit on the prosthesis, after 3 weeks of wearing the device, the learning had progressed to a stage of freeing up degrees of freedom to increase flexibility and adaptability of the locomoting system. This was captured by a significant increase in stride-to-stride fluctuations at the prosthetic ankle compared to the second visit.

Clinically, it is important to note the lack of statistical difference in the λ at the prosthetic ankle at the initial fitting of the device and after a proper adaptation period. This may indicate the potential to measure stride-to-stride fluctuations with the λ at the initial fitting and not necessarily needing to wait 3 weeks to assess the function of the device. This, however, would need further testing to determine whether this is a statistical finding or whether the λ value truly is similar before and after adaptation. Importantly, the lack of statistical difference though between baseline and post-adaptation does not mean that the mechanism driving the variability from stride-to-stride at the initial fitting and post-adaptation are similar. In fact, the points made previously would rather indicate very different mechanisms: initially increased noise and lack of control compared to ultimate mastery of redundant degrees of freedom leading to greater flexibility and adaptability. Nevertheless, if the initial fitting possibly discloses the stride-to-stride fluctuations expected after adaptation, then it may be possible to use the λ as a means for initial evaluation of prosthesis functionality. Furthermore, future studies measuring λ of joint motion in the lower limb amputee may not need to necessarily incorporate adaptation periods, which can be costly to the study both in terms of monetary funds, time, and potential subject dropout.

There are limitations to this study. First our design setup heavily relied on the subject's prosthetist/physician to have properly classified the patient with regards to their activity level (i.e. K2, K3, or K4). This in itself is problematic for a multitude of reasons, including the ambiguity under which patients are classified [17] and the undeniable fact that the activity level for individuals ambulating with a prosthesis is not possibly four distinct categories but rather represented as a continuum across a spectrum. The only clinical tool available currently to help with patient classification in the Amputee Mobility Predictor [17], but even this tool is known to have large standard deviations making it difficult on the individual level to objectively categorize patients. Furthermore, while we set out to recruit patients from multiple activity levels, specifically K2 and K3 as the break between these levels represents the largest break between prosthesis componentry classifications, we were unable to recruit any individuals that were previously classified as K2 level ("has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulatory" [17,33]). While the authors felt there were a few individuals that may have been classified by other providers as K2, our study design was set up such that we would utilize the classification by the subject's prosthetist/physician to improve real world translation. Future work may improve our study design by utilizing a technique to better objectively classify patients, however as it is currently such objective measures do not exist. Furthermore, while we were able to secure multiple high activity feet for the study, with the exception of 1 subject that wore a Walktek foot (K2 foot from Freedom Innovations, Irvine, CA, USA), all low activity feet were SACH feet (The Ohio Willow Wood Company, Mt. Sterling, OH, USA) which helped to improve study logistics (authors were then only needing to acquire high activity feet for each subject once enrolled). As a result, it could be our findings are simply a measured difference between high activity feet and the traditional SACH foot and may not be found in a newer technology K2 (low activity) level foot. However, low activity (or K2) feet are generally more rigid with less flexing and motion, provide a more stable platform for the person to balance on and the functional differences between low activity feet may not be as much as expressed in material costs. The outlined theoretical basis in this manuscript would not seem to support such a simplification of results being limited to the SACH foot. We also see our major findings occurring about the motion of the ankle, which for the majority of prostheses, there is no true ankle joint which could a problem for motion capture [34,35]. But as noted in Wurdeman et al. [4], it is the deflection and bending about the ankle that recreates flexion/extension, which is the kinematic motion we are measuring.

Conclusion

The prosthetic leg has increased stride-to-stride fluctuations about the ankle compared to the sound leg, a finding first reported by Wurdeman et al. [2]. In addition, when individuals were fitted with a "more appropriate" and a "less appropriate" prosthesis based on their activity level classification and the prosthesis activity level classification, the "more appropriate" design resulted in decreased stride-to-stride fluctuations. The design that leads to reduced stride-to-stride fluctuations is permitting greater cooperation between the biological system (i.e. amputee) and the mechanical system (i.e. prosthesis) to accomplish the task of walking. When the amputee and the prosthesis are not cooperating and working together, the result is increased stride-to-stride fluctuations as the two systems struggle to operate as a single cohesive unit. Finally, through the course of an adaptation period, the individual's neuromuscular system is undergoing learning as it reconciles the problem of properly integrating a foreign device into its natural movement strategy. Initially this period is characterized by a freezing of the degrees of freedom as the system becomes more rigid [31,32]. At the end of adaptation, there is a freeing of the degrees of freedom as the system increases its flexibility and adaptability [31,32].

Gait Biomechanics of Individuals with Transtibial Amputation: Effect of Suspension System

Abstract

Prosthetic suspension system is an important component of lower limb prostheses. Suspension efficiency can be best evaluated during one of the vital activities of daily living, i.e. walking. A new magnetic prosthetic suspension system has been developed, but its effects on gait biomechanics have not been studied. This study aimed to explore the effect of suspension type on kinetic and kinematic gait parameters during level walking with the new suspension system as well as two other commonly used systems (the Seal-In and pin/lock). Thirteen persons with transtibial amputation participated in this study. A Vicon motion system (six cameras, two force platforms) was utilized to obtain gait kinetic and kinematic variables, as well as pistoning within the prosthetic socket. The gait deviation index was also calculated based on the kinematic data. The findings indicated significant difference in the pistoning values among the three suspension systems. The Seal-In system resulted in the least pistoning compared with the other two systems. Several kinetic and kinematic variables were also affected by the suspension type. The ground reaction force data showed that lower load was applied to the limb joints with the magnetic suspension system compared with the pin/lock suspension. The gait deviation index showed significant deviation from the normal with all the systems, but the systems did not differ significantly. Main significant effects of the suspension type were seen in the GRF (vertical and fore-aft), knee and ankle angles. The new magnetic suspension system showed comparable effects in the remaining kinetic and kinematic gait parameters to the other studied systems. This study may have implications on the selection of suspension systems for transtibial prostheses.

Trial Registration: Iranian Registry of Clinical Trials IRCT2013061813706N1.

Introduction

The primary goal of rehabilitation of lower limb amputees is to resume normal gait as much as possible. Prosthetic devices should allow normal gait function using the most appropriate components. Gait asymmetry is one of the main concerns in unilateral lower limb amputees to avoid exertion of excessive load on the sound limb [1,2]. Previous research findings have been controversial over the kinetic and kinematic differences between the amputated and sound legs. Several studies indicated higher reliance on the sound leg by increased loading and stance time, which has been attributed to ankle loss in transtibial amputees [3,4]. On the other hand, some literature supported the idea that amputees may not need to rely on the intact leg owing to the compensatory mechanisms adopted by the amputated leg [5]. Winter and Sienko (1988) explained that the amputee-related literature increasingly refers to variables that measure gait symmetry [6]. Therefore, a scientific justification is needed to encourage more symmetrical walking pattern.

The influence of various prosthetic components on the gait of lower limb amputees has been evaluated. Extensive research has been conducted on the effects of prosthetic foot as transtibial amputees lose normal ankle mechanics while retain the anatomical knee joint [7–10]. Moreover, the improper fit of the prosthetic socket and failure of the suspension system can result in pistoning, which in turn will affect the walking pattern. Total surface bearing (TSB) socket was introduced as new concept, and its total contact was said to eliminate pistoning during walking [11–14]. Researchers have also studied the effects of prosthetic liner on the gait of transtibial amputees and revealed that liner thickness can affect the gait variables [15].

Current suspension systems for transtibial amputees are either pin/lock or seal liners, which are both provided with TSB sockets. Suspension systems have been investigated in terms of interface pressure, interface dynamics (pistoning) and comfort. Pin/lock systems are said to cause pain and discomfort inside the prosthetic socket, leading to skin changes in the long term. Discomfort may cause changes in gait parameters as the amputee would be reluctant to bear load over the prosthetic socket during walking. The Seal-In suspension liner can relieve the distal end pressure by applying more loads to the proximal tissues of the residual limb. Both systems control pistoning, but the Seal-In liner is more successful. These two suspension types have not been studied in terms of gait parameters during level walking.

A new magnetic prosthetic suspension system (MPSS) has been introduced, and compared with the pin/lock and Seal-In liners in terms of pistoning through gait simulation, as well as interface pressure [16,17]. This hypothesis-generating study aimed to examine the changes in gait characteristics of transtibial amputees with the MPSS, pin/lock and Seal-In suspension systems. We were interested to find out what gait parameters show significant changes. It was also intended to see how deviated was the gait pattern with every suspension type from the gait of normal individuals. The main hypothesis of this study was that the type of suspension may significantly alter the kinetic and kinematic gait parameters as well as pistoning. Furthermore, it was assumed that the sound and prosthetic legs would exhibit significantly different patterns.

Materials and Methods

The protocol for this trial is available as supporting information; see Protocol S1.

Ethics Statement

The ethics committee of the University of Malaya Medical Center approved the study. The subjects signed consent forms prior to participation.

Methods

In a clinical trial, fifteen individuals with transtibial amputation were selected to participate in the study as sample of convenience. Amputees were eligible for the study if they were unilateral transtibial, could ambulate independently, had a stump free of ulcer and pain, had undergone amputation at least one year prior to the study, and had healthy upper limbs to don and doff the prosthesis without help. The subject recruitment was performed from March 2012 to March 2013.

Inconsistency of the prosthetic fabrication techniques, alignment, and fitting can significantly influence the outcome. Therefore, one of the authors (a registered prosthetist) fabricated three prosthetic systems for each participant. The only difference between the prostheses was the suspension system. The suspension systems were: a) pin/lock suspension (Dermo liner with shuttle lock), b) new magnetic lock (MPSS), and c) Seal-In system (Seal-In X5 liner) (Figure 1). The third system required a separate negative cast; whereas the first two systems were fabricated from a single negative cast. The prosthetist ensured the fit of each prosthetic socket through a transparent check socket (Northplex, North Sea Plastic Ltd) while standing in the alignment frame and during walking. The sockets were required to be TSB; therefore, the transparent material allowed close inspection of fit.

The characteristics of the new prosthetic suspension system have been described elsewhere [17]. In brief, the new system was designed to be used with silicone liners as they are commonly used. To this end, a cap was designed that matched both the main body of the new coupling device, and the liner's distal end. The dimensions were purposely designed to match the liner proportions. A central screw enabled coupling to the liner. The body of the coupling device was source of magnetic power. As such, the cap was made of mild steel to produce high gripping force. A permanent magnet was utilized that was capable of generating a strong magnetic power. The housing intensified the magnetic field by flanges. In order to control the magnetic power, a mechanical switch was affixed to the housing and the magnet. When the rotary switch was in the "On" position, the cap was attracted to the housing, whereas it was released from the lower body of the coupling device when the switch was in the "Off" position.

Pyramid adapters connected the TSB sockets to the aluminum alloy pylon and prosthetic foot (Flex-foot Talux, Ossur). The subjects were also provided with three definitive sockets for the acclimation period of four weeks. The aligning procedure was performed using a laser liner to ensure accuracy. The subjects were trained for walking with the new prosthetic legs as follows. After ensuring the fit of prosthetic sockets, the training prostheses were fabricated. Every participant was required to attend the Brace & Limb Laboratory, University of Malaya for the gait training during one week. The gait training was performed in the parallel bars to check the dynamic alignment during level walking. Next, the amputees participated in training out of the parallel bars, climbing the stairs and ramp in real environment. Necessary adjustments were applied so that the participants were fully confident to ambulate without pain or discomfort. The subjects used identical shoes in all the experiments.

A Vicon motion analysis system (612 Oxford Metrics; Oxford, UK) with six cameras (MXF20) was utilized to evaluate the gait kinematics and pistoning between the prosthetic socket and liners. Kinetic data was recorded using two Kistler force platforms (type 28112A2-3S, Kistler Holding AG, Switzerland). The synchronized frequency was set at 200 Hz. For the pistoning measurement, the authors introduced a new measurement technique using the Vicon motion system [18]; the same method was adopted in this study. The location of the ankle reflective marker on the prosthetic foot approximated the axis of rotation for the sound ankle. The subjects walked with each prosthesis type adopting self-selected speed on a 10-meter level walkway. Five successful trials were selected for the kinetic and kinematic analyses. A trial was considered as appropriate if both feet landed properly on the force plates (whole foot was on the force plate). The participants could rest between the trials. All data was collected at the motion laboratory of Center for Applied Biomechanics, University of Malaya. Butterworth filter with a cutoff frequency of 10 Hz was used to filter the data.

Data Analysis

Kinematic and kinetic gait parameters were processed using the Vicon Nexus (Oxford Metrics, Ltd.) software. Data was analyzed based on the percentage of gait cycle. The average values of the five trials were used for the analysis. Statistical analyses were performed using SPSS 18.0. The normality of variables was verified by the Kolmogorov-Smirnov test. The one-way Repeated Measures Analysis of Variance (ANOVA) with the Bonferroni test was used to compare the three suspension systems. The paired samples t test was adopted to compare between the sound and prosthetic legs. In comparisons among the suspension systems, only the prosthetic limb was considered. The level of significance was set at 0.05. The Cohen's *d* of 0.2 to 0.3 might show a "small" effect, around 0.5 is a "medium" effect and 0.8 to infinity may be considered a "large"n effect. The pistoning was measured during the stance and swing phases of gait. The parameter values were averaged over 5 trials, not over the suspension systems. That is, every individual was tested separately with each of the suspension systems, which is considered as repeated measure. Additionally, each testing procedure with each suspension system was repeated for 5 times. Then, the average score of 5 trials with each system was separately used in the repeated measures ANOVA.

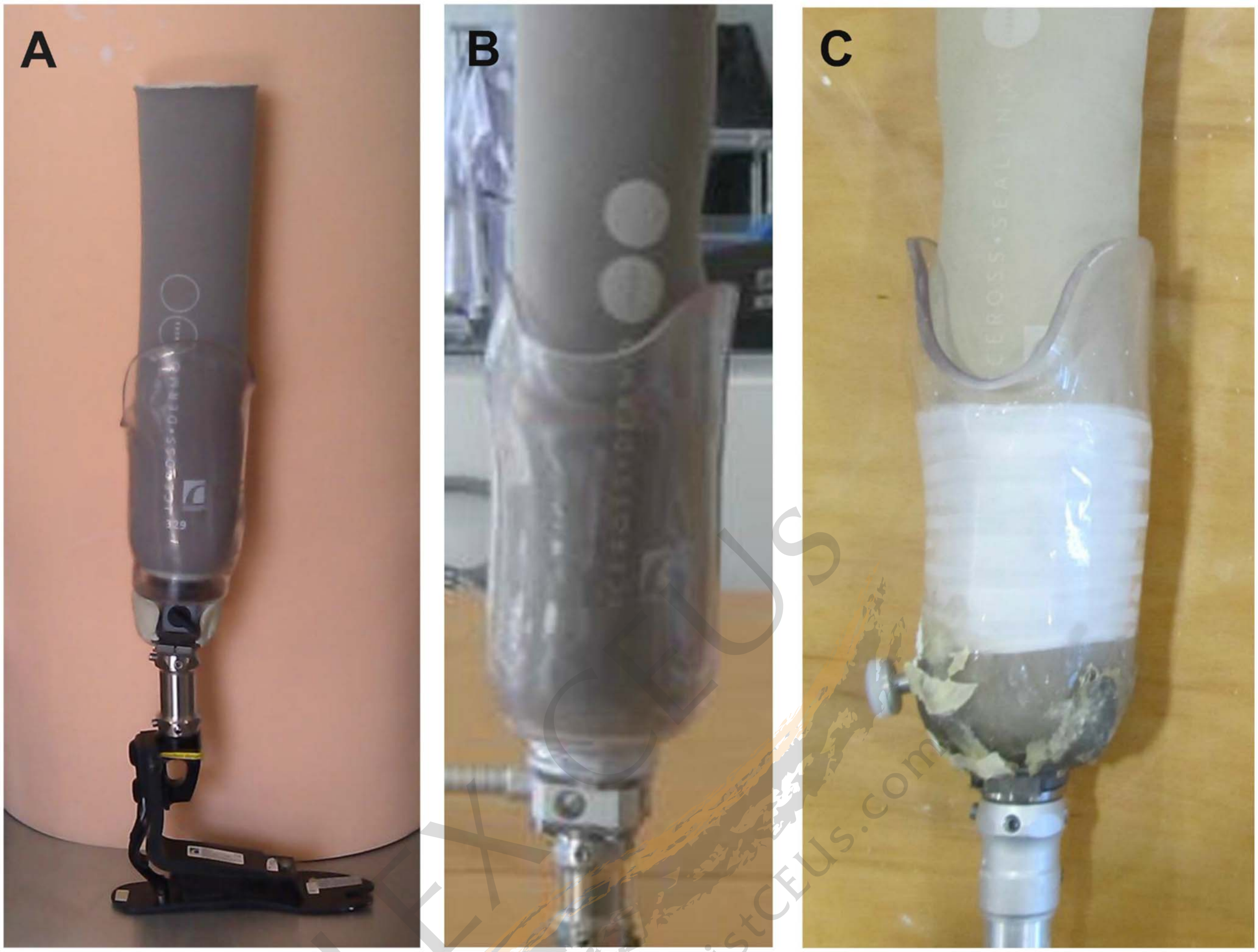

Figure 1. The suspension systems used in this study. A) MPSS; B) Pin/lock and C) Seal-In suspension systems.
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The following kinetic and kinematic gait parameters were evaluated: step length, walking speed, stance and swing time (percentage), vertical ground reaction force (GRF), fore-and-aft GRF hip, knee and ankle angles. The step cycle for both legs started with the heel strike. Data for each time frame were normalized to the whole stride time due to the variability in walking speed [19]. Furthermore, the fore-aft and vertical GRF were normalized to the body weight.

The gait deviation index (GDI) was also calculated for each system. The electronic template of the developers was used to calculate the GDI [21]. This template compares the input data with a database of 166 normal subjects. The measures were calculated for the prosthetic limbs of every subject and for each suspension system. The sound limb may exhibit higher kinematic deviations than the prosthetic limb because of the compensatory mechanisms. Thus, the average data for every gait summary measure was used to generate a one-dimensional gait deviation measure.

GDI calculation necessitated a matrix of healthy control data. In brief, the data comprised rows of kinematic data at 2% increments of the gait cycle (459 datum = 9 angles 51 points), as well as columns of data from different subjects [21]. Kinematic data included ankle dorsi/plantarflexion, knee flex/extension, hip and pelvic angles in all three planes, and foot progression.

The GDI for amputee subject α based on the distance between the normal control (TD) and the amputee subject was calculated from the following equation [21]:

$$GDI^{\alpha} = 100 - \left[10 \times \frac{GDI^{\alpha}_{raw} - Mean\left(GDI^{TD}_{raw}\right)}{S.D.\left(GDI^{TD}_{raw}\right)} \right] \qquad (1)$$

As GDI determines the distance from the mean normal gait, GDI of 100 or greater shows that gait pathology is absent. With every deviation of 10 points from 100, the gait is one standard deviation away from the normal. For instance, if $GDI^{\alpha} = 55$, the gait of subject α is 4.5 standard deviation away from the normal.

Results

From the 15 participants, only the data for thirteen individuals were included in the statistical analysis. The protocol required the subjects to participate in several casting, fitting and training sessions for 3 different prosthesis types in addition to the experiment sessions. Two subjects did not manage to complete the sessions due to their job limitations and were excluded from the study. The individual characteristics ants are shown in Table 1.

Table 1. Characteristics of the participants.

Subject no.	Age	Height (cm)	Mass (Kg)	Amputated side	Cause of amputation
1	42	173	75	Left	Diabetes
2	37	168	90	Left	Trauma
3	30	182	60	Left	Trauma
4	72	166	75	Left	Diabetes
5	46	167	64	Left	Trauma
6	35	170	99	Left	Diabetes
7	49	164	57	Right	Diabetes
8	53	177	60	Right	Diabetes
9	41	167	66	Right	Trauma
10	33	162	94	Left	Trauma
11	26	170	79	Left	Trauma
12	60	176	83	Right	Diabetes
13	59	169	75	Right	Diabetes

doi:10.1371/journal.pone.0096988.t001

Pistoning

The repeated measures ANOVA indicated significant differences among the three studied suspension systems during gait ($F(2,24) = 27.81$, $P = 0.000$ and $\eta_p^2 = 0.70$). In the swing phase, $F(2,24) = 46.49$, $P = 0.000$ and $\eta_p^2 = 0.79$, while it was $F(2,24) = 27.13$, $P = 0.000$ and $\eta_p^2 = 0.69$ during stance. Overall, the magnitude of pistoning with the Seal-In suspension was considerably lower compared with the pin/lock and MPSS during swing ($P = 0.000$ and $P = 0.001$, respectively).

Comparisons between the MPSS and Seal-In systems revealed higher vertical displacements (piston motion) when the prosthetic limb was suspended using the MPSS ($P = 0.001$). This significantly higher pistoning was evident during the swing phase; yet, the magnitudes of pistoning were higher for the Seal-In liner during the stance ($P = 0.000$).

Statistical analyses indicated lower pistoning values with the MPSS compared with the pin/lock system during the swing phase ($P = 0.035$). During one gait cycle, 4.06 mm and 2.88 mm of pistoning was observed with the pin/lock and MPSS ($P = 0.019$).

Kinetics and Kinematics

The suspension type did not alter the walking speed, stance and swing time significantly ($P > 0.05$). The swing time of the prosthetic side were significantly longer than the sound limb with the three suspension systems ($P < 0.05$) (Table 2). However, the stance time was significantly lower on the prosthetic limb than the sound limb. Significant differences were found between the suspension systems in the first peak of vertical GRF (loading response) ($F(2,24) = 13.01$, $P = 0.000$, $\eta_p^2 = 0.52$). The comparison between the MPSS and pin/lock as well as the Seal-In and pin/lock revealed significant differences ($P = 0.042$ & $P = 0.006$, respectively). With all three systems, weight transfer during the transition from double- to single-limb support occurred in a shorter period for the sound leg compared with the prosthetic leg (Table 2).

The vertical GRF during the loading response (2nd peak) was significantly different among the three systems ($F(2,24) = 18.80$, $P = 0.000$, $\eta_p^2 = 0.79$). None of the systems showed significant difference between the sound and prosthetic leg. From the double- to single-limb support (swing time), the weight shift occurred at a considerably shorter period for the sound limb compared with the prosthetic limb for all the systems (all $P = 0.000$).

The suspension systems not only changed the first peak of the fore-aft GRF significantly ($F(2,24) = 14.57$, $P = 0.003$, $\eta_p^2 = 0.65$), but also there was significant difference between the sound and prosthetic legs within every suspension type (all Cohen's $d > 0.8$). The magnitudes of 1st peak fore-aft GRF were significantly lower on the prosthetic leg compared with the sound leg for all the systems (all $P = 0.000$, $d > 0.8$) (Table 2). The lowest mean difference was seen with the Seal-In system (2.40).

The average knee range of motion (ROM) was significantly different among the three studied systems ($F(2,24) = 46.48$, $P = 0.000$, $\eta_p^2 = 0.79$). The highest knee ROM with the prosthetic leg was seen with the Seal-In (70.7°). There was no significant difference between the pin/lock and MPSS ($P = 0.075$). The knee ROM was significantly different between the legs for the Seal-In, pin/lock and MPSS ($P = 0.000$; $d = 4.4$, $d = 2.7$, $d = 2.1$, respectively). A significant difference was observed among the three systems in the maximum knee flexion ($F(2,48) = 18.40$, $P = 0.000$, $\eta_p^2 = 0.60$). The highest knee flexion was seen with the Seal-In, followed by the MPSS and pin/lock ($P = 0.006$ & 0.001, respectively).

Tables 2 and 3 show the mean values, confidence intervals and effect sizes of kinetic and kinematic gait parameters based on the suspension type. Figure 2 illustrates the comparison of kinematic values among the suspension systems for the prosthetic limb.

GDI

The mean GDI for 13 subjects were 43.33, 40.57, and 39.87 with the Seal-In, pin/lock, and MPSS, respectively. Suspension type did not result in significant difference of the GDI values ($F(2,24) = 2.11$, $P = 0.143$, $\eta_p^2 = 0.15$). Figure 3 presents the comparison of mean GDI index values among the suspension systems.

Discussion

The gait of lower limb amputees has long been studied to understand the kinematic and kinetic deviations resulting from the loss of ankle-foot (transtibial amputees) or knee-ankle-foot complex (transfemoral amputees). The effects of various prosthesis components on the gait of individuals with amputation have been investigated. Primarily, this study attempted to examine the effect

Table 2. Kinetic and kinematic differences between the sound and prosthetic limbs within every suspension type; Mean (95% CI).

Parameters	Seal-In		*P* value	MD (CI)	*d*	Pin/lock		*P* value	MD (CI)	*d*	MPSS		*P* value	MD (CI)	*d*
	Sound	Prosthesis				Sound	Prosthesis				Sound	Prosthesis			
Step length (m)	0.57 (0.53–0.61)	0.61 (0.55–0.66)	0.320	0.04 (−0.84–3.09)	0.1	0.54 (0.47–0.62)	0.62 (0.54–0.69)	0.134	0.08 (−0.03–0.17)	0.5	0.56 (0.5–0.62)	0.59 (0.51–0.67)	0.536	0.03 (−0.07–0.12)	0.2
Cadence (step/min)	94.09 (92.73–95.46)	95.21 (94.02–96.41)	0.183	1.12 (−0.85–3.09)	0.2	93.03 (91.77–94.3)	95.60 (94.13–97.25)	**0.031**	2.57 (0.28–4.03)	0.4	93.03 (91.77–94.3)	95.06 (93.37–96.75)	0.145	2.03 (−0.73–4.4)	0.6
Stance time (% of gait cycle)	65.56 (64.1–67.03)	62.28 (60.89–63.70)	**0.002**	3.28 (−5.11–−1.45)	1.3	66.7 (65.53–67.87)	60.73 (59.74–61.73)	**<0.001**	5.97 (−7.38–−4.55)	3.4	65.57 (64.34–66.8)	62.31 (61.19–63.42)	**0.001**	3.26 (−4.77–−1.75)	1.7
Swing time (% of gait cycle)	34.46 (33.31–35.61)	37.70 (65.60–67.80)	**0.001**	32.24 (30.74–33.75)	1.4	33.32 (31.64–35)	38.30 (36.95–39.65)	**<0.001**	4.98 (3.32–6.64)	2.1	34.14 (32.75–35.52)	37.56 (36.39–38.73)	**0.001**	3.42 (1.83–5.02)	1.7
Vertical GRF, 1^{st} peak (%BW)	121.11 (118.05–124.17)	99.68 (97.15–102.22)	**<0.001**	21.43 (−25.15–−17.7)	4.8	126.68 (123.88–129.48)	104.22 (101.58–106.87)	**<0.001**	22.46 (−26.03–−18.89)	4.9	115.27 (109.13 –121.42)	96.42 (91.84–101.02)	**<0.001**	18.85 (−25.2–−12.49)	2.3
Vertical GRF, 2^{nd} peak (%BW)	101.99 (99.59–104.4)	102.63 (100.19–105.06)	0.706	0.64 (−1.69–2.96)	0.1	101.12 (98.87–103.38)	99.09 (96.34–101.85)	0.301	2.03 (−6.12–2.06)	0.4	105.18 (102.38 –107.98)	91.69 (88.51–94.87)	**<0.001**	13.49 (−17.49–−9.49)	2.4
Fore-aft GRF, 1^{st} peak (%BW)	7.86 (7.1–8.62)	5.45 (4.79–6.12)	**<0.001**	2.41 (−3.34–−1.47)	2.1	9.34 (8.4–10.28)	4.66 (3.98–5.35)	**<0.001**	4.68 (−5.7–−3.66)	3.9	9.86 (8.94 –10.78)	4.11 (3.43–4.80)	**<0.001**	5.75 (−6.87–−4.61)	4.8
Fore-aft GRF, 2^{nd} peak (%BW)	−7.51 (−8.25–−6.77)	−8.10 (−8.76–−7.43)	0.208	0.59 (−1.37–0.19)	0.5	−7.13 (−8.84–−6.45)	−8.11 (−8.91– −7.31)	0.058	0.98 (−2.04–0.04)	0.7	−7.01 (−8.10–−6.25)	−7.41 (−8.13–−6.69)	0.390	0.40 (−1.25–0.52)	0.3
Hip position-initial contact	35.89 (33.81–37.97)	32.8 (30.95–34.65)	0.193	3.09 (−5.38–−0.8)	0.9	32.6 (30.94–34.26)	33.11 (31.04–35.17)	0.543	0.51 (−1.26–2.27)	0.2	34.15 (32.11–35.81)	33.04 (31.08–35.00)	0.318	1.11 (−3.44–1.21)	0.4
Max Hip Ext	−2.13 (−2.46–−1.81)	3.06 (2.71–3.42)	**<0.001**	5.19 (4.83–5.56)	3.6	−2.42 (−2.98–−1.85)	2.62 (2.18–3.05)	**<0.001**	5.04 (4.36–5.71)	3.6	−2.42 (−2.75–−1.67)	2.5 (1.97–3.04)	**<0.001**	4.92 (4.29–5.53)	5.4
Hip ROM	38.42 (37.37–39.47)	37.31 (35.83–38.79)	0.193	1.11 (−2.66–0.43)	0.5	37.23 (35.03–38.80)	36.13 (34.92–37.33)	0.121	1.1 (−2.55–0.34)	0.5	37.52 (35.67–39.45)	36.7 (35.25–38.16)	0.261	0.82 (−2.18–0.65)	0.4
Knee position-initial contact	1.41 (1.14–1.67)	5.4 (4.55–6.25)	**<0.001**	3.99 (3.12–4.87)	3.8	4.1 (3.17–5.02)	5.73 (4.9–6.57)	**0.022**	1.63 (0.28–2.99)	1.1	3.9 (3.35–4.45)	5.53 (4.34–6.71)	**0.023**	1.63 (0.27–2.98)	1.1
Max Knee Flex-stance	15.12 (14.09–16.15)	13.72 (12.59–14.86)	0.059	1.40 (−2.98–0.18)	0.8	13.43 (11.86–15.01)	12.47 (11.08–13.85)	0.302	0.96 (−2.93–0.99)	0.4	14.24 (12.66–15.82)	12.84 (11.5–14.19)	0.235	1.40 (−3.83–1.04)	0.6
Max Knee Flex-swing	55.17 (53.58–56.75)	75.40 (73.21–77.57)	**<0.001**	20.23 (17.32–23.13)	6.4	52.52 (51.08–53.96)	66.92 (64.77–69.08)	**<0.001**	14.4 (11.49–17.32)	4.7	54.02 (52.06–55.97)	70.81 (68.7–72.93)	**<0.001**	16.79 (14.21–19.38)	5.0
Knee ROM	56.14 (54.57–57.7)	70.68 (68.34–73.04)	**<0.001**	14.54 (11.54–17.57)	4.4	52.61 (51.12–54.09)	61.42 (58.99–63.81)	**<0.001**	8.81 (6.28–11.31)	2.7	52.79 (51.28–54.3)	58.25 (56.55–59.94)	**<0.001**	5.46 (3.02–7.89)	2.1
Ankle position-initial contact	2.12 (1.59–2.65)	−0.81 (−1.21–−0.41)	**<0.001**	2.93 (−3.67–−2.19)	3.8	-4.21 (−4.88–−3.54)	0.27 (0.07–0.46)	**<0.001**	4.48 (3.76–5.19)	5.5	−2.29 (−2.81–−1.77)	−0.6 (−0.93–−0.28)	**<0.001**	1.69 (1.01–2.37)	2.3
Max ankle PF-stance	−6.68 (−8.33–−5.02)	−7.19 (−8.3–−6.07)	0.583	0.51 (−2.75–1.73)	0.2	−5.92 (−7.23–−4.62)	−5.89 (−6.98–−4.81)	0.951	0.03 (−1.09–1.15)	0.0	−6.12 (−7.41–−4.82)	−3.02 (−3.73–−2.31)	**0.002**	3.10 (1.42–4.77)	1.8

Table 2. Cont.

Parameters	Seal-In					Pin/lock					MPSS				
	Sound	Prosthesis	*P* value	MD (CI)	*d*	Sound	Prosthesis	*P* value	MD (CI)	*d*	Sound	Prosthesis	*P* value	MD (CI)	*d*
Max ankle DF-stance	7.3 (6.23–8.37)	14.49 (13.34–15.63)	**<0.001**	7.19 (5.44–8.93)	3.9	8.09 (7.07–9.1)	15.11 (14.24–15.98)	**<0.001**	7.02 (5.72–8.32)	4.5	7.92 (6.78–9.06)	14.67 (13.93–15.41)	**<0.001**	6.75 (5.43–8.06)	4.2
Max ankle PF-swing	−13.2 (−14.7–−11.7)	0.33 (0.12–0.55)	**<0.001**	13.53 (12.02–15.05)	7.6	−12.15 (−13.2–−11.1)	1.37 (1.13–1.67)	**<0.001**	13.52 (12.45–14.64)	5.7	−12.17 (−13.05–−11.29)	1.13 (0.93–1.33)	**<0.001**	13.30 (12.38–14.21)	5.2
Ankle ROM	20.67 (19.1–22.24)	21.73 (20.35–23.1)	0.280	1.06 (−1.23–3.35)	0.4	20.08 (18.68–21.48)	20.87 (19.32–22.43)	0.508	0.79 (−1.74–3.33)	0.3	20.25 (18.5–21.99)	20.69 (19.55–21.83)	0.700	0.44 (−2.00–2.88)	0.2

CI = Confidence interval; PF = plantar flexion; DF = dorsiflexion; Flex = flexion; Ext = extension; ROM = range of motion; MD = mean difference.
*Values of significance ($P<0.05$) have been shown in bold.
d equals to values of Cohen's d; 0.2 = small, 0.5 = medium, >0.8 = large.
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of suspension type on walking kinetics and kinematics, pistoning and gait deviation with three different suspension systems. The previous research showed that the interface pressure with the suspension systems used in the current study were considerably different [16]. Thus, we hypothesized that gait characteristics would also be notably different among the MPSS, Seal-In, and pin/lock systems.

Transtibial amputees have different gait patterns from healthy individuals. As a result, the intact limb is said to undergo higher loading. To compensate, amputees adopt mechanisms, such as decreased walking speed, increased knee and hip moments and higher ankle ROM on the sound limb [2]. Based on the literature, the asymmetry in amputee gait reduces the time of stance [22–24] and the ground reaction forces [22,25,26] of the prosthetic limb compared with the sound limb.

Healthy individuals have a gait velocity of 1.2 m/s–1.5 m/s [27,28]. No significant difference was observed in gait speed among the three suspension systems ($P = 0.075$). Also, previous studies revealed higher walking speed for transtibial amputees than our findings [15,29,30].

Pistoning

Pistoning is used as a measure of suspension efficiency [31]. The findings in this study revealed that pistoning values were significantly different among the suspension systems during level walking both in the stance and swing phase with medium and large effect sizes of 0.69 and 0.79, respectively. The magnitudes of pistoning with the MPSS and pin/lock systems were compatible. The Seal-In system exhibited significantly lower pistoning during the swing phase compared with the pin/lock (2.0 vs. 4.9 mm, $P = 0.002$, $\eta_p^2 = 0.57$) and MPSS (2.0 vs. 3.3 mm, $P = 0.002$, $\eta_p^2 = 0.57$). The values were well-matched to those obtained during gait simulation in our previous study [17]; the gait simulation showed a pistoning range of 0 to 5.8 mm and the pistoning in the current study ranged between 0 to 5.1 mm.

Ground Reaction Force

The external forces exerted on the lower limbs during walking are defined as GRFs [32,33]. The magnitude of peak GRF can determine level of shock absorption. All the suspension systems exhibited significant differences in the first peak of vertical GRF between the sound and prosthetic limbs. The sound limb exhibited significantly higher first peak vertical GRF compared with the prosthetic leg in the previous literature [30,34,35]. Our findings were consistent with those findings as the participants showed higher first peak value for the sound limb with all the systems (Table 2). Also, the suspension systems showed significantly different 1st peak GRF values ($F(2,24) = 13.01$, $P = 0.000$, $\eta_p^2 = 0.52$). High magnitude of first peak GRF indicates higher loading transferred to the limb joints. The MPSS showed lower values than the pin/lock (mean difference = 7.8; $P = 0.006$), which may indicate that lower external loading was applied to the joints (Figure 4).

Generally, there was significant difference between the suspension systems in the 2nd peak of vertical GRF ($F(2,24) = 18.80$, $P = 0.000$, $\eta_p^2 = 0.61$). None of the suspension systems showed significant differences between the prosthetic and sound legs. Thus, it can be deduced that the dynamic foot used in this study (Talux) generated an added force during push off by storing energy and simulating the anatomical ankle plantar flexion. However, the magnitude of the second peak of vertical GRF was lower with the MPSS than the pin/lock (mean difference = 7.67). This result may be associated with the lower interface pressure within the prosthetic socket observed in the previous study [16].

Table 3. Comparison of kinetics and kinematic variables with regards to the suspension system type in the prosthetic limb.

Parameter	Suspension type			*P* value	Effect size
	Mean (95% CI)				
	Seal-In	Pin/lock	MPSS		
Step length (m)	0.61	0.62	0.60	0.817	0.03
	(0.55–0.66)	(0.54–0.69)	(0.51–0.67)		
Cadence (step/min)	95.2	95.70	95.06	0.844	0.14
	(94.02–96.41)	(94.13–97.25)	(93.37–96.75)		
Velocity (m/s)	0.94	0.91	0.98	0.075	0.23
	(0.91–0.98)	(0.86–0.96)	(0.95–1.01)		
Stride length (m)	1.21	1.12	1.08	0.118	0.16
	(1.14–1.29)	(1.03–1.20)	(0.95–1.22)		
Stance time (% of gait cycle)	62.28	61.73	62.50	0.062	0.39
	(60.89–63.70)	(59.74–61.73)	(61.19–63.42)		
Swing time (% of gait cycle)	37.70	38.30	37.56	0.435	0.06
	(65.60–67.80)	(36.95–39.65)	(36.39–38.73)		
Vertical GRF, 1st peak (%BW)	99.68	104.22[a,c]	96.42[b]	**<0.001***	0.52
	(97.15–102.22)	(101.58–106.87)	(91.84–101.02)		
Vertical GRF, 2nd peak (%BW)	102.63	99.09	91.69[a,b]	**<0.001***	0.61
	(100.19–105.06)	(96.34–101.85)	(88.51–94.87)		
Fore-aft GRF, 1st peak (%BW)	5.45	4.66[a]	4.11[a,b]	**0.003***	0.65
	(4.79–6.12)	(3.98–5.35)	(3.43–4.80)		
Fore-aft GRF, 2nd peak (%BW)	−8.02	−8.11	−7.41	0.095	0.34
	(−8.76–−7.43)	(−8.91–−7.31)	(−8.13–−6.69)		
Hip position-initial contact	32.8	33.11	33.04	0.931	0.006
	(30.95–34.65)	(31.04–35.17)	(31.08–35)		
Max Hip Ext	3.06	2.62	2.5	0.210	0.12
	(2.71–3.42)	(2.18–3.05)	(1.97–3.04)		
Hip ROM	37.31	36.13	36.7	0.278	0.10
	(35.83–38.79)	(34.92–37.33)	(35.25–38.16)		
Knee position-initial contact	5.4	5.73	5.53	0.876	0.01
	(4.55–6.25)	(4.9–6.57)	(4.34–6.71)		
Max Knee Flex -stance	13.72	12.47	12.8	0.291	0.09
	(12.59–14.86)	(11.08–13.85)	(11.5–14.19)		
Max Knee Flex-swing	75.40	66.92[a]	70.81[a,b]	**<0.001***	0.60
	(73.21–77.57)	(64.77–69.08)	(68.7–72.93)		
Knee ROM	70.68	61.42[a]	58.25[a]	**<0.001***	0.79
	(68.34–73.04)	(58.99–63.81)	(56.55–59.94)		
Ankle position-initial contact	−0.81	0.27[a]	−0.6[b]	**0.001***	0.71
	(−1.21–−0.41)	(0.07–0.46)	(−0.93–−0.28)		
Max ankle PF-stance	−7.19	−5.89	−3.02[a,b]	**<0.001***	0.80
	(−8.3–−6.07)	(−6.98–−4.81)	(−3.73–−2.31)		
Max ankle DF-stance	14.49	15.11	14.67	0.556	0.04
	(13.34–15.63)	(14.24–15.98)	(13.93–15.41)		
Max ankle PF-swing	0.33	1.37[a]	1.13[a]	**<0.001***	0.76
	(0.12–0.55)	(1.13–1.67)	(0.93–1.33)		
Ankle ROM	21.73	20.8	20.69	0.417	0.07
	(20.35–23.1)	(19.32–22.43)	(19.55–21.83)		

CI = Confidence interval; PF = plantar flexion; DF = dorsiflexion; Flex = flexion; Ext = extension; ROM = range of motion.
[a]Mean difference is significant at the 0.05 level compared with the Seal-In suspension.
[b]Mean difference is significant at the 0.05 level compared with the pin/lock suspension.
*shows significant differences among the three suspension systems.
doi:10.1371/journal.pone.0096988.t003

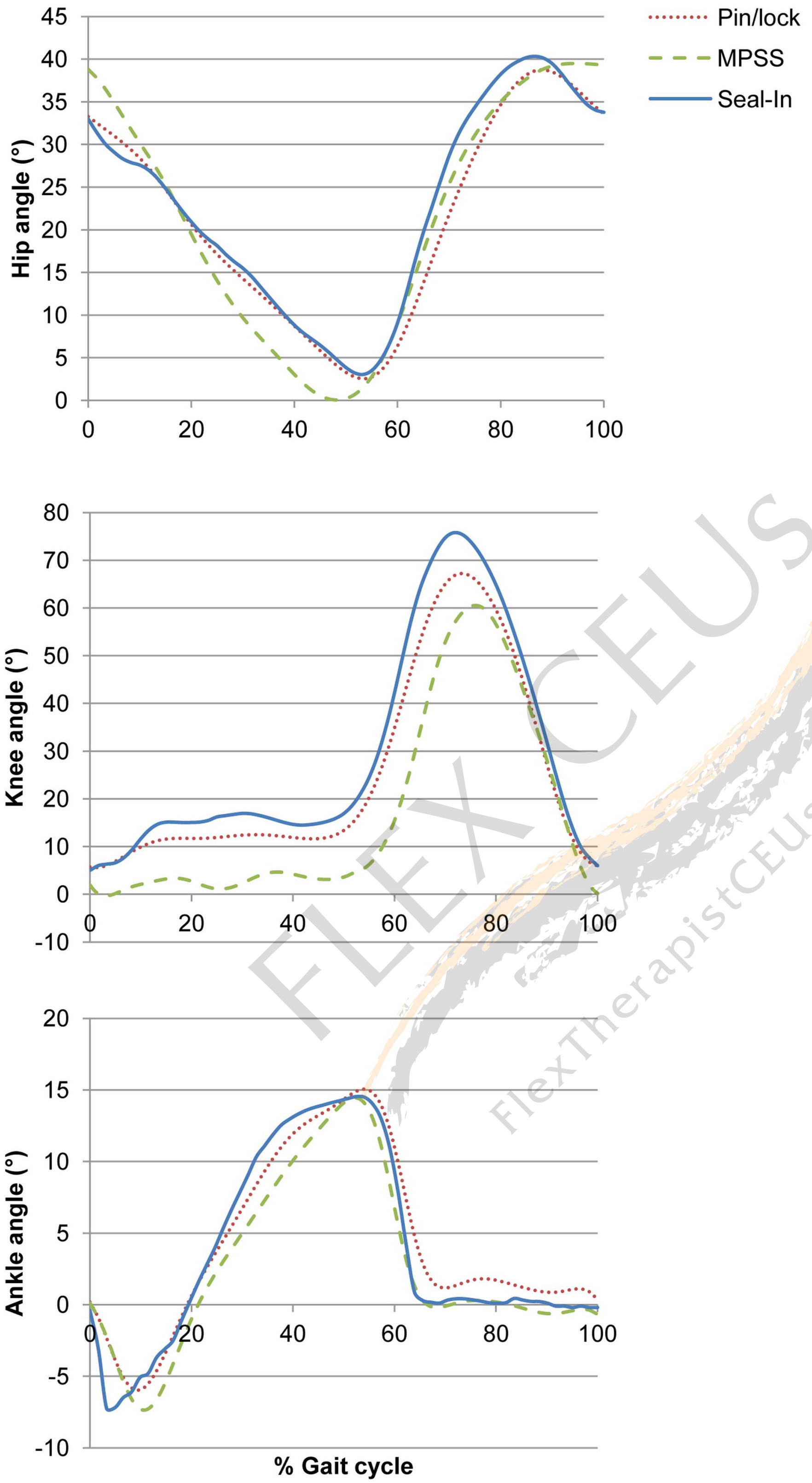

Figure 2. Kinematic values based on the suspension type. Comparison of kinematic values for prosthetic limbs among the different suspension systems (n = 13).
doi:10.1371/journal.pone.0096988.g002

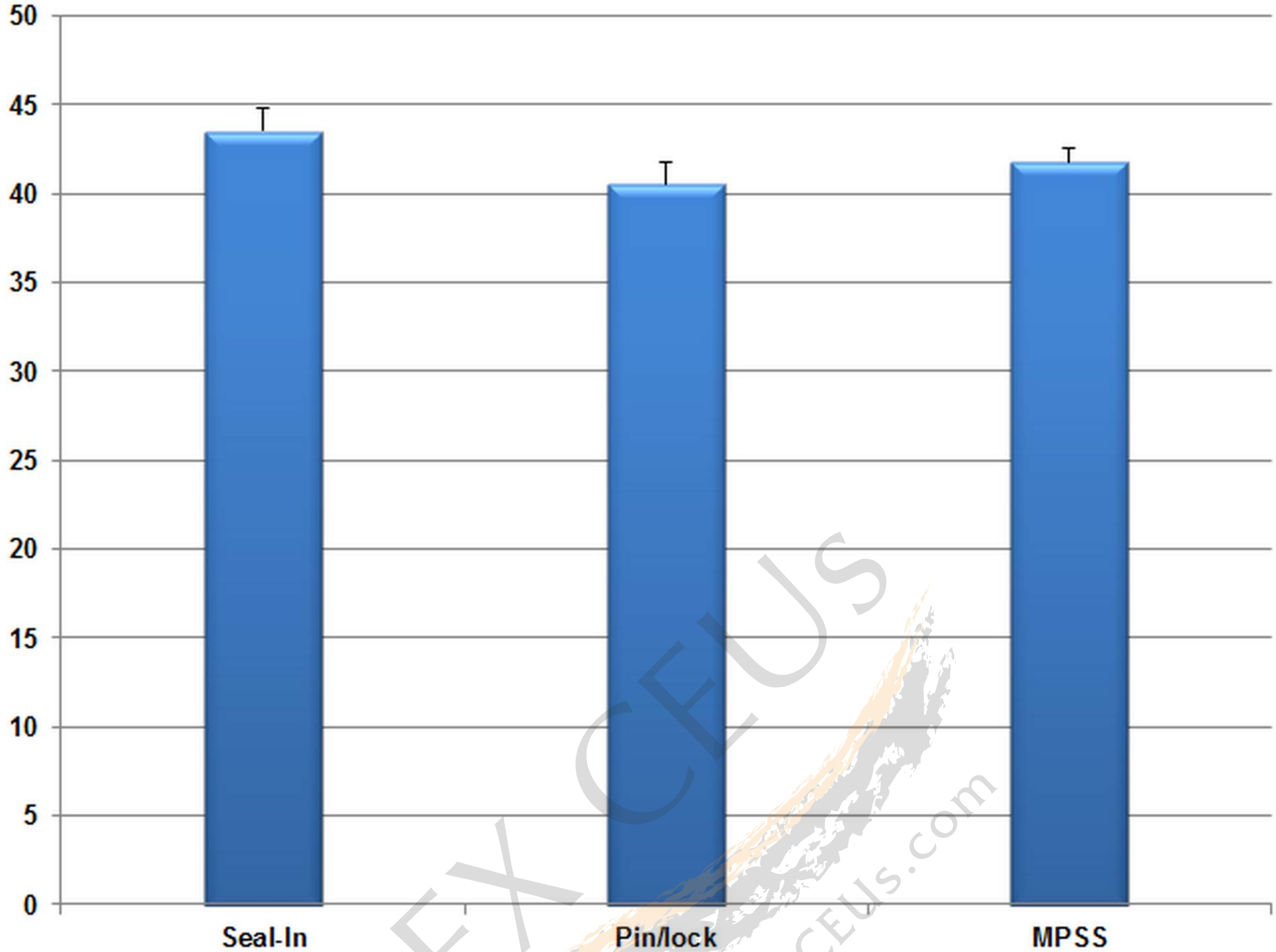

Figure 3. The comparison of GDI values among the suspension systems. Error bars show the standard error values.
doi:10.1371/journal.pone.0096988.g003

The pattern of resultant fore-aft GRF revealed comparable acceleration forces for all the suspension systems ($F(2,24) = 2.45$, $P = 0.107$), and for both limbs. A larger deceleration force (braking force) was observed with the sound limb ($P = 0.000$ for all the systems), which conforms to the previous finding by Zmitrewicz et al. (2006) [36]. However, several minor differences in magnitudes are evident between the two studies, possibly due to the variations in prosthetic components, particularly the foot and walking velocity. The highest actual mean difference between the legs was seen with the MPSS (5.75). Braking peaks of prosthetic limb were lower with the MPSS than the pin/lock ($P = 0.016$, $d = 0.78$). This result possibly indicates better shock absorption with the MPSS. The duration of deceleration force was also dissimilar between the limbs, as the prosthetic side showed a larger value than the sound limb, which is compatible with the findings of Zmitrewicz et al. (2006) [36]. Propulsive force contributes to symmetrical gait pattern, balanced loading and steady walking speed. All the systems demonstrated similar magnitudes of propulsion force (for-aft GRF, 2nd peak) for both limbs. This observation may reveal symmetry between the lower limbs.

Spatiotemporal Parameters

Compared with the normal individuals, the amputee gait is characterized by lower velocity, greater swing time, longer step length, and increased cadence [28]. These characteristics are compensatory means of reducing instability and imbalance. In this study, cadence (number of steps per time unit) did not differ considerably between the sound and prosthetic legs for all suspension systems. However, the Seal-In system exhibited more homogenous cadence values between the legs (Table 2). The magnitudes were similar to the cadence values of other studies [27,28].

Inconsistent step length is generally the result of uneven weight bearing through the lower limbs. Longer step length helps in relieving the load off the residual limb. There was no significant difference among the three systems ($F(2,24 = 0.13$, $P = 0.817$) and between the limbs. This was not consistent with the previous studies that showed significant difference in step length between the legs [29].

Prosthesis users tend to shift weight to the sound leg; consequently, the timing of prosthesis stance phase is lower [34]. Similarly, the stance phase was shorter with the prosthetic leg than the sound limb for all the suspension systems in our study ($d = 1.3$, 3.4 and 1.7 for the Seal-In, pin/lock and MPSS, respectively). The highest actual difference was seen with the pin/lock (66.7 vs. 61.7), while the lowest with the Seal-In (65.6 vs. 62.3) (Table 2). These results indicate that possibly the participants were more comfortable to walk with the Seal-In system, while probably the milking phenomenon resulted in pain and discomfort with the pin/lock suspension. Although statistically different, the actual differences might not be clinically relevant. The longer swing phase may be

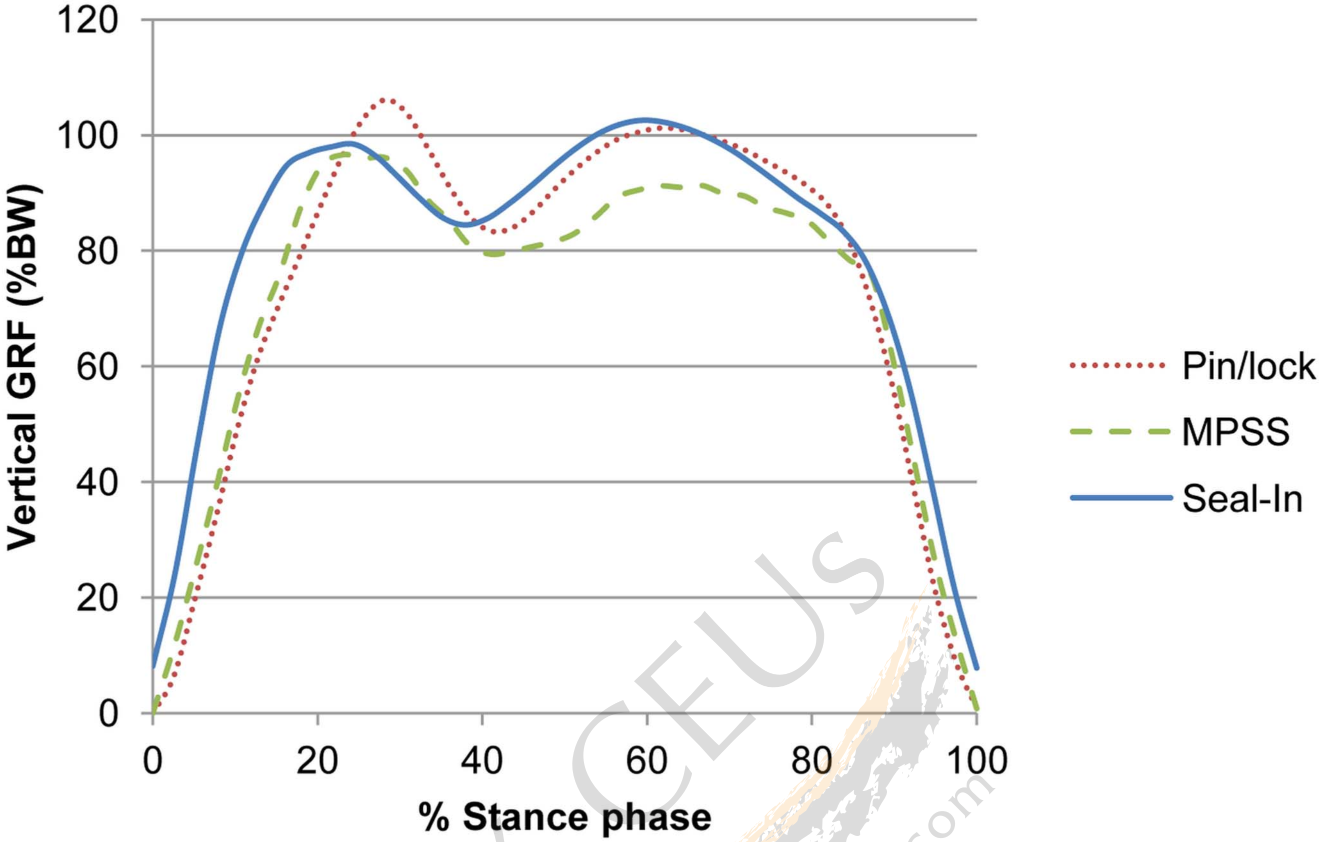

Figure 4. Vertical GRF for each suspension type. The vertical ground reaction force (GRF) pattern of the prosthetic limb for the three suspension systems.
doi:10.1371/journal.pone.0096988.g004

the result of the lighter prosthetic foot (carbon Talux) than the anatomical one [29].

Kinematics

The previous literature on amputee's gait biomechanics demonstrated slight deviations from the able-bodied gait pattern [28,34]. Also, there are differences between the sound and amputated legs in unilateral amputees. In our study, the magnitudes of hip ROM were slightly higher with the sound leg than the prosthetic leg; however, the statistical analysis did not show any significance. Similarly, Bateni and Olney (2002) showed relative smaller ranges of hip angle for the amputated side [34]. There was no significant difference among the three systems on the prosthetic side ($P = 0.240$).

In the previous studies, less knee flexion was observed on the amputated side in comparison with the normal values in stance phase. Similarly, less knee flexion was seen in our study. This finding can be attributed to the inability of the prosthetic foot to produce the controlled plantar flexion as dorsiflexor eccentric contraction is missing [37]. Knee and foot motions are often synchronized. In most prosthetic feet, the ankle does not allow plantar flexion when weight is transferred to the toe section. If the knee at the amputated side is flexed to the mean normal value, excessive trunk lowering would produce an abnormal, inept gait [34]. However, the dynamic Talux foot allowed certain degrees of plantar flexion in this study.

Significant differences were seen in the maximum knee flexion on the prosthetic leg during the swing phase among the three suspension systems ($F(2,24) = 18.40$, $P = 0.000$, $\eta_p^2 = 0.60$). Significantly higher flexion was observed with the Seal-In system than the MPSS ($P = 0.006$). Also, the maximum knee flexion with the MPSS was higher than the pin/lock suspension ($P = 0.041$). The actual mean difference was higher between the Seal-In and pin/lock systems (8.48). The knee ROM was significantly higher on the prosthetic limb than the sound limb with all the systems and effect sizes were large (Table 2). The highest actual mean difference was seen with the Seal-In system (14.54), which may be clinically relevant as the knee ROM is important for foot clearance and demanding activities such as running. This finding is consistent with Colborne et al. (1992) [38]. The amputees often flex the amputated knee more than the sound knee to ensure foot clearance during the swing.

Gait progression is affected by the absence of anatomical ankle as more than 80% of mechanical power is generated by the plantar flexion in healthy individuals. The maximum ankle plantar flexion during the swing phase was significantly different among the systems ($F(3,53) = 38.57$, $P = 0.000$, $\eta_p^2 = 0.76$), and higher with the sound limb compared with the prosthetic limb with all the suspension systems (large effect sizes). The actual mean differences may be clinically relevant as the differences were high (more than 10°). Significant differences also existed in the ankle dorsiflexion in the stance phase between the sound and prosthetic limbs; the values were higher with the prosthetic leg (the actual mean differences were less than 8°). This can be attributed to the stiffness of prosthetic foot. The Talux foot has been reported to produce similar gait characteristics to the human foot [29]. Our participants also indicated that the Talux foot was more comfortable than their previous foot, particularly at heel strike and push off.

GDI

Gait summary measures have been recently adopted as an index of gait deviations for various pathologies, such as cerebral palsy, Parkinson's, and lower limb loss [20,21,39]. We adopted the GDI to investigate the possible gait deviation from the normal pattern with every suspension system. Kark et al. (2010) reported that the GDI is an appropriate measure for those with lower limb amputation [20]. They reported an average GDI of 84.2 (SD 9.4) for transtibial amputees. Nevertheless, our subjects showed GDI values from 39.87 to 43.33. The difference in findings may be attributed to the fact that Kark et al. (2010) did not consider hip rotation in their calculations. In our study, the Seal-In, MPSS and pin/lock were 5.54, 5.89, and 5.94 standard deviations away from the normal kinematics. There was no significant difference among the three suspension systems; only slight mean differences were seen. The previous studies showed high interface pressure and discomfort during walking with the Seal-In [16,40]. In the current study, it showed the least deviation from the normal gait kinematics, which can be attributed to lower pistoning during gait reported in the former literature [17].

A previous study on the MPSS revealed higher satisfaction rates compared with the Seal-In and pin/lock suspension systems [17]. Lower peak pressure than the pin/lock suspension, particularly during the swing phase, has been also demonstrated [16]. Not surprisingly, the GDI scores revealed inferior gait kinematics than the normal individuals; yet, the three suspension systems exhibited similar clinical outcomes that enabled the amputees to ambulate. These findings need to be further investigated on amputees with different activity levels, and with various prosthetic feet. Moreover, the effect of parameters such as the residual limb length, volume, cause of amputation, skin conditions can be further studied on the gait pattern with various suspension systems. Although, the main differences among the suspension types had high effect sizes, larger sample size may provide stronger evidence for the current findings. It is likely that those parameters that showed no difference exhibit significance if tested on higher number of amputees.

While it is common to observe significant differences between the sound and prosthetic limbs in amputees, non-significance may be considered as positive effect of prosthetic components. On the other hand, several kinetic and kinematic parameters did not show high actual mean differences among the suspension systems in this study. The main differences with high effect sizes were seen for the 2nd peak of vertical GRF and the knee range of motion between the Seal-In and MPSS (10.94 and 12.43, respectively). In summary, it may be concluded from the overall findings that the new prosthetic suspension system (MPSS) can be used clinically as an alternative suspension system for lower limb amputees.

Conclusions

Gait biomechanics was significantly influenced by the suspension type. Main differences between the suspension systems were evident in the GRF (vertical and fore-aft), knee and ankle angles; yet, not all of them are considered clinically relevant. Most specifically, the ankle angles are mainly influenced by the type of prosthetic foot, not the suspension system. The MPSS may reduce the loading over the proximal limb joints compared with the pin/lock system. Pistoning was also significantly altered by the types of suspension system. The Seal-In liner was the most effective suspension system in reducing the vertical movement during level walking. We should emphasize that prosthetic foot characteristics and alignment will also influence the gait pattern in addition to the suspension system. This study is hoped to enhance the knowledge of clinicians on gait biomechanics with various available suspension systems.

Effects of a powered ankle-foot prosthesis on kinetic loading of the unaffected leg during level-ground walking

Abstract

Background: People with a lower-extremity amputation that use conventional passive-elastic ankle-foot prostheses encounter a series of stress-related challenges during walking such as greater forces on their unaffected leg, and may thus be predisposed to secondary musculoskeletal injuries such as chronic joint disorders. Specifically, people with a unilateral transtibial amputation have an increased susceptibility to knee osteoarthritis, especially in their unaffected leg. Previous studies have hypothesized that the development of this disorder is linked to the abnormally high peak knee external adduction moments encountered during walking. An ankle-foot prosthesis that supplies biomimetic power could potentially mitigate the forces and knee adduction moments applied to the unaffected leg of a person with a transtibial amputation, which could, in turn, reduce the risk of knee osteoarthritis. We hypothesized that compared to using a passive-elastic prosthesis, people with a transtibial amputation using a powered ankle-foot prosthesis would have lower peak resultant ground reaction forces, peak external knee adduction moments, and corresponding loading rates applied to their unaffected leg during walking over a wide range of speeds.

Methods: We analyzed ground reaction forces and knee joint kinetics of the unaffected leg of seven participants with a unilateral transtibial amputation and seven age-, height- and weight-matched non-amputees during level-ground walking at 0.75, 1.00, 1.25, 1.50, and 1.75 m/s. Subjects with an amputation walked while using their own passive-elastic prosthesis and a powered ankle-foot prosthesis capable of providing net positive mechanical work and powered ankle plantar flexion during late stance.

Results: Use of the powered prosthesis significantly decreased unaffected leg peak resultant forces by 2-11% at 0.75-1.50 m/s, and first peak knee external adduction moments by 21 and 12% at 1.50 and 1.75 m/s, respectively. Loading rates were not significantly different between prosthetic feet.

Conclusions: Use of a biomimetic powered ankle-foot prosthesis decreased peak resultant force at slow and moderate speeds and knee external adduction moment at moderate and fast speeds on the unaffected leg of people with a transtibial amputation during level-ground walking. Thus, use of an ankle-foot prosthesis that provides net positive mechanical work could reduce the risk of comorbidities such as knee osteoarthritis.

Keywords: Amputee, Ankle, Biomechanics, Bionic, Gait, Loading rate, Prosthesis, Transtibial, Walking

Background

There are over one million people in the United States that live with a lower-extremity amputation [1-3] and this number continues to grow appreciably due to the increased prevalence of diabetes. The continued development of carbon-fiber passive-elastic prostheses has enhanced the use of lower-extremity prostheses, but these passive prostheses can only store and return energy. Unlike the biological ankle, passive-elastic prostheses cannot generate non-conservative positive power or work [4-6]. Further, quasi-passive prosthetic ankle joints that employ computer-controlled swing phase position modulation (Proprio Foot Ankle Prosthesis from Össur) propose a measured benefit [7-11], but are incapable of emulating normal biomechanical ankle function during the stance phase of walking. People with a lower-extremity amputation using passive and quasi-passive prostheses continue to experience gait pathologies such as higher metabolic demands, greater kinematic and kinetic leg asymmetries, and reduced self-selected walking speeds [12-17]. Though many potential factors could be causally related to the increased prevalence of musculoskeletal injury in people with a leg amputation, asymmetrical gait patterns such as greater unaffected leg resultant forces and knee moments, have been postulated to increase the risk of unaffected leg musculoskeletal injury, including joint degradation and excessive leg pain [18,19]. Further, when people with a leg amputation use a passive-elastic prosthesis, and walk at faster speeds, they experience greater kinematic and kinetic leg asymmetries, including greater unaffected leg forces [15,20].

People with a transtibial amputation using passive or quasi-passive prostheses display abnormal gait mechanics due in part to the absence of function normally delivered by the muscles surrounding the ankle joint and the absence of ankle range of motion. Most critically, the muscles responsible for plantar flexion of the ankle, the gastrocnemius and soleus, play a key role in human walking [21-23]. These plantar-flexors generate propulsive force during the mid- to late-stance phase and thereby propel the body upward and forward with each walking step [21-23]. Passive-elastic prostheses release less than one-half the mechanical energy, and less than one-eighth the mechanical power normally generated by the soleus and gastrocnemius during the stance phase of level-ground walking at moderate speeds [4-6] and are therefore unable to replicate the function of a biological ankle. Walking at faster speeds requires greater force and power, therefore there are larger kinematic and kinetic discrepancies between passive-elastic prosthetic and biological ankle mechanics [15,20].

The knee external adduction moment (EAM) indicates the load distributed between the medial and lateral compartments of the knee and is strongly associated with the incidence and progression of osteoarthritis in a non-amputee population [24,25]. People with a unilateral transtibial amputation have an increased susceptibility to knee pain and osteoarthritis, especially in their unaffected leg [18,19,26-28], however, they have a decreased prevalence of knee pain in their affected leg [18]. Previous studies have hypothesized that there is a link between the development of osteoarthritis and abnormally high peak knee external adduction moments (EAM) encountered during walking [18,19,24,25,27,29]. Royer and Wasilewski [19] reported significantly higher peak EAM ($p = 0.028$) in the unaffected leg of subjects with a unilateral transtibial amputation (0.55 ± 0.18 Nm/kg) compared to their affected leg (0.38 ± 0.22 Nm/kg). Similar findings have been reported by Lloyd and colleagues [30]. When faced with knee pain in their unaffected leg, people with an amputation may reduce or forgo recreation, social, and family activities compared to non-amputees [18].

One of the major factors contributing to the prevalence of knee osteoarthritis in the unaffected leg of people with a unilateral transtibial amputation is believed to be related to the asymmetrical loading of the joint. Greater forces and loading rates observed in the unaffected leg may add to the risk of knee osteoarthritis. Kinetic loading rates have been used in previous studies to distinguish people with musculoskeletal injury from those without injury. Prior research has shown that people with a history of musculoskeletal running injuries such as plantar fasciitis and tibial stress fractures have greater vertical ground reaction force loading rates, defined as the slope of the vertical ground reaction force curve from 20–80% of heel-strike to first peak vertical force, compared to uninjured runners [31,32]. Mundermann et al. [29] found that vertical ground reaction force loading rates in patients with knee osteoarthritis during walking were elevated by 50.1% compared with those of matched uninjured subjects. However, to our knowledge, no one has compared resultant ground reaction force loading rates in subjects with an amputation. Further, we know of no studies that have calculated the loading rate of the knee EAM. Presumably, reductions in peak knee EAM would correlate with reductions in EAM loading rate.

During a single level-ground walking stride, both legs must perform positive and negative work on the center of mass (COM) to transition between steps [33-35]. Individual leg work equals the time integral of the dot product of the leg's ground reaction force and the COM velocity vector during the step-to-step transition, or double support phase, of walking. Step-to-step transitions are optimal when the positive push-off work and negative collision work are equal in magnitude [36,37].

When people with a unilateral amputation use a passive-elastic prosthesis, their affected trailing leg performs insufficient positive work during step-to-step transitions [4-6] and thus their unaffected leading leg compensates by absorbing a greater amount of negative work [38,39]. Further, the work absorbed by the unaffected leading leg increases with faster walking speeds [38]. Previous analytical studies of walking suggest that the application of a push-off force by the trailing leg just prior to the leading leg heel-strike is the most efficient method of decreasing the large negative work absorbed during step-to-step transitions [35,37]. Motivated in part by this biomechanical model finding, a novel powered ankle-foot prosthesis, the BiOM, now commercially-available from iWalk, Inc., has been designed to generate biomimetic ankle power [40-46] and allows people with transtibial amputations to achieve normative preferred walking speeds, metabolic demands, and step-to-step transition work across a wide range of speeds compared to non-amputees [38]. This powered prosthesis provides net positive work during step-to-step transitions, thereby increasing trailing leg work, and decreasing leading leg collision work compared to a passive-elastic prosthesis [38]. Use of a prosthesis that generates normative ankle power could decrease kinetic asymmetries between the affected and unaffected legs of people with a unilateral transtibial amputation. By providing adequate push-off work via a powered ankle-foot prosthesis, collision work on the unaffected leg is reduced, which presumably reduces the peak resultant force and first peak knee EAM.

We seek to determine the kinetic effects of a powered ankle-foot prosthesis on the unaffected leg of people with a unilateral transtibial amputation over level-ground across the full range of walking speeds. We hypothesize that, compared to using a passive-elastic prosthesis, people with a unilateral transtibial amputation using a powered ankle-foot prosthesis will have lower peak resultant ground reaction forces, peak external knee adduction moments, and the associated loading rates applied to their unaffected leg during level-ground walking over a range of speeds. We also hypothesize that compared to non-amputees, people with a unilateral transtibial amputation using a powered ankle-foot prosthesis will have equivalent peak resultant ground reaction forces, peak external knee adduction moments, and the associated loading rates applied to their unaffected leg during level-ground walking over a range of speeds.

Methods

Study participants

Seven people with a unilateral transtibial amputation and seven age-, sex-, height- and weight-matched non-amputees gave informed written consent according to the Department of Veterans Affairs Research Service Providence VA Medical Center Institutional Review Board (IRB # 00001402) prior to participation. All research was conducted in compliance with the Helsinki Declaration. Subjects with an amputation were at least two years post-amputation, had an amputation due to trauma, and were at or above a K3 Medicare Functional Classification Level. All subjects had no known cardiovascular, pulmonary, or neurological disease or disorder, and no additional musculoskeletal injury (Table 1). Prior to participation, subjects with an amputation were evaluated by a certified prosthetist that quantified and confirmed their level of amputation and disability. All subjects with an amputation used conventional passive-elastic prostheses to walk during their normal daily activities.

Powered ankle-foot prosthesis

The powered ankle-foot prosthesis (Figure 1) employs both passive and motorized elements to more closely emulate human ankle-foot functions. Like the biological ankle, the device generates net positive work during the stance phase and biological levels of mechanical power during terminal stance [42]. The prosthesis uses a series-elastic actuator, configured with a brushless motor and ball screw transmission in series with a carbon composite leaf spring, to store and release motor energy; thus improving efficiency and power output (Figure 1). Like state-of-the-art passive and quasi-passive ankles, the powered prosthesis features a carbon-composite foot at its base for added compliance. All electronics are encapsulated within a single housing. A modular Lithium-Polymer battery powers the motor and slides into an external compartment (Figure 1). The mass of the prosthesis is approximately 2.0 kg including the battery, similar to the mass of a biological foot and partial shank of an 80 kg male [47].

Feedback data from prosthetic ankle torque sensors ensure that the powered prosthesis achieves biomimetic function by constantly varying actuator torque and impedance throughout the gait cycle to match biological norms. Biologically-inspired control schemes govern the behavior of the device, enabling proper timing and magnitude of ankle power for a wide range of walking speeds [45,46]. The adaptive ankle controller employs positive torque feedback reflex control, using sensory information from both the actuator torque and the net torque on the ankle joint.

Procedure

Subjects with an amputation completed two randomized experimental walking sessions; one using their own passive-elastic prosthesis and one using the powered ankle-foot prosthesis. Non-amputee subjects completed one experimental session. All data were collected at the

Table 1 Anthropometric characteristics

Amputee	Age (yrs)	Height (m)	Mass (kg)	Leg length (m)	Years since amputation	Prosthesis
1	37	1.89	90.0	1.02	17	Ossur Flex-Foot VSP
2	45	1.74	92.7	0.93	19	College Park Venture
3	50	1.74	90.7	0.92	39	Freedom Innov. Renegade
4	50	1.80	106.7	0.98	31	Ossur Flex-Foot Re-Flex VSP
5	39	1.94	111.0	1.02	20	Ossur Flex-Foot Vari-Flex EVO
6	42	1.82	112.7	1.00	20	Otto Bock Axtion
7	51	1.73	92.6	0.95	2	Ohio Willow Wood Limb Logic
Amputee Avg. (S.D.)	**45 (6)**	**1.81 (0.08)**	**99.5 (10.2)**	**0.97 (0.04)**	**21.1 (11.6)**	
Control Avg. (S.D.)	**48 (7)**	**1.86 (0.06)**	**97.7 (11.9)**	**1.02 (0.03)**		

All subjects with an amputation were at a K3 level of ambulation, had an amputation due to trauma, and were male. Non-amputee subjects (Control) were age-, sex-, height-, and weight-matched.

Gait and Motion Analysis Laboratory of the Providence, RI VA Medical Center, Center for Restorative and Regenerative Medicine. Before experimental sessions with the powered ankle-foot prosthesis, subjects with an amputation completed a fitting and acclimation session of at least 2 hours. During this session, a certified prosthetist ensured that the prosthesis was properly fit and aligned. Then, each subject walked at 0.75, 1.00, 1.25, 1.50, and 1.75 m/s, while we adjusted the stiffness and power delivery of the powered prosthesis so that prosthetic ankle angle at toe-off and net positive mechanical work, the time integral of ankle power during the entire stance phase, matched average biological ankle data [23,48] within two standard deviations of the mean [38] (Table 2). The prosthesis was not tuned to a specific walking speed, but rather the same set of control parameters were used across all speeds.

Prior to each data collection session, we placed reflective markers on the following lower body anatomical landmarks of each leg: anterior superior iliac spine, posterior superior iliac spine, iliac crest, greater trochanter, medial and lateral femoral condyles, medial and lateral malleoli, 1st and 5th metatarsal heads, base of the 5th metatarsal, calcaneus, clusters of at least 3 markers along

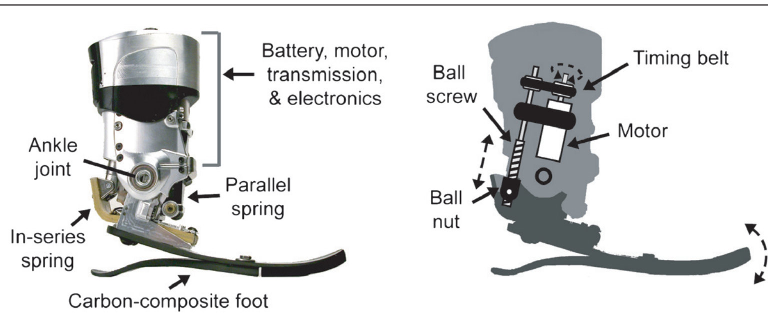

Figure 1 Powered ankle-foot prosthesis. The powered prosthesis uses a series-elastic actuator comprised of a brushless 200 Watt DC motor, ball screw transmission, and carbon-composite series leaf spring. The actuator is capable of performing non-conservative positive work about the ankle joint. The motor, transmission, and electronics are contained above the prosthetic ankle joint, and a modular Lithium-Polymer battery is housed most proximal to the ankle joint. The base of the prosthesis consists of a carbon-composite leaf spring, which adds compliance at the heel and forefoot.

Table 2 Dynamic behavior of the powered prosthesis

Speed	Toe-off angle (deg)		Ankle net work (J/kg)		Peak ankle power (W/kg)	
(m/s)	Control	Powered	Control	Powered	Control	Powered
0.75	12.0 ± 4.6	13.2 ± 2.5	−0.03 ± 0.08	0.12 ± 0.06*	1.4 ± 0.5	1.3 ± 0.3
1.00	15.3 ± 4.7	15.3 ± 2.3	0.02 ± 0.07	0.14 ± 0.07*	2.2 ± 0.6	1.7 ± 0.4
1.25	16.8 ± 4.4	16.7 ± 1.9	0.07 ± 0.06	0.17 ± 0.09*	2.8 ± 0.6	2.6 ± 0.4
1.50	18.2 ± 5.9	18.6 ± 1.6	0.12 ± 0.09	0.22 ± 0.07*	3.4 ± 0.6	3.8 ± 0.5
1.75	19.1 ± 3.5	19.0 ± 1.2	0.16 ± 0.06	0.25 ± 0.08	4.2 ± 0.7	4.2 ± 0.6

Average ± S.D. ankle angle at toe-off, net mechanical work during the entire stance phase, and peak mechanical power for subjects with an amputation using a powered ankle-foot prosthesis (Powered) compared to non-amputees (Control) across walking speeds. We used data from sensors within the prosthetic ankle to compute toe-off angle and net work from the powered prosthesis. We used inverse dynamics to compute data from non-amputees and peak power for both groups. * indicates a significant difference ($P \le 0.05$) between subjects with an amputation using the powered prosthesis and non-amputees.

the thigh and shank segments, and over the 7th cervical vertebrae of each subject. Marker placements for the affected leg were matched to those of the unaffected leg. During each experimental session, subjects walked 0.75, 1.00, 1.25, 1.50, and 1.75 m/s across a 10 m instrumented level walkway. We used a 3-D motion analysis system (Qualysis Oqus, Gothenburg, Sweden) and two force platforms (Advanced Medical Technology Incorporated, Watertown, MA) embedded in the walkway to simultaneously measure ground reaction forces at 1000 Hz and kinematics at 100 Hz during each set of experimental trials. We analyzed 3 trials from each subject at each velocity and only considered walking trials where the participant's velocity, measured as the horizontal distance per unit time of the marker placed over the 7th cervical vertebrae, was within 0.10 m/s of the target velocity, and where each foot made full contact with each force plate. We asked subjects to repeat the walking trials until they met these criteria.

We digitized the reflective marker positions using motion tracking software (Qualysis Track Manager, Gothenburg, Sweden). Then we filtered the marker data with a 6 Hz Butterworth low-pass filter and used inverse dynamics (Visual 3D, C-Motion, Inc.) to determine sagittal plane ankle joint power over the entire stance phase for the powered prosthetic ankle and the biological ankle, and frontal plane knee moments over the entire stance phase for the unaffected legs of all subjects. We calculated biological ankle power and powered prosthetic ankle power using inverse dynamics. Because the powered prosthesis has a mass that is equivalent to the mass of the biological foot and partial shank of an 80 kg male [42], and the center of ankle rotation is similar to that of a biological ankle, we assumed that an inverse dynamics approach was appropriate to calculate powered prosthetic ankle power. We created a custom Matlab program (Matlab, Mathworks, Natick, MA) to calculate resultant force, or the magnitude of the ground reaction force vector, and to detect stance phases using a 10 N resultant force threshold. Then we up-sampled the joint kinematic and kinetic data, combined them with the ground reaction force data and normalized all the data to a step.

We calculated the impact peak of the resultant ground reaction force as the maximum force during the first half of the stance phase and calculated the first peak knee external adduction moment (EAM) as the maximum EAM during the first half of the stance phase. We calculated average loading rates of the resultant ground reaction forces and the EAMs from 20 to 80% of the time between foot-strike and the first peak of each variable [31]. This portion of each curve indicates the linear loading response of the resultant force and the external adduction moment. We calculated the average loading rate from the change in force or EAM divided by change in time during this period.

Statistics

We compared unaffected leg peak resultant ground reaction force, peak knee EAM, and the corresponding loading rates from subjects with a unilateral transtibial amputation using a passive-elastic prosthesis to the same subjects using a powered prosthesis with repeated-measures ANOVAs. We also compared these data from subjects with a unilateral transtibial amputation using a passive or powered prosthesis to non-amputees with one-way ANOVAs. And we compared ankle toe-off angle, net positive work, and peak power from subjects with a unilateral transtibial amputation using a powered prosthesis to non-amputees with one-way ANOVAs. Significant differences were further analyzed with a Tukey HSD follow-up procedure and detected as $P \le 0.05$. We performed post-hoc statistical power analyses on our data with $n = 7$ for peak resultant force, peak EAM, and the respective loading rates for subjects using the powered prosthesis [49]. We averaged the statistical powers across all the velocities and calculated an average statistical power of 0.96 to detect a 15 per cent difference and 0.84 to detect a 10 per cent difference in peak resultant force, 0.57 to detect a 15 per cent difference and 0.35 to detect a 10 per cent difference in peak EAM, 0.39 to detect a 15 per cent difference and 0.23 to detect a 10 per cent difference in resultant force loading rate, and 0.37 to detect a 15 per cent difference and 0.22 to detect a 10 per cent difference in EAM loading rate. Thus, we believe we had strong statistical power for detecting differences in peak resultant forces, moderate statistical power for detecting differences in peak EAMs, and insufficient statistical power for detecting differences in loading rates.

Results

Use of a powered ankle-foot prosthesis reduced the peak resultant forces on the unaffected leg of subjects with an amputation at slow and moderate walking speeds compared to use of a passive-elastic prosthesis. The impact peaks of the resultant ground reaction forces (GRFs) from the unaffected leg were significantly lower when subjects with an amputation used the powered prosthesis compared to using their own passive-elastic prosthesis at speeds of 0.75, 1.00, 1.25, and 1.50 m/s (P = 0.04, 0.01, 0.05, and 0.04, respectively; Table 3). On average, across speeds of 0.75-1.50 m/s, the impact peak resultant GRFs on the unaffected leg were 6.6% lower for subjects using the powered prosthesis compared to using their passive-elastic prosthesis. The average resultant GRF loading rates of the unaffected leg were between 4-13% lower when subjects with an amputation used the powered prosthesis compared to their passive-elastic prosthesis across walking speeds of 0.75-1.75 m/s, but these loading rates were not significantly different (Table 3).

Use of a powered ankle-foot prosthesis reduced the external adduction moment (EAM) on the unaffected knee of subjects with an amputation compared to use of a passive-elastic prosthesis at the two fastest walking speeds. The unaffected leg first peak knee EAM was significantly lower when subjects with an amputation used the powered prosthesis compared to their passive-elastic prosthesis during walking at 1.50 and 1.75 m/s (P = 0.03 and 0.05, respectively; Table 4). Peak EAM was 20.6% and 12.2% lower for subjects using a powered compared to a passive-elastic prosthesis at 1.50 m/s and 1.75 m/s, respectively. We did not find statistical differences in peak EAM at speeds of 0.75, 1.00, and 1.25 m/s (P = 0.36, 0.88, and 0.44, respectively). The average unaffected knee EAM loading rates were 5-22% lower when subjects with an amputation used the powered prosthesis compared their passive-elastic prosthesis across walking speeds of 0.75-1.75 m/s, but these loading rates were not significantly different (Table 4).

We found that when subjects with an amputation used the powered prosthesis compared to their passive-elastic prosthesis, they reduced the peak resultant forces and EAMs on their unaffected leg across a range of walking speeds, but their GRF and EAM traces did not directly match those of non-amputees (Figure 2). Compared to non-amputees, subjects with an amputation that used their own passive-elastic prosthesis had greater peak resultant forces on their unaffected leg at walking speeds of 0.75, 1.25, 1.50, and 1.75 m/s (P = 0.04, 0.04, 0.05, and 0.03, respectively; Table 3). However, when subjects with an amputation used the powered prosthesis, the peak resultant forces on their unaffected leg were not significantly different from non-amputees. At one speed, 1.25 m/s, the resultant GRF loading rate for non-amputees was significantly lower than both prosthetic conditions in subjects with an amputation (P = 0.03 and 0.04 for passive-elastic and powered prostheses, respectively). Even though peak resultant forces were different between subjects with an amputation using a passive-elastic prosthesis and non-amputees, there were no significant differences in peak knee EAM or EAM loading rates between these groups (Table 4).

Discussion

Our results partially confirm our hypotheses. Compared to using a passive-elastic prosthesis, people with a unilateral transtibial amputation using a powered ankle-foot prosthesis had significantly lower peak resultant GRFs at

Table 3 Unaffected leg resultant ground reaction force impact peaks and loading rates

Speed	Unaffected leg 1st peak GRF (N/kg)				Unaffected leg GRF rate (N/kg/s)			
(m/s)	Passive	Powered	% Diff	Control	Passive	Powered	% Diff	Control
0.75	9.97 ± 0.21*^	9.76 ± 0.13	−2.1	9.79 ± 0.27	71.7 ± 36.6	68.8 ± 26.2	−4.0	49.2 ± 16.5
1.00	10.39 ± 0.40*	9.75 ± 0.22	−6.2	9.86 ± 0.37	87.0 ± 39.2	82.5 ± 23.1	−5.2	73.5 ± 15.0
1.25	11.33 ± 0.67*^	10.52 ± 0.75	−7.2	10.62 ± 0.39	118.7 ± 41.9^	103.7 ± 28.8^	−12.6	79.6 ± 7.4
1.50	12.77 ± 1.10*^	11.41 ± 1.28	−10.7	11.58 ± 0.75	137.1 ± 53.2	123.6 ± 22.9	−9.8	104.5 ± 18.9
1.75	13.87 ± 1.24^	13.42 ± 1.70	−3.3	12.32 ± 0.41	176.6 ± 46.8	160.5 ± 44.6	−9.1	151.6 ± 43.5

Average ± S.D. resultant ground reaction force impact peaks and resultant ground reaction force loading rates of each subject with an amputation using a passive-elastic (Passive) or powered (Powered) prosthesis, and non-amputee subjects (Control) across a range of walking speeds. The decreases in peak GRFs and loading rates between the passive-elastic and powered prostheses are shown as a percentage difference (% Diff). * indicates a significant difference (P ≤ 0.05) between subjects with an amputation using the passive-elastic versus powered prostheses. ^ indicates a significant difference (P ≤ 0.05) between subjects with an amputation and non-amputees (Control). P-values for GRF loading rates between subjects with an amputation using the passive-elastic versus powered prostheses were 0.81, 0.70, 0.27, 0.36, and 0.14 at speeds of 0.75, 1.00, 1.25, 1.50, and 1.75 m/s, respectively.

Table 4 Unaffected leg peak knee EAMs and loading rates

Speed	Unaffected leg 1st peak EAM (Nm/kg)				Unaffected leg EAM rate (Nm/kg/s)			
(m/s)	Passive	Powered	% Diff	Control	Passive	Powered	% Diff	Control
0.75	0.41 ± 0.13	0.39 ± 0.08	−5.1	0.39 ± 0.13	1.95 ± 0.85	1.84 ± 0.42	−5.4	1.74 ± 0.88
1.00	0.42 ± 0.12	0.42 ± 0.09	−0.8	0.34 ± 0.14	2.73 ± 1.10	2.24 ± 0.68	−17.9	1.86 ± 1.08
1.25	0.50 ± 0.14	0.47 ± 0.10	−5.5	0.38 ± 0.11	3.89 ± 1.43	3.38 ± 1.02	−12.9	2.64 ± 1.15
1.50	0.61 ± 0.16*	0.49 ± 0.06	−20.6	0.44 ± 0.14	4.79 ± 1.55	3.73 ± 0.82	−22.1	3.72 ± 1.79
1.75	0.68 ± 0.16*	0.60 ± 0.14	−12.2	0.50 ± 0.15	6.01 ± 1.60	5.11 ± 1.66	−15.0	4.49 ± 1.29

Average ± S.D. first peak knee EAMs and loading rates of the unaffected leg of each subject with an amputation using a passive-elastic (Passive) or powered (Powered) prosthesis, and non-amputee subjects (Control) across a range of walking speeds. * indicates a significant difference ($P \leq 0.05$) between subjects with an amputation using the passive-elastic versus powered prostheses. P-values for EAM loading rates between subjects with an amputation using the passive-elastic versus powered prostheses were 0.60, 0.07, 0.14, 0.07, and 0.17, at speeds of 0.75, 1.00, 1.25, 1.50, and 1.75 m/s, respectively.

0.75-1.50 m/s, and peak knee EAMs at 1.50 and 1.75 m/s applied to their unaffected leg during level-ground walking. Though there were no statistical differences in unaffected leg loading rates for GRFs and knee EAMs, there were trends of reduced loading rates when subjects used the powered prosthesis compared to the passive-elastic prosthesis. The lack of statistical differences in loading rates may be due to the high variability in our loading rate data (Tables 3 and 4). A greater number of subjects and more than three steps per condition (e.g. using an instrumented treadmill) would increase the statistical power and likely reduce the variability of the loading rates, thus confirming or refuting expected differences in unaffected leg loading rates between prostheses.

There is a greater prevalence of knee osteoarthritis in the unaffected compared to the affected leg of people with an amputation using a passive-elastic prosthesis [18,19,26-28]. We found that the unaffected leg peak knee EAMs were greater when subjects used a passive-elastic compared to a powered prosthesis, which is likely due to the limited push off provided by a passive prosthesis. Morgenroth et al. [39] has suggested that the first peak knee EAM scales with net positive ankle work and found that a passive-elastic prosthesis with the greatest net positive ankle push-off work resulted in the lowest unaffected leg first peak knee EAM compared to prostheses with little ankle push-off work.

At speeds of 0.75 and 1.00 m/s, the unaffected leg first peak knee EAMs were similar between subjects with an amputation using a passive-elastic prosthesis and a powered prosthesis, and non-amputees. At these slow walking speeds, the passive-elastic and powered prostheses, as well as the biological ankle behave in a spring-like manner, where the net mechanical work is nearly zero across the entire stance phase (Table 2). Whereas, at the two fastest speeds of 1.50 and 1.75 m/s, there were significant differences in unaffected leg peak knee EAMs (Table 4, Figure 2). The significantly greater unaffected leg peak knee EAM in subjects with an amputation using a passive-elastic prosthesis is likely due to the limited amount of push-off work provided by the passive prosthesis [38]. Thus, the reason for differences in unaffected leg peak knee EAM is likely due to the net positive work performed at faster speeds by the powered prosthesis (Table 2).

Researchers have hypothesized that peak resultant force and knee EAM are factors that may be linked to common medical complications such as knee osteoarthritis [27], thus we believe that a powered ankle-foot prosthesis may reduce the risk of these complications by decreasing unaffected leg peak resultant forces and knee EAM over a range of walking speeds. Previous studies and models have shown the importance of powered plantar flexion during the walking gait cycle [39]. People with unilateral transtibial amputations using passive-elastic prostheses employ compensatory mechanisms such as an increased dependence on the unaffected leg during walking that result in greater peak forces on the unaffected leg compared to the affected leg [15,20,50]. Our results show that use of a powered ankle-foot prosthesis decreases the unaffected leg peak impact resultant force and loading rate. This suggests that increased powered plantar flexion may mitigate some of the compensatory mechanics used by people with unilateral transtibial amputation over a wide range of walking speeds.

Our results support the notion that greater prosthetic ankle work and power are associated with reductions in the first EAM peak on the unaffected knee. Similar to Morgenroth et al. [39], who examined the effects of different passive-elastic prostheses on the unaffected knee EAM, we also found that a prosthesis that performs more net positive work results in a lower unaffected leg first peak knee EAM (Figure 3). We calculated prosthetic ankle work during the entire stance phase, whereas Morgenroth et al. [39] calculated prosthetic ankle work only during the push-off phase of the gait cycle. In distinction to Morgenroth et al. [39], we compared knee EAM across a range of speeds and found statistical differences in peak EAM when subjects used the powered ankle-foot prosthesis compared to their own prescribed passive-elastic prosthesis at the two

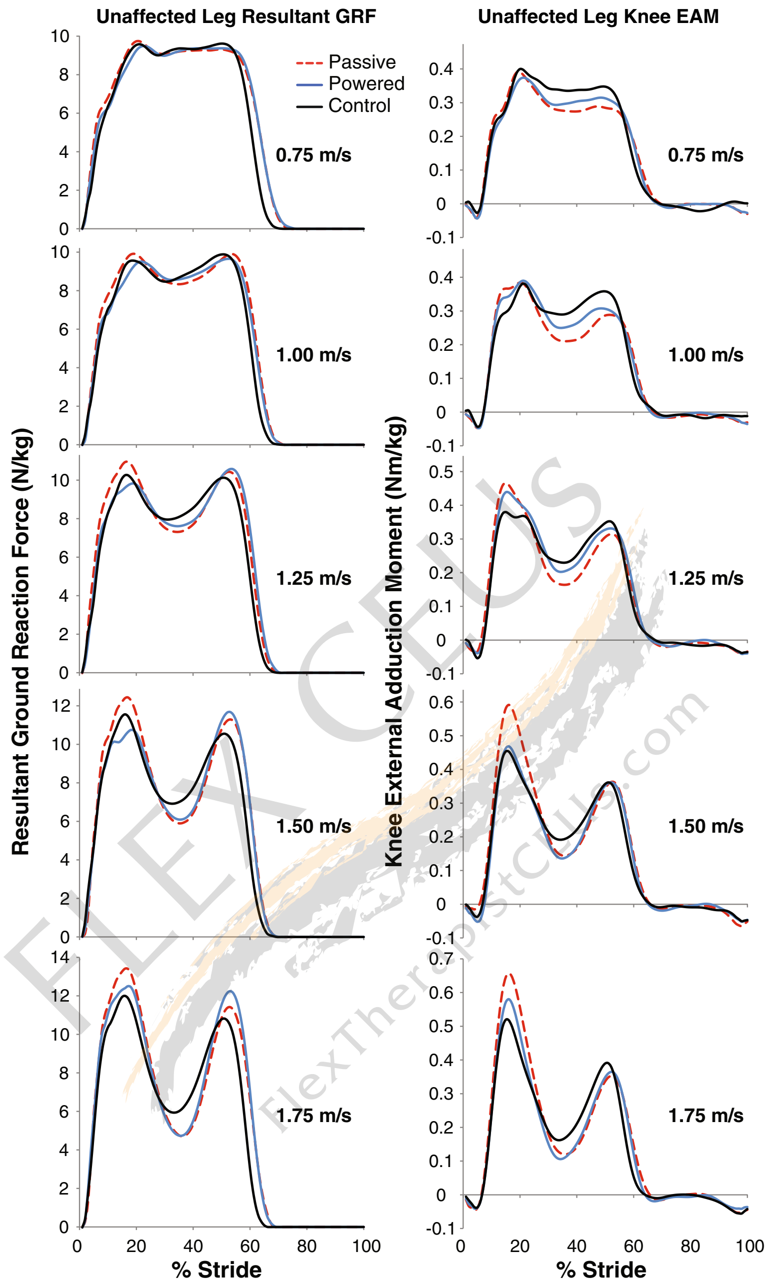

Figure 2 Average unaffected leg resultant ground reaction force (GRF) and knee external adduction moment (EAM). Dashed red lines indicate GRFs (left column) and EAMs (right column) of the unaffected leg while subjects walked using a passive-elastic prosthesis (Passive) across a range of speeds. Blue lines represent GRFs (left column) and EAMs (right column) of the unaffected leg while subjects walked using the powered prosthesis (Powered). Black lines represent GRFs (left column) and EAMs (right column) of non-amputees (Control). The average of three steps from all subjects is shown. Data are plotted versus percentage of a stride, where 0% occurs at heel strike.

fastest walking speeds. Herr & Grabowski [38] found that subjects with an amputation using a powered ankle-foot prosthesis prefer to walk at 1.42 m/s, equivalent to the preferred speed of non-amputees, and 20% faster than their preferred speed when they used a passive-elastic prosthesis. Thus a significant reduction in peak EAM at a walking speed of 1.50 m/s has the potential to decrease the risk of knee osteoarthritis. Future research is warranted to systematically determine the effects of prosthetic ankle power and net positive ankle work on the unaffected knee EAM.

Previous research that measured the effect of lateral wedge insoles on a population with knee osteoarthritis has argued that a decrease of 5-7% in peak knee EAM

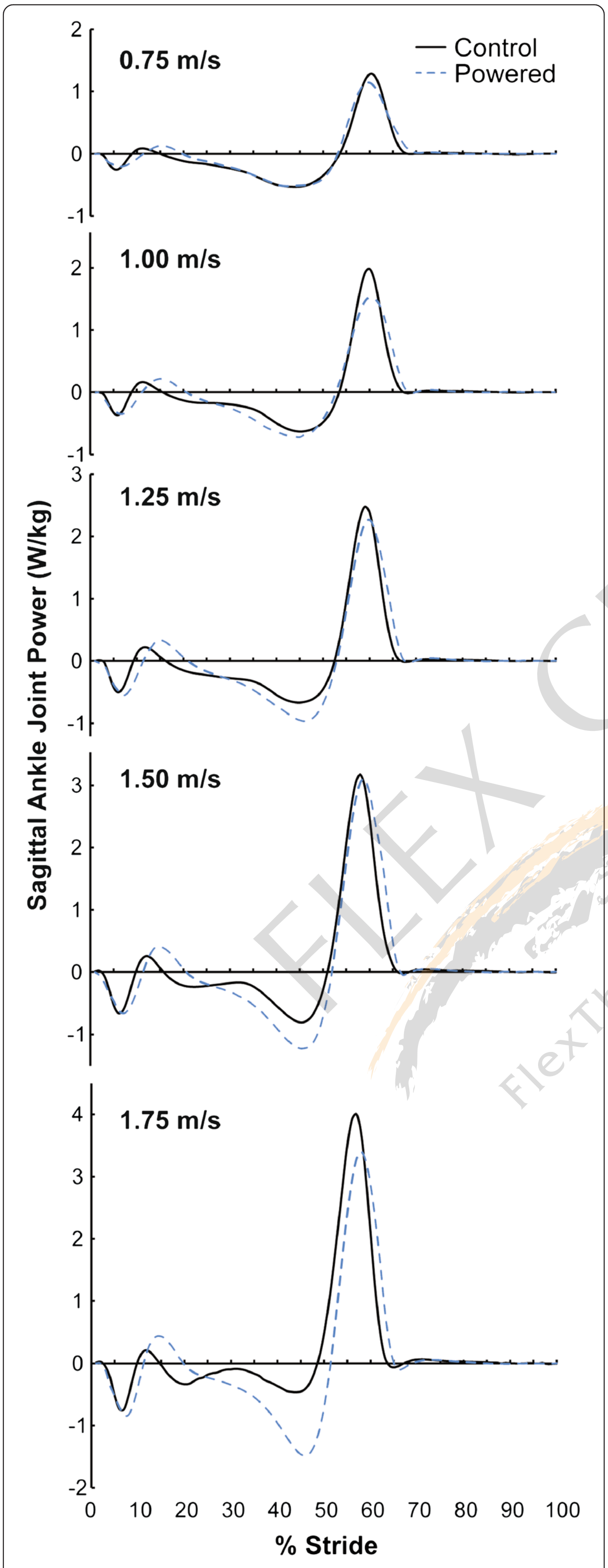

Figure 3 Average powered prosthetic and biological sagittal ankle joint power. Blue dashed lines represent prosthetic ankle joint power of the affected leg while subjects walked using the powered prosthesis (Powered). Black lines represent ankle joint power of non-amputees (Control). The average of three steps from all subjects is shown. Data are plotted versus percentage of a stride, where 0% occurs at heel strike.

may have significant clinical implications [51]. Though not statistically different, we found that the unaffected leg peak knee EAM of subjects using a powered prosthesis was 5.1 and 5.5% lower compared to using their own passive-elastic prosthesis at 0.75 and 1.25 m/s, respectively, and that the loading rate of knee EAM was more than 5% lower at all speeds when subjects used a powered compared to a passive-elastic prosthesis. Thus, use of a powered ankle-foot prosthesis could have important clinical implications by lowering unaffected leg knee moments and thereby reducing the risk of knee osteoarthritis.

Parameter tuning is a critical step in the setup procedure for the powered ankle-foot prosthesis. During tuning, we adjusted the amount of powered plantar flexion, the timing of powered plantar flexion, and the stiffness of the device during controlled plantar flexion until normative values of ankle toe-off angle, net prosthetic ankle work, and peak prosthetic ankle power were achieved (Table 2). We obtained data from the sensors on board the powered prosthesis and compared these values to normative biological data collected from previous studies [23,48]. Using these comparisons, we adjusted the control parameters to produce values within two standard deviations of the mean biological ankle data. The biological ankle data that we used for tuning net positive work [48] were not the same as the biological ankle data we obtained from our non-amputee subjects (Table 2), such that the values of net positive ankle work were all significantly greater for the powered prosthesis than for the biological ankle data we collected. We computed ankle toe-off angles and net positive work for the powered prosthesis using data obtained from the prosthetic ankle, and computed ankle toe-off angles and net positive work for non-amputees using inverse dynamics. This differential in the normative tuning data may have caused variability in our results. In the future, better tuning may yield more beneficial effects. Future studies are planned to understand the complexities inherent in tuning parameter optimization.

We found large percentage decreases in the loading rates of subjects using a powered compared to a passive-elastic prosthesis, but these differences were not significant. Therefore, our study may have been limited by a low number of participants (n=7) to detect differences in loading rates. In addition, the powered prosthesis accommodation period may have been too short. Our accommodation period is consistent with similar studies [39,52], however a longer accommodation period could allow people with an amputation to become more comfortable with the prosthesis, potentially decreasing their muscle co-contraction, adapting their mechanics and thus benefitting more from the powered prosthesis. A longer accommodation time could also allow the prosthesis to be re-tuned following any potential adaptation. Future studies are needed to determine the optimal accommodation times for and adaptations to novel prostheses.

We asked subjects to walk over ground at speeds within 0.10 m/s of five different target speeds. Though subjects walked within the speed range, they could have consistently walked faster or slower than the desired speed. We measured walking speeds from the position versus time of a marker placed over the 7th cervical vertebrae and found that some walking speeds were significantly different between subject groups. Subjects with an amputation using a passive-elastic prosthesis walked at 0.76 (0.04), 1.03 (0.06), 1.25 (0.08), 1.53 (0.06), and 1.73 (0.05) m/s, subjects with an amputation using a powered prosthesis walked at 0.77 (0.05), 0.96 (0.06), 1.21 (0.04), 1.45 (0.04), and 1.67 (0.02) m/s, and non-amputees walked at 0.76 (0.04), 0.99 (0.05), 1.21 (0.05), 1.45 (0.06), and 1.70 (0.06) m/s. When using a passive-elastic prosthesis, subjects with an amputation walked significantly faster at the target speeds of 1.00, 1.25, and 1.75 m/s (P = 0.03, 0.004, and 0.04, respectively) compared to when they used a powered prosthesis. Additionally, subjects with an amputation using a passive-elastic prosthesis walked significantly faster at the target speed of 1.25 m/s compared to non-amputees (P = 0.04). These walking speed discrepancies were 6.8, 3.2, and 3.5% different on average for 1.00, 1.25, and 1.75 m/s, and are not likely to affect our results. However, future studies are planned that control walking speed and analyze the effects of using a powered prosthesis with an instrumented treadmill.

Conclusions

A passive-elastic prosthesis cannot emulate normative biological function during the stance phase of walking; thus people with a lower-extremity amputation employ compensatory mechanics and have a higher incidence of musculoskeletal injury, specifically knee osteoarthritis in their unaffected leg. A biomimetic prosthesis could mitigate the risk of knee osteoarthritis by decreasing unaffected leg forces and knee moments. In this investigation, we found that when people with a unilateral transtibial amputation due to trauma and K3 level of ambulation used a powered ankle-foot prosthesis during level-ground walking over a range of speeds, they reduced the peak resultant force and knee adduction moment on their unaffected leg compared to when they used their own passive-elastic prosthesis. At the walking speed closest to preferred, subjects with an amputation using a powered ankle-foot prosthesis reduced their unaffected peak knee EAM by over 20%. A significant reduction in peak knee EAM has the potential to decrease the risk of knee osteoarthritis. Based on these results, we conclude that a biomimetic powered ankle-foot prosthesis could potentially limit musculoskeletal stress to the contralateral leg during walking, thus decreasing the risk of secondary injury in people with a lower-extremity amputation.

Muscle activation patterns during walking from transtibial amputees recorded within the residual limb-prosthetic interface

Abstract

Background: Powered lower limb prostheses could be more functional if they had access to feedforward control signals from the user's nervous system. Myoelectric signals are one potential control source. The purpose of this study was to determine if muscle activation signals could be recorded from residual lower limb muscles within the prosthetic socket-limb interface during walking.

Methods: We recorded surface electromyography from three lower leg muscles (*tibilias anterior*, *gastrocnemius medial head*, *gastrocnemius lateral head*) and four upper leg muscles (*vastus lateralis*, *rectus femoris*, *biceps femoris*, and *gluteus medius*) of 12 unilateral transtibial amputee subjects and 12 non-amputee subjects during treadmill walking at 0.7, 1.0, 1.3, and 1.6 m/s. Muscle signals were recorded from the amputated leg of amputee subjects and the right leg of control subjects. For amputee subjects, lower leg muscle signals were recorded from within the limb-socket interface and from muscles above the knee. We quantified differences in the muscle activation profile between amputee and control groups during treadmill walking using cross-correlation analyses. We also assessed the step-to-step inter-subject variability of these profiles by calculating variance-to-signal ratios.

Results: We found that amputee subjects demonstrated reliable muscle recruitment signals from residual lower leg muscles recorded within the prosthetic socket during walking, which were locked to particular phases of the gait cycle. However, muscle activation profile variability was higher for amputee subjects than for control subjects.

Conclusion: Robotic lower limb prostheses could use myoelectric signals recorded from surface electrodes within the socket-limb interface to derive feedforward commands from the amputee's nervous system.

Keywords: Amputee, Gait, Rehabilitation, Prosthesis, Electromyography

Introduction

Recent advances in robotic technology have allowed for the development of powered lower limb prostheses that improve ambulation for amputees. A major feature of these new devices is the ability to interject mechanical power into the gait cycle to replace the mechanical power that is lost due to missing biological muscles. Hugh Herr's research group at the Massachusetts's Institute of Technology has developed a robotic ankle that uses a finite state controller to modulate ankle dynamics during gait and add power to the trailing limb during push off [1-3]. The prosthesis uses intrinsic sensing of kinetics and kinematics (e.g., heel- and toe-contact, ankle angle, and ankle torque) to determine when to transition between gait phases during walking. Their powered prosthesis resulted in lower metabolic cost compared to traditional passive elastic prostheses for level ground walking [4]. In addition to a robotic ankle, they have developed a variable impedance robotic knee that uses intrinsic sensing and a finite state controller to modulate knee stiffness during level ground walking [5]. Michael Goldfarb's research group at Vanderbilt University has developed a robotic knee and ankle for transfemoral amputees that also uses intrinsic sensing and finite state control [6-8]. Tom Sugar's research group at

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Arizona State University developed a powered ankle that relies on elastic elements to store energy and amplify mechanical power generated by the actuator [9]. It uses intrinsic sensing to detect heel strike and then the controller initiates a predetermined gait pattern. This sampling of robotic prostheses is representative of the intrinsic sensing approaches that are beginning to be utilized for prosthetic control [10,11].

There are advantages and disadvantages of controlling prosthetic lower limbs via intrinsic sensing. An advantage of prosthetics that rely on kinetic and kinematic sensing to infer user intent is that all of the sensors and associated computational hardware are built directly into the prosthetic. The interface with the human is purely mechanical, which simplifies socket design. These prosthetics generally have low step-to-step variability due to the robustness of the finite state controllers and the low sensor noise. Controllers based on intrinsic sensing tend to work well for stereotyped or cyclical tasks, such as gait. One of the inherent drawbacks of these devices is that control based on intrinsic sensing is not very good at aperiodic or highly variable motor tasks. For example, going up on the toes to reach a higher shelf would be very difficult for a state-based controller to perform using intrinsic sensing. Similarly, tasks with highly variable step-to-step kinematics such as traversing obstacles in the terrain, traversing unstable terrain, or negotiating through a crowd of people, or dealing with a variety of natural surfaces like sand and rocks would be difficult to deal with using intrinsic sensing alone.

An alternative to controllers that rely solely on intrinsic kinematic and kinetic sensing is to directly connect the prosthesis dynamics to the user's nervous system via electromyography [12-14]. Myoelectric control has been implemented for powered upper limb prostheses. High costs have limited widespread acceptance of these devices but cost will continue to fall with continued technological advances. A more lasting obstacle to widespread acceptance of powered upper limb prostheses is the degrees of freedom that must be controlled. The human hand and wrist have more than 20 mechanical degrees of freedom but upper limb prostheses usually rely on fewer than 6 myoelectric control sources. This limits the ability for users to accurately and reliably control prosthesis mechanics. For the lower limb, fewer mechanical degrees of freedom are necessary to provide functional motor ability. For a transtibial amputee, active mechanical plantar flexion/dorsiflexion and passive foot elasticity can provide a huge energetic improvement compared to passive lower limb prostheses [4].

Controlling a limited number of mechanical degrees of freedom with myoelectric signals is feasible. Transfemoral amputees can learn to volitionally control virtual knee/ankle joint movements using myoelectric control signals from residual thigh muscles while seated and not wearing their prosthesis [15,16]. In addition, transtibial amputees can learn to volitionally activate residual muscles during the swing phase of walking to switch between level-ground walking and stair-descent locomotion modes [1]. To the best of our knowledge, this is the only case where myoelectric signals have been recorded from within the socket-limb interface during walking and used for user movement intent recognition.

To implement more robust myoelectric controllers for transtibial prostheses, it is important to assess lower leg electromyographic signal quality, variability, and adaptability during amputee gait. In the near future, it may be possible to use intramuscular electromyography sensors (IMES) to transmit electromyographic signals through the socket interface without breaking the skin [17-19]. These IMES would make it feasible to implement a wide range of myoelectric control methods with powered prostheses. However, rather than waiting for these IMES to be approved for human testing, we have recorded electromyography from lower leg muscles of transtibial amputees within the socket interface using surface electrodes. The purposes of this study were 1) to determine if surface electromyography signals can be recorded from residual lower leg muscles inside the prosthetic socket during walking, and 2) to quantify differences in muscle activation patterns between amputee and non-amputee subjects during walking.

Methods

Subjects

We recruited twelve unilateral transtibial amputee subjects (10 male, 2 female; age = 46 ± 18 yrs.; height = 175 ± 8 cm.; mass = 81 ± 10 kg.; mean ± s.d.) and twelve non-amputee subjects (8 male, 4 female; age = 37 ± 15 yrs.; height = 173 ± 15 cm.; mass = 76 ± 18 kg.) to participate in this study. All subjects were free of musculoskeletal and cardiovascular conditions that would limit their ability to walk safely on a treadmill. All amputee subjects had been using their prosthesis for at least six months, were accustomed to walking on their prosthesis all day, and could walk comfortably without the use of an additional ambulatory aid. Amputee subject details are provided in Table 1.

Instrumentation

We collected surface electromyography (EMG) from seven lower limb muscles: *tibialis anterior*, *gastrocnemius medial head*, *gastrocnemius lateral head*, *vastus lateralis*, *rectus femoris*, *biceps femoris*, and *gluteus medius*. We recorded EMG signals at 1000 Hz using preamplifier electrodes (Biometrics Ltd, SX230) from the amputated leg of amputee subjects and the right leg of non-amputee subjects. For upper leg muscles of all subjects and lower leg muscles of control subjects, we

Table 1 Amputee subject details

Subject	Reason	Age (yrs.)	Post-Amputation (yrs.)
A01	Cancer	20	11
A02	Trauma	49	7
A03	Cancer	18	6
A04	Trauma	66	7
A05	Trauma	31	1
A06	Trauma	55	1
A07	Trauma	56	40
A08	Trauma	44	5
A09	Dysvascular	65	10
A10	Trauma	61	41
A11	Trauma	59	8
A12	Trauma	27	3

placed the electrode over the muscle belly and along the direction of the muscle fibers. To determine the location an orientation of each electrode, we palpated each muscle area while subjects performed a series of voluntary muscle activations. For the lower leg muscles (*tibialis anterior*, *gastrocnemii*) of amputee subjects, we marked a grid of potential recording sites on the skin surface over each muscle that we identified by palpating underlying tissue and bone. We avoided sensitive skin areas and bony protuberances. We subjectively ranked each recording site on the grid based on muscle quality (perceived by palpating the muscle area during voluntary muscle activations). We positioned one electrode over the "best" recording site on each muscle and subjects donned their prosthesis and walked around the laboratory to assess comfort. We did not make any modifications to their prosthesis. To adjust socket fit, subjects changed the thickness of socks they wore between the gel liner and prosthesis socket. If subjects expressed discomfort with an electrode, we shifted the position slightly or chose a secondary recording site. Once the recording sites were finalized, we placed silicone putty around the edges of the electrodes and secured the electrodes to the skin using Tegaderm^{TM} dressing. The silicon putty minimized skin irritation around the electrode edges. The sensor placement procedure is outlined in Figure 1. We placed the ground electrode on the *lateral malleolus* of the intact leg for amputee subjects and the *lateral malleolus* of the right leg for non-amputee subjects.

We recorded ground reaction forces in the vertical, medial-lateral, and fore-aft directions at 1000 Hz using a custom-built instrumented split-belt treadmill [20]. We defined heel-strike and toe-off events from vertical ground reaction force.

Protocol

The first part of the test protocol assessed the subject's ability to differentiate plantar flexor and dorsiflexor muscle activation. Subjects performed maximum voluntary activation trials where they tried to isolate the activation of their *tibialis anterior* (dorsiflexion trial) and *gastrocnemii* (plantar flexion trial) muscles. Subjects were seated upright on a raised platform so that their feet did not contact the ground during the maximum voluntary activation trials. To obtain maximal activation of the *tibialis anterior*, we instructed subjects to point their feet and toes towards the ceiling as hard as possible and sustain muscle activation at maximum dorsiflexion. To obtain maximal activation of the *gastrocnemii*, we instructed subjects to point their feet and toes towards the ground as hard as possible and sustain muscle activation at maximum plantar flexion. All ankle movements were performed bilaterally. We instructed amputee subjects to activate their lower leg muscles as if they had an intact ankle and foot. During practice trials, we displayed real time EMG signals to amputee subjects to provide feedback on the level of muscle activation. Once EMG signals appeared consistent, we recorded three repetitions for each maximum voluntary activation task. For each repetition, we asked the subjects to sustain the maximum voluntary activation for five seconds then rest with muscles fully relaxed for five seconds.

The second part of the test protocol assessed muscle activation patterns during walking. Subjects walked on a treadmill at four speeds (0.7, 1.0, 1.3, and 1.6 m/s) for two minutes at each speed. Not all subjects were able to walk at the two faster speeds. To determine the fastest walking trial that subjects could complete safely, we asked each subject to practice walking on the treadmill starting at the slowest speed. If they could walk comfortably at the given speed, we increased the treadmill speed gradually to the next level. We continued this until the fastest treadmill speed was reached or until the subject could no longer maintain walking speed. All subjects completed the 0.7 and 1.0 m/s trials. Eight of the twelve amputee subjects and eleven of the twelve control subjects completed the 1.3 m/s trial. Seven of the twelve amputee subjects and eleven of the twelve control subjects completed the 1.6 m/s trial.

Signal processing

We performed all signal processing and statistical analyses using the R computing environment (R Development Core Team, 1999). We processed EMG signals using two separate methods. To look at raw EMG, we applied a high-pass filter (bidirectional Butterworth, 4th order, 50 Hz cutoff frequency) and then demeaned the signal. We chose a cutoff frequency of 50 Hz to ensure that motion artifacts were attenuated. To analyze the frequency

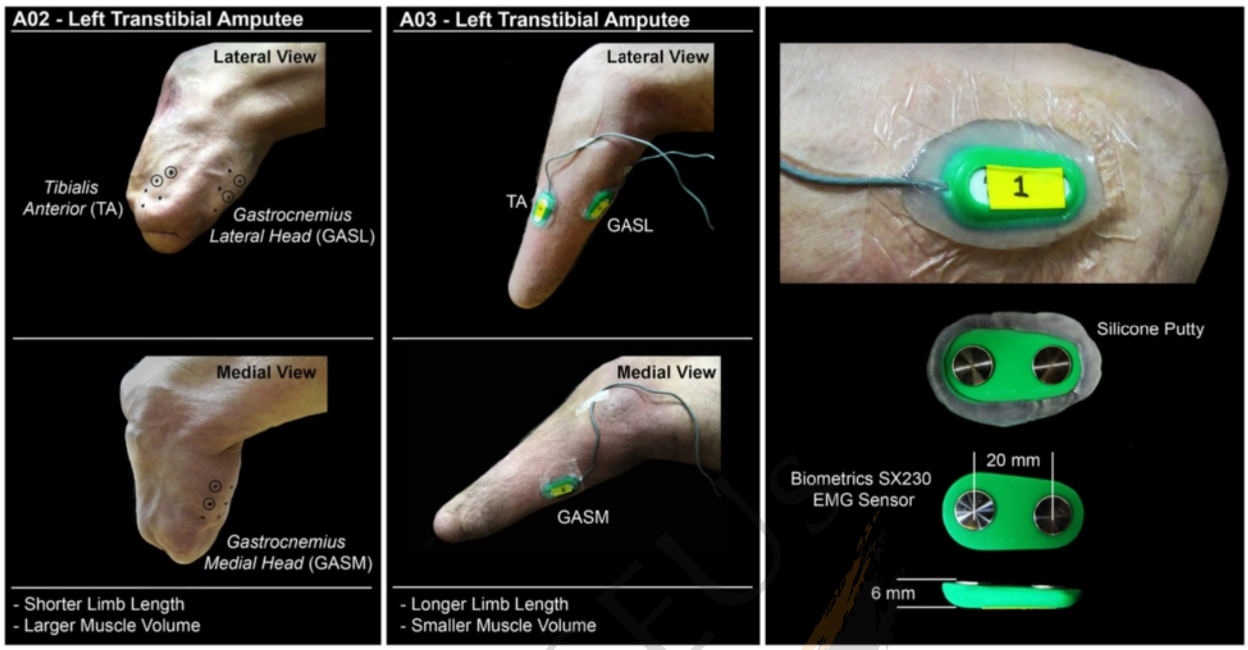

Figure 1 Surface electrode placement for residual lower leg muscles. *Tibialis Anterior* (TA), *Gastrocnemius Medial Head* (GASM), *Gastrocnemius Lateral Head* (GASL). Two amputee subjects (*A02*, *A03*) show the extent of variation in lower leg shape of our amputee subjects. Subject *A02* (49 year old, amputation due to trauma at age 42) has a relatively short lower leg with relatively large muscle volume. In comparison, subject *A03* (18 year old, amputation due to cancer at age 12) has a longer lower leg with smaller muscle volume. As shown on subject *A02*, a grid of potential electrode locations was marked on the skin surface over the lower leg TA, GASM, and GASL. From each grid, the primary electrode site was determined by palpation during voluntary contractions of the muscle. Electrodes were placed over the primary electrode site and the gel liner and socket were worn over the electrodes. No modifications to the gel liner or socket were made. Socks of varying thickness were used to adjust socket-fit. Subjects were asked to walk around the laboratory to assess comfort at the primary electrode sites. If there was discomfort, electrodes were repositioned slightly or secondary sites were selected. The final electrode sites for subject *A02* are circled. After the electrode sites were finalized, silicone putty was placed around the electrode and the electrode was secured to the skin using a piece of Tegaderm™ dressing.

content of the signal, we calculated a smoothed periodogram estimated by a discrete Fourier transform and filtered using Daniell smoothers (single span of length 5). We calculated an empirical cumulative distribution function of the power spectrum to compare the distribution of frequency content between the amputee and control groups.

For the maximum voluntary activation trials, we performed frequency analysis of the *tibilias anterior* and *gastrocnemii* EMG for two seconds of sustained activation. For each subject, we selected the repetition where the maximum amplitude of the rectified signal (high-pass filtered and demeaned) was the greatest across trials. For some amputee subjects, the residual limb *tibialis anterior* was activated more than the *gastrocnemii* during the plantar flexion trial and vice versa during the dorsiflexion trial. For 1.0 m/s walking, we performed frequency analysis of the *tibilias anterior* and *gastrocnemii* for a single gait cycle. For each subject, we selected the gait cycle where the variance of the signal (high-pass filtered and demeaned) was closest to the mean variance of all cycles.

To quantify muscle activation profiles, we calculated EMG intensity using a wavelet decomposition method [21]. We calculated an intensity curve by summing across wavelets 4 (center frequency = 62.1 Hz) through 11 (center frequency = 395.5 Hz) in time. This method was chosen over other methods (e.g. generating a linear envelope using a low-pass filter) because the intensity curve provided a more distinct profile, specifically at transitions between baseline and activation. We divided the intensity curve into cycles defined by consecutive heel strike events. We normalized time by interpolating over 500 equally spaced points per cycle using cubic splines, and we normalized the amplitude to the maximum amplitude across all walking speeds. We calculated a mean intensity curve from 40 consecutive time- and amplitude-normalized cycles. To quantify the repeatability of the recorded EMG signals, we calculated a variance-to-signal ratio (VSR) as the sum of the signal variance over the sum of the signal mean squared across the 40 consecutive normalized intensity curves: $VSR = \frac{\Sigma_{i=1}^{500}\sigma_i^2}{\Sigma_{i=1}^{500}\mu_i^2}$ [22]. To quantify differences in EMG shape, we used mean intensity curves to calculate normalized cross-correlations with zero time lag [23] between: 1) control group grand mean and control subject mean $\rho_{\bar{X}X_i}$, 2) control group grand mean and amputee subject mean $\rho_{\bar{X}Y_i}$, and 3) amputee group grand mean and amputee subject mean $\rho_{\bar{Y}Y_i}$. For cross-correlations $\rho_{\bar{X}X_i}$ and $\rho_{\bar{Y}Y_i}$, individual subject data was excluded from the group mean. Normalized cross-correlations were calculated for EMG from all seven muscles using the subset of subjects who completed all four walking speeds.

Statistical analyses

We performed two separate ANOVAs to determine if there were significant differences in median EMG frequency between subject groups during either maximum voluntary activations or treadmill walking at 1.0 m/s. (model: *median frequency* ~ *muscle* + *group*). We performed another ANOVA to determine if there were significant differences in median EMG frequency between maximum voluntary activation and treadmill walking (factor: *task*) at 1.0 m/s for lower leg muscles only (model: *median frequency* ~ *muscle* + *group***task*). We performed two ANOVAs to determine if there were significant differences in cross-correlation (*R*-value) between subject groups (model: *R*-value ~ *muscle* + *group*). For the first ANOVA, the independent variable was $\rho_{\bar{X}X_i}$ for control subjects and $\rho_{\bar{X}Y_i}$ for amputee subjects. For the second ANOVA, the independent variable was $\rho_{\bar{X}X_i}$ for control subjects and $\rho_{\bar{Y}Y_i}$ for amputee subjects. For all ANOVAs, if factors of interest were significant ($p < 0.05$), we performed a Tukey's Honestly Significant Difference test to determine which contrasts were significant ($p < 0.05$).

Results

Maximum voluntary activation of lower Leg muscles

Amputee subjects were able to volitionally activate their lower leg muscles during the maximum voluntary activation trials but the relative activation of agonist and antagonist muscles was not consistent across subjects (Figure 2A). All control subjects had high and well-sustained agonist muscle activation and low antagonist muscle activation during the trials. Some amputee subjects had muscle activation patterns similar to controls (e.g., Figure 2A, subjects *A05*, *A06*, *A07*, *A09*, and *A10*). These subjects had a range of 1–41 years since amputation (Table 1). A couple of amputee subjects had high activation of both agonist and antagonist muscles during plantar flexion and little to no activation of agonist or antagonist muscles during dorsiflexion (e.g., Figure 2A, subjects *A02* and *A08*). Although most amputee subjects were able to sustain activation levels as well as control subjects, some had difficulty maintaining activation levels (e.g., Figure 2A, subjects *A01* and *A04*).

Lower Leg EMG during walking

During treadmill walking, *tibialis anterior*, *gastrocnemius medial head*, and *gastrocnemius lateral head* activation patterns in amputee subjects had much higher inter-subject variability and were substantially different than the patterns of the control subjects (Figure 3A, Figure 5A, Figure 7). The high inter-subject variability in amputee EMG patterns is demonstrated by a significant difference (ANOVA, $p < 0.001$) in EMG pattern cross-correlation between the amputee individual data vs. amputee mean, compared to the control individual data vs. the control mean $\rho_{\bar{Y}Y_i}, \rho_{\bar{X}X_i}$ (Table 2). Mean cross-correlations for individual amputee EMG patterns vs. the amputee mean $\rho_{\bar{Y}Y_i}$ ranged from 0.20-0.53 for the *tibialis anterior*, *gastrocnemius medial head*, and *gastrocnemius lateral head* (Table 2). In comparison, mean cross-correlations for individual control EMG patterns vs. the control mean $\rho_{\bar{X}X_i}$ ranged from 0.73-0.92 for the same muscles (Table 2). In addition to the difference in inter-subject variability, the cross-correlations also provide evidence of the difference in shape of the EMG activation patterns between amputee and control subjects. There was a significant difference (ANOVA, $p < 0.001$) in EMG pattern cross-correlation between the amputee individual data vs. control mean, compared to the control individual data vs. control mean $\rho_{\bar{X}Y_i}, \rho_{\bar{X}X_i}$ (Table 2). In the amputee group, mean cross-correlations against the control mean $\rho_{\bar{X}Y_i}$ ranged from −0.33 to 0.48 for the *tibialis anterior*, *gastrocnemius medial head*, and *gastrocnemius lateral head*. In the control group, mean cross-correlation against the control mean $\rho_{\bar{X}X_i}$ ranged from 0.73-0.92 for the same muscles.

Upper Leg EMG during walking

Compared to lower leg muscles, upper leg muscle activation patterns during walking were more similar between amputee and control subjects (Figure 4A, Figure 6A, Figure 8). There was no significant difference in inter-subject variability between amputees and controls for the *vastus lateralis* and *rectus femoris* $\rho_{\bar{Y}Y_i}, \rho_{\bar{X}X_i}$; post-hoc *t*-test $p > 0.05$) (Table 2). Mean cross-correlation for individual amputee EMG patterns vs. the amputee mean $\rho_{\bar{Y}Y_i}$ for these muscles ranged from 0.66-0.90 (Table 2). In comparison, mean cross-correlation for individual control EMG patterns vs. the control mean $\rho_{\bar{X}X_i}$ ranged from 0.63-0.90 for the same muscles (Table 2). For the *biceps femoris* and *gluteus medius*, there was a significant difference (post-hoc *t*-test $p < 0.001$) in EMG pattern cross-correlation between the amputee individual data vs. amputee mean, compared to

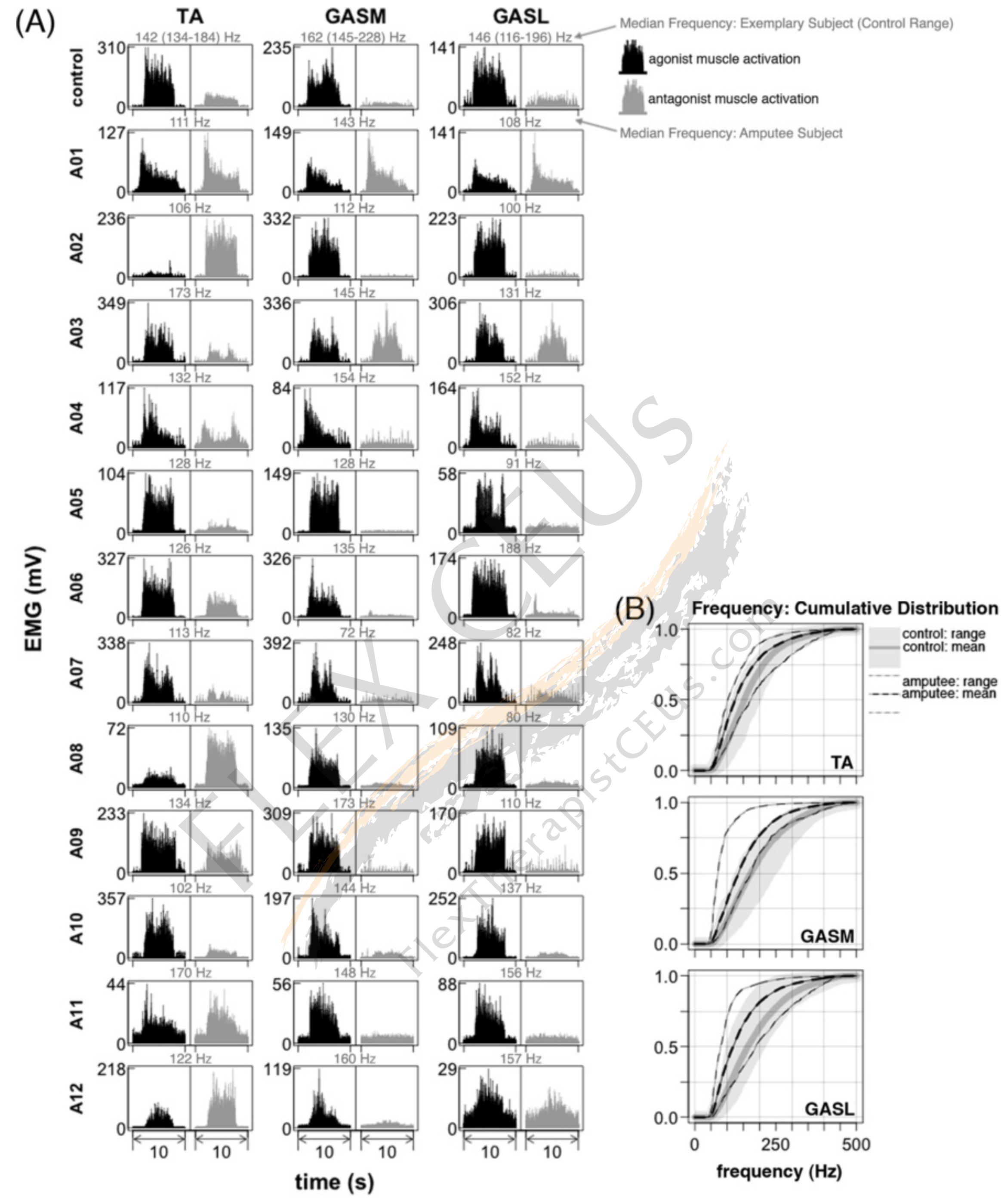

Figure 2 Lower leg EMG maximum voluntary activation. *Tibialis Anterior* (TA), *Gastrocnemius Medial Head* (GASM), *Gastrocnemius Lateral Head* (GASL). (**A**) EMG during maximum voluntary activation of the *tibialis anterior* and *gastrocnemii* muscles during seated dorsiflexion and plantar flexion. Data is shown for one exemplary control subject and twelve amputee subjects. Signals are high-pass filtered, demeaned, and rectified (for visualization). Signals in black indicate that the muscle is expected to act as an agonist to the ankle movement. Signals in gray indicate that the muscle is expected to act as an antagonist to the ankle movement. Median frequency during maximum voluntary activation (agonist or antagonist depending on which activation had the greatest amplitude) is shown above each plot in gray. In control subjects, there was high agonist muscle activation (black) and low antagonist muscle activation (gray). This activation pattern was not consistent in amputee subjects. Amputee subjects *A02* and *A08* had little to no lower leg muscle activation during dorsiflexion and high activation of both the *tibialis anterior* and *gastrocnemii* muscles during plantar flexion. *A01* had activation of all lower leg muscles for both dorsiflexion and plantar flexion, but the activation level was not well sustained. Some amputee subjects had activation patterns similar to controls (*A05*, *A06*, *A07*, *A09*, *A10*). (**B**) Empirical cumulative density function of EMG power spectrum. Lines are shown for group means and boundaries indicate group range.

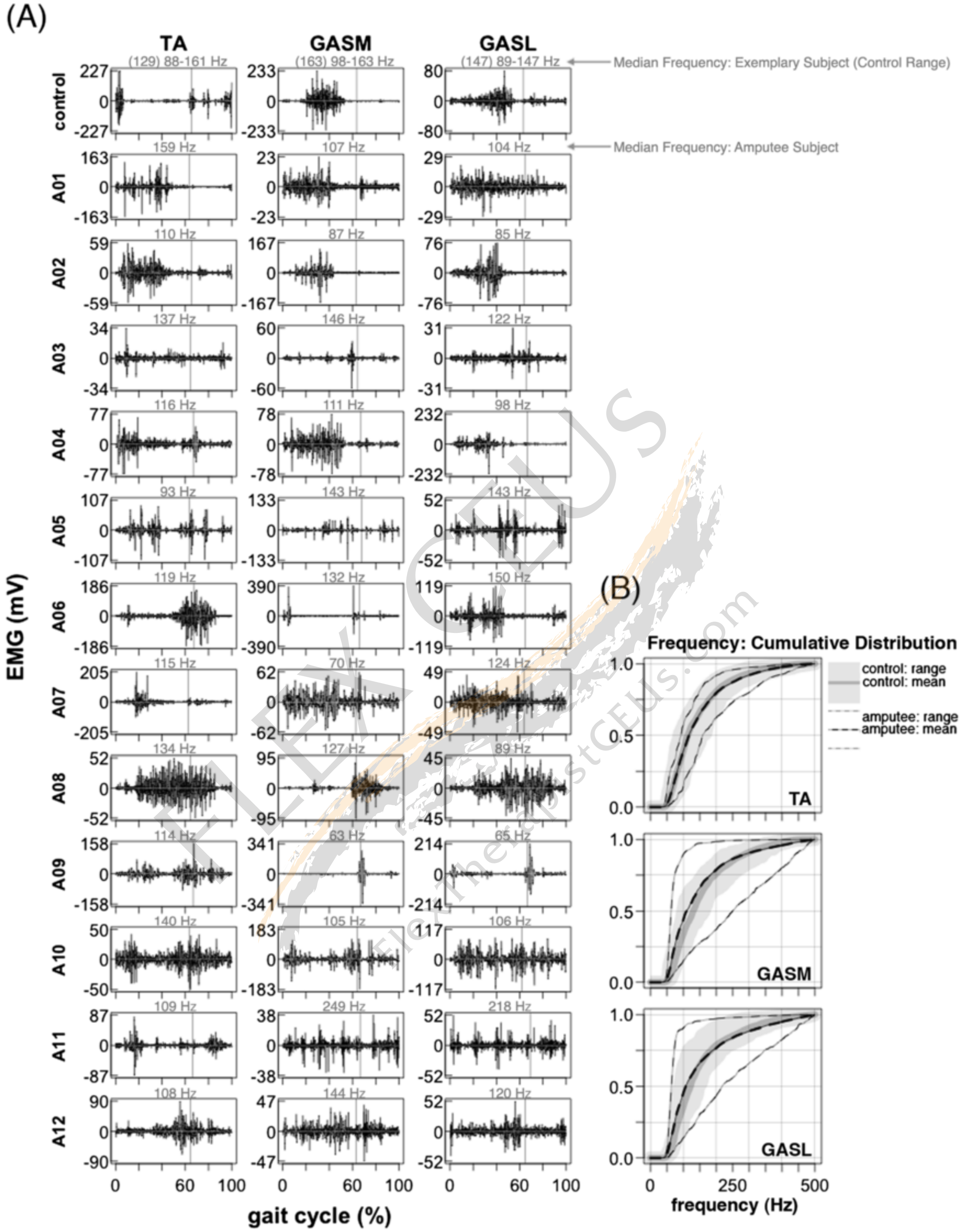

Figure 3 Lower leg EMG activation during 1.0 m/s walking. *Tibialis Anterior* (TA), *Gastrocnemius Medial Head* (GASM), *Gastrocnemius Lateral Head* (GASL). (**A**) Raw EMG signals from the *tibialis anterior* and *gastrocnemii* muscles for a single stride (1.0 m/s). Data is shown for one exemplary control subject and twelve amputee subjects. EMG signals are high-pass filtered and demeaned. Vertical lines show toe-off. Median frequency is shown above each plot in gray. There was a lot of variability in EMG signal patterns across amputee subjects. Amputee subject *A11* (GASM, GASL) had several EMG bursts that were approximately equally spaced and of similar amplitude across the gait cycle. A similar pattern was seen in *A10* (GASL) and *A05* (TA). Amputee subject *A09* (GASM, GASL) had short EMG bursts of high amplitude that occurred shortly after toe-off. A similar pattern was seen in *A06* (GASM) with two high-amplitude EMG bursts that occurred shortly after heel-strike and shorty before toe-off. In both *A06* and *A09,* the amplitude of the EMG bursts exceeded those recorded during maximum activation trials. (**B**) Empirical cumulative density function of EMG power spectrum. Lines are shown for group means and boundaries indicate group range.

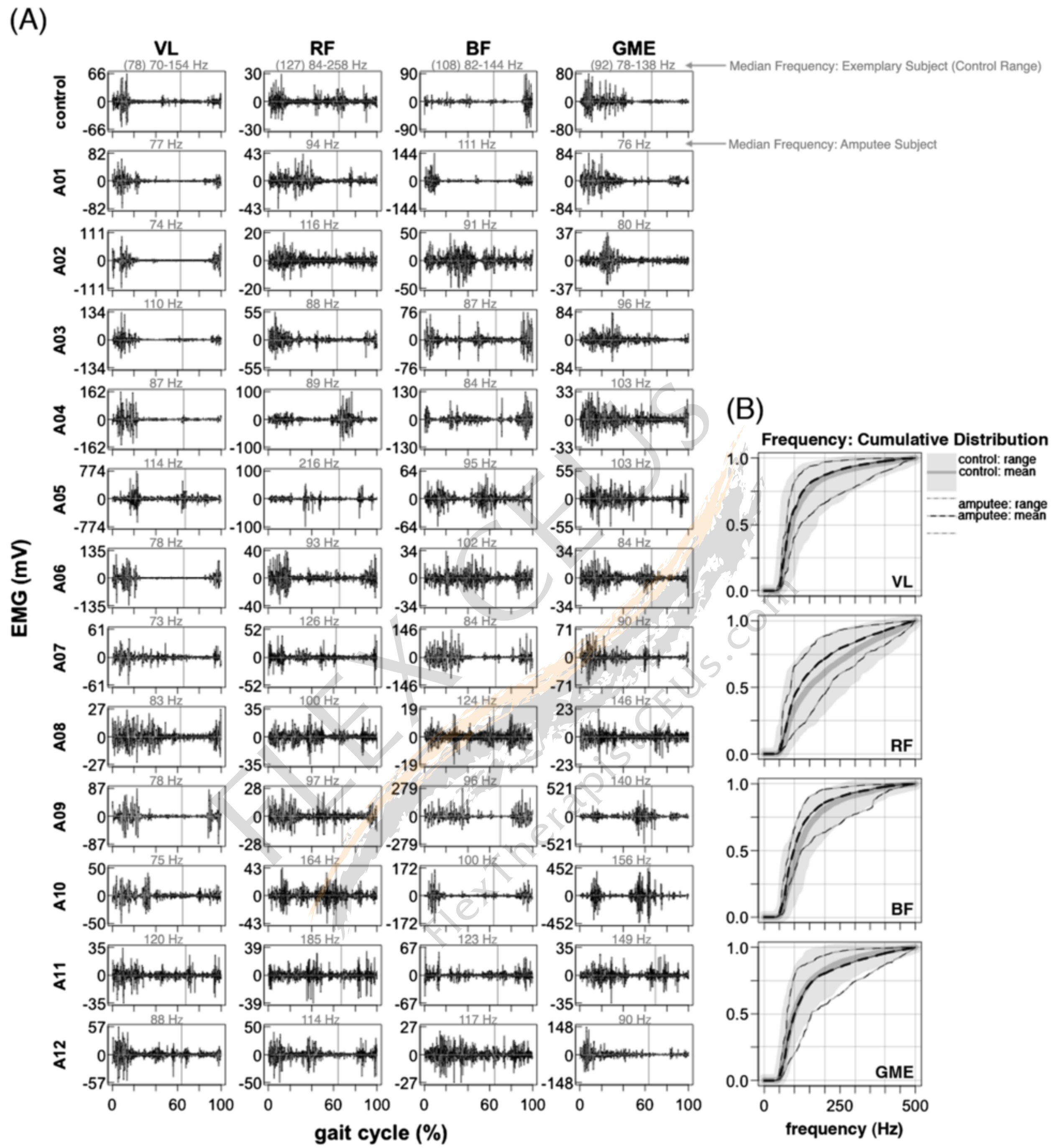

Figure 4 Lower leg EMG activation profiles during 1.0 m/s walking. *Tibialis Anterior* (TA), *Gastrocnemius Medial Head* (GASM), *Gastrocnemius Lateral Head* (GASL). (**A**) Normalized mean EMG intensity curves for the *tibialis anterior* and *gastrocnemii* muscles calculated from forty consecutive strides (1.0 m/s). Control data is the grand mean of twelve control subjects. Maximum mean EMG intensity across the gait cycle is 1.0. One standard deviation above the mean is shown in gray. Vertical lines show average toe-off. Variance-to-signal ratio is shown above each plot in gray. (**B**) Variance-to-signal ratio of lower leg muscles calculated from 40 consecutive cycles at 1.0 m/s.

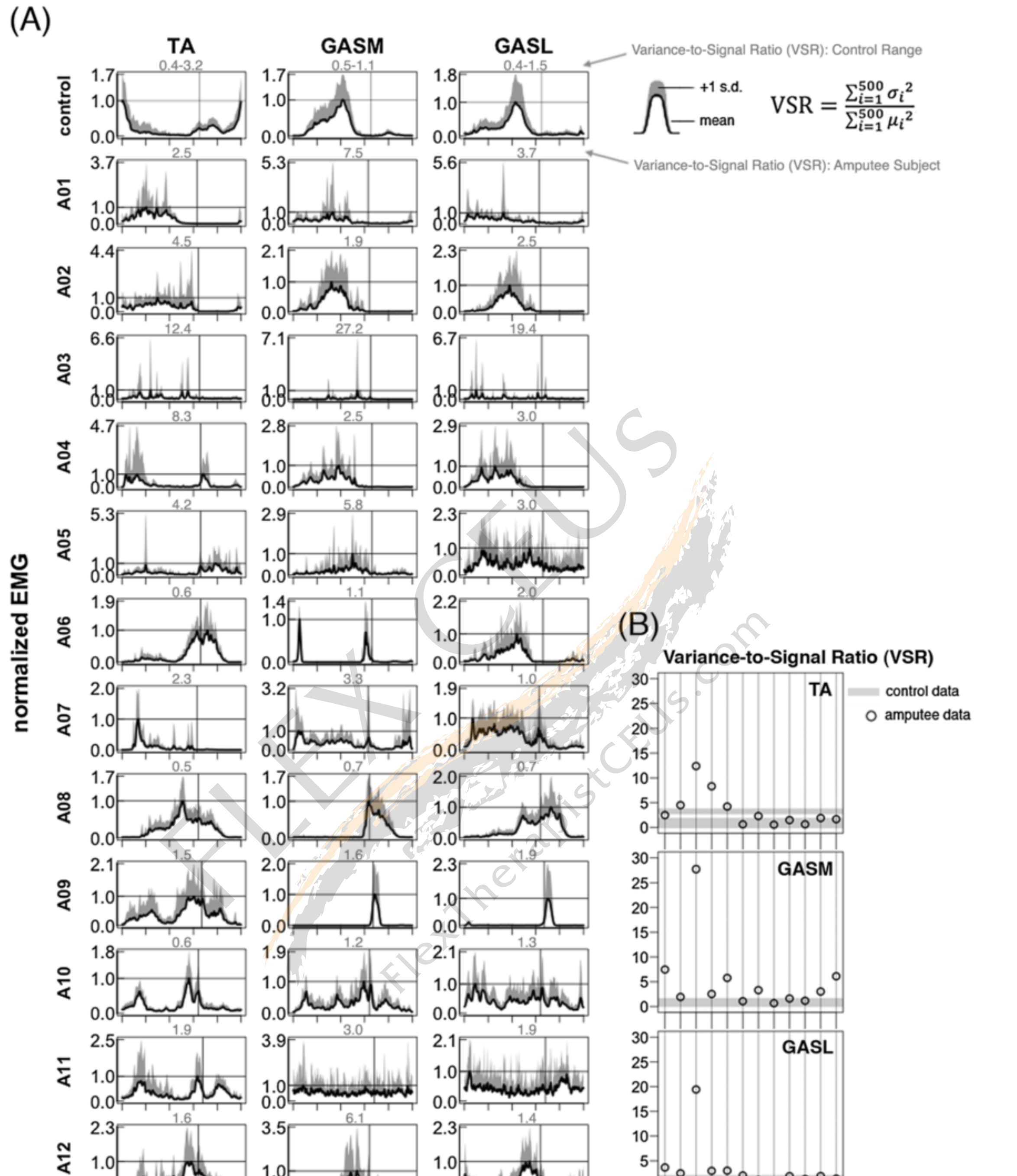

Figure 5 Lower leg EMG activation profiles during 1.0 m/s walking. *Tibialis Anterior* (TA), *Gastrocnemius Medial Head* (GASM), *Gastrocnemius Lateral Head* (GASL). Mean EMG intensity curves of lower leg muscles for control group and seven amputee subjects during 0.7, 1.0, 1.3, and 1.6 m/s treadmill walking. Mean curves are calculated from 40 consecutive cycles. The grand mean curve is shown for the control group. Vertical lines show average toe-off events for the fastest and slowest walking speeds. In amputee subjects, the trend of increasing EMG amplitude with walking speed was not seen across amputee subjects. In amputee subject *A02*, the TA amplitude at 80-100% gait cycle scaled with speed and the GASM/GASL amplitude decreased with speed from 0.7-1.3 m/s then increased at 1.6 m/s. In subject *A07*, the TA at 0-20% gait cycle had relatively low activation higher speeds and high activation at 0.7-1.0 m/s. A similar pattern was seen in A12 with very high activation of the TA at 20-40% gait cycle at the slowest speed and relatively low activation at 0.7-1.3 m/s. In subject *A11*, the GASM/GASL at 0-20% of the gait cycle had relatively low activation at 0.7-1.3 m/s, but had large increase in amplitude at 1.6 m/s. In subject *A12*, there was a phase shift and increase in amplitude with speed for the TA and GASM/GASL at 40-60% gait cycle.

Table 2 EMG activation pattern cross-correlations

0.7 m/s	$\rho_{\bar{X}X_i}$ mean (sd)	$\rho_{\bar{X}Y_i}$ mean (sd)	$\rho_{\bar{Y}Y_i}$ mean (sd)
Tibialis Anterior	0.73 (0.11) *°	−0.33 (0.13) °	0.44 (0.21) *
Gastrocnemius Medial Head	0.90 (0.09) *°	0.48 (0.42) °	0.45 (0.32) *
Gastrocnemius Lateral Head	0.79 (0.17) *°	0.37 (0.40) °	0.37 (0.35) *
Vastus Lateralis	0.81 (0.19)	0.83 (0.08)	0.89 (0.07)
Rectus Femoris	0.63 (0.28)	0.70 (0.23)	0.71 (0.18)
Biceps Femoris	0.75 (0.10) *°	0.31 (0.48) °	0.35 (0.36) *
Gluteus Medius	0.72 (0.31) *	0.66 (0.32)	0.67 (0.28) *
1.0 m/s	$\rho_{\bar{X}X_i}$ mean (sd)	$\rho_{\bar{X}Y_i}$ mean (sd)	$\rho_{\bar{Y}Y_i}$ mean (sd)
Tibialis Anterior	0.80 (0.09) *°	−0.24 (0.08) °	0.32 (0.25) *
Gastrocnemius Medial Head	0.87 (0.08) *°	0.23 (0.40) °	0.20 (0.19) *
Gastrocnemius Lateral Head	0.83 (0.12) *°	0.20 (0.37) °	0.24 (0.37) *
Vastus Lateralis	0.86 (0.08)	0.83 (0.10)	0.90 (0.06)
Rectus Femoris	0.77 (0.16)	0.70 (0.23)	0.70 (0.23)
Biceps Femoris	0.86 (0.06) *°	0.38 (0.39) °	0.53 (0.30) *
Gluteus Medius	0.82 (0.14) *	0.63 (0.36)	0.61 (0.32) *
1.3 m/s	$\rho_{\bar{X}X_i}$ mean (sd)	$\rho_{\bar{X}Y_i}$ mean (sd)	$\rho_{\bar{Y}Y_i}$ mean (sd)
Tibialis Anterior	0.84 (0.08) *°	−0.09 (0.18) °	0.20 (0.22) *
Gastrocnemius Medial Head	0.88 (0.07) *°	0.32 (0.26) °	0.41 (0.24) *
Gastrocnemius Lateral Head	0.92 (0.07) *°	0.32 (0.26) °	0.22 (0.32) *
Vastus Lateralis	0.89 (0.05)	0.84 (0.11)	0.84 (0.11)
Rectus Femoris	0.82 (0.15)	0.70 (0.23)	0.70 (0.23)
Biceps Femoris	0.89 (0.05) *°	0.33 (0.34) °	0.55 (0.26) *
Gluteus Medius	0.77 (0.19) *	0.63 (0.38)	0.56 (0.35) *
1.6 m/s	$\rho_{\bar{X}X_i}$ mean (sd)	$\rho_{\bar{X}Y_i}$ mean (sd)	$\rho_{\bar{Y}Y_i}$ mean (sd)
Tibialis Anterior	0.85 (0.07) *°	−0.05 (0.36) °	0.27 (0.28) *
Gastrocnemius Medial Head	0.88 (0.07) *°	0.48 (0.28) °	0.53 (0.15) *
Gastrocnemius Lateral Head	0.91 (0.09) *°	0.40 (0.40) °	0.46 (0.34) *
Vastus Lateralis	0.90 (0.06)	0.77 (0.20)	0.74 (0.15)
Rectus Femoris	0.74 (0.15)	0.58 (0.30)	0.66 (0.33)
Biceps Femoris	0.89 (0.07) *°	0.31 (0.26) °	0.72 (0.13) *
Gluteus Medius	0.75 (0.18) *	0.50 (0.40)	0.45 (0.30) *

X = controls, Y = amputees; *$p < 0.001$ for $\rho_{\bar{X}X_i}$ vs. $\rho_{\bar{Y}Y_i}$; °$p < 0.001$ for $\rho_{\bar{X}X_i}$ vs. $\rho_{\bar{X}Y_i}$.

the control individual data vs. the control mean $\rho_{\bar{Y}Y_i}, \rho_{\bar{X}X_i}$. Mean cross-correlation for individual amputee EMG patterns vs. the amputee mean $\rho_{\bar{Y}Y_i}$ ranged from 0.35-0.72 for the *biceps femoris* and *gluteus medius*. In comparison, mean cross-correlation for individual control EMG patterns vs. the control mean $\rho_{\bar{X}X_i}$ ranged from 0.72- 0.89 for the same muscles (Table 2). There was no significant difference (post-hoc *t*-test $p > 0.05$) in EMG activation shape between amputees and controls for the *vastus lateralis*, *rectus femoris*, and *gluteus medius* $\rho_{\bar{X}Y_i}, \rho_{\bar{X}X_i}$ (Table 2). Mean cross-correlation for individual amputee EMG patterns vs. the amputee mean $\rho_{\bar{X}Y_i}$ ranged from 0.50-0.84 for the *vastus lateralis*, *rectus femoris*, and *gluteus medius* (Table 2). Mean cross-correlation for individual control EMG patterns vs. the control mean $\rho_{\bar{X}X_i}$ ranged from 0.63-0.90 for the same muscles (Table 2). However, the EMG activation shape for the *biceps femoris* was significantly different between the amputee subjects and the control subjects (post-hoc *t*-test $p < 0.001$). Mean cross-correlation for individual amputee EMG pa 8tterns against the control mean $\rho_{\bar{X}Y_i}$ ranged from 0.31-0.38 for the *biceps femoris* (Table 2). Mean cross-correlation for individual control EMG patterns against the control mean $\rho_{\bar{X}X_i}$ ranged from 0.75-0.89 for the same muscle (Table 2).

Inter-stride variability of EMG during walking

Variance-to-signal ratios of EMG during 1.0 m/s treadmill walking were significantly greater in the amputee group compared to the control group (control mean = 1.0, amputee mean = 2.4; ANOVA group effect, $p < 0.001$) (Table 3, Figures 5 and 6). However, post-hoc t-tests revealed that the only muscle with a significant difference between groups was the *gastrocnemius medial head* (post-hoc *t*-test $p < 0.001$).

EMG median frequencies

During maximum voluntary activation, median EMG frequencies for lower leg muscles were significantly lower in amputee subjects compared to control subjects (ANOVA group effect, $p < 0.001$) (Table 4, Figure 2B). However, during 1.0 m/s treadmill walking, median EMG frequencies for upper and lower leg muscles of amputee and control subjects were not significantly different (ANOVA group effect, $p > 0.10$) (Table 4, Figures 3 and 4). In the amputee group, median EMG frequencies of residual lower leg muscles were similar for maximum voluntary activation and 1.0 m/s treadmill walking (post-hoc *t*-test, $p > 0.50$) (Table 4). In the control group, median EMG frequencies of lower leg muscles were significantly greater during maximum voluntary activation compared to 1.0 m/s treadmill walking (post-hoc *t*-test, $p < 0.001$) (Table 4).

Discussion

The main finding of this study is that during walking, most amputee subjects had residual lower leg muscle activation patterns that were entrained to the gait cycle but highly variable across subjects. The residual lower leg muscle activation patterns were very different from the

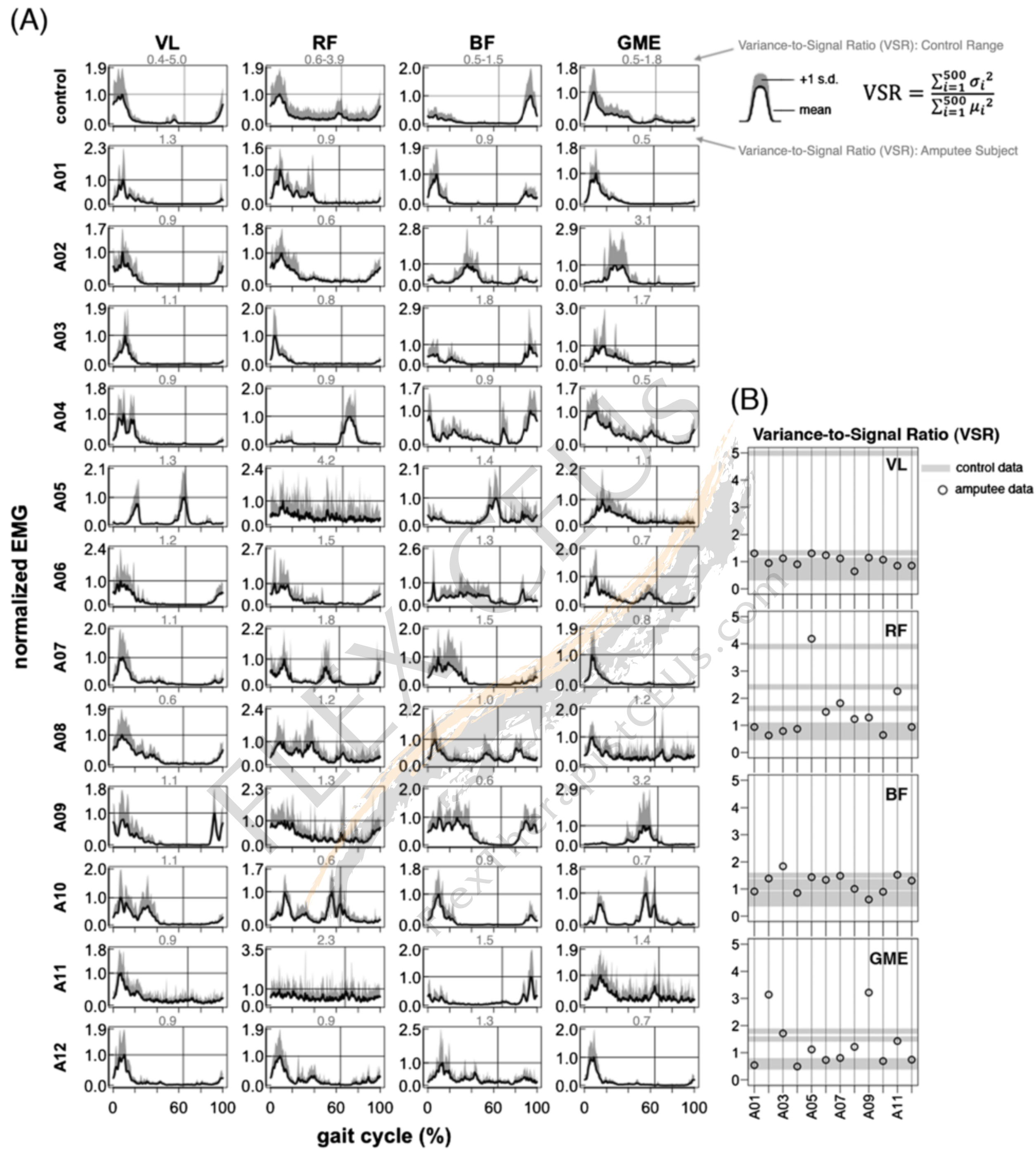

Figure 6 Upper leg EMG activation during walking. *Vastus Lateralis* (VL), *Rectus Femoris* (RF), *Biceps Femoris* (BF), *Gluteus Medius* (GME). Raw EMG signals from the *vastus lateralis*, *rectus femoris*, *biceps femoris, and gluteus medius* muscles for a single stride (1.0 m/s). Data is shown for one exemplary control subject and twelve amputee subjects. EMG signals are high-pass filtered and demeaned. Vertical lines show toe-off. Median frequency is shown above each plot in gray. Many EMG patterns of amputee subjects are different from the control and there is a large amount of variability in EMG patterns across amputees. (**B**) Empirical cumulative density function of EMG power spectrum. Lines are shown for group means and boundaries indicate group range.

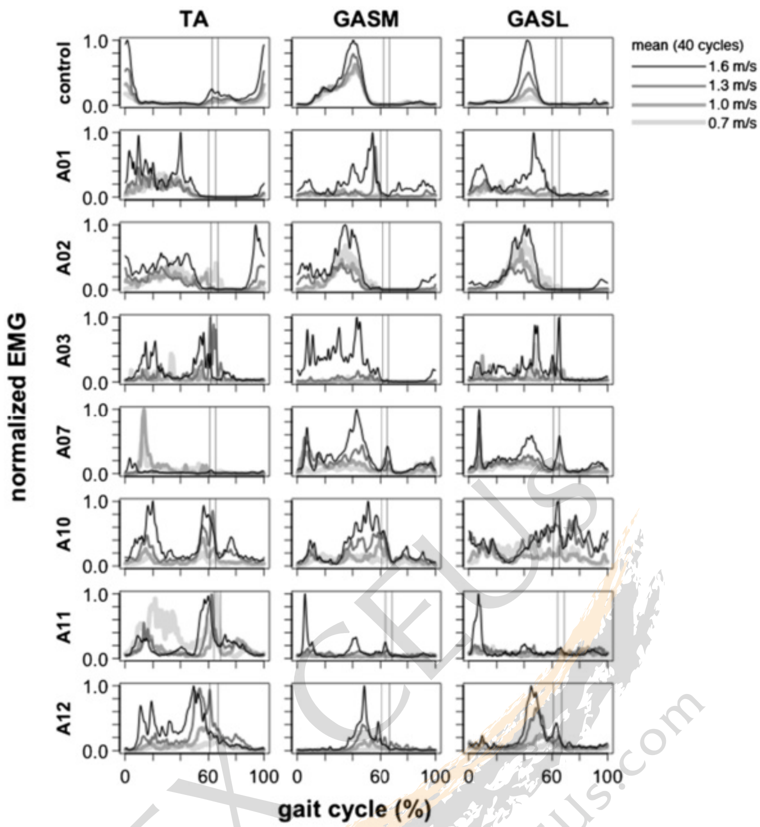

Figure 7 Upper leg EMG activation profiles during walking. *Vastus Lateralis* (VL), *Rectus Femoris* (RF), *Biceps Femoris* (BF), *Gluteus Medius* (GME). (**A**) Normalized mean EMG intensity curves for the *vastus lateralis*, *rectus femoris*, *biceps femoris*, and *gluteous medius* muscles calculated from forty consecutive strides (1.0 m/s). Control data is the grand mean of twelve control subjects. Maximum mean EMG intensity across the gait cycle is 1.0. One standard deviation above the mean is shown in gray. Vertical lines show average toe-off. Variance-to-signal ratio is shown above each plot in gray. (**B**) Variance-to-signal ratio of lower leg muscles calculated from 40 consecutive cycles at 1.0 m/s.

normal control patterns (Figure 5). This is evidenced by the low EMG cross-correlation values between amputee subjects and the control mean for *tibialis anterior* and *gastrocnemii* (Table 2). Despite the high variability in residual lower leg EMG patterns across amputee subjects, inter-stride variability was similar to that of control subjects. The *gastrocnemius medial head* was the only muscle with a variance-to-signal ratio significantly greater in the amputee group compared to the control group. This significant difference in variance-to-signal ratio between groups was due to a single amputee subject whose variance-to-signal noise ratio was magnitudes greater than other amputee subjects (Figure 5, subject *A03*). Subject *A03* had high inter-stride variability for all three residual lower leg muscles (Figure 5). The inter-stride variability could be problematic if it continued when using a powered lower limb prosthesis under myoelectric control. However, it seems reasonable to presume that the inter-stride variability would decrease if the residual muscle activity had a functional purpose during walking (e.g., to control dynamics of a powered prosthesis). Future studies should document the variability in muscle recruitment patterns while subjects learn to use powered prostheses.

Another finding of this study is that many, but not all, amputee subjects had robust volitional control of residual lower leg muscle activation. During maximum voluntary dorsiflexion and plantar flexion, residual muscle activation profiles in several amputee subjects were similar to controls (Figure 2). The maximum activation levels were well above resting baseline, the time to reach maximum activation from resting baseline was short, and the activation levels were well sustained. Some of the amputee subjects were able to differentiate *tibialis anterior* and *gastrocnemii* activation and had coactivation levels similar to control subjects (e.g., Figure 2A, subjects *A05* and *A09*). Other amputee subjects were not able to differentiate *tibialis anterior* and *gastrocnemii* activation during volitional maximum activation. As a result, there was either complete coactivation for both plantar flexion and dorsiflexion tasks (e.g., Figure 2A, subject *A01*) or an inability to recruit any muscles strongly during

Table 3 Variance-to-signal ratios for 1.0 m/s walking

	Controls mean (sd)	Amputees mean (sd)
Tibialis Anterior	1.0 (0.8)	3.4 (3.6)
Gastrocnemius Medial Head	0.8 (0.2) *	5.2 (7.4) *
Gastrocnemius Lateral Head	0.9 (0.3)	3.5 (5.1)
Vastus Lateralis	1.1 (1.2)	1.0 (0.2)
Rectus Femoris	1.2 (1.0)	1.4 (1.0)
Biceps Femoris	0.9 (0.3)	1.2 (0.4)
Gluteus Medius	0.7 (0.4)	1.3 (0.9)

*p < 0.001 for controls vs. amputees.

dorsiflexion (e.g., Figure 2A, subjects *A02* and *A08*). For the subjects that demonstrated complete coactivation, synchronous recruitment of residual muscles was not hard-wired because their *tibialis anterior* and *gastrocnemii* activation patterns were distinctly different from each other during walking, especially at faster walking speeds (e.g., Figure 2A, subjects *A01* and *A02*). One reason that the amputee subjects may have lost robust volitional control of the residual limb muscles is the lack of proprioceptive or visual feedback of muscle activity. Without an ankle joint to provide sensory information about joint position, there is no clear information reinforcing the consequences of muscle activity. It seems likely that coupling a powered prosthetic limb to the residual limb muscle activity would increase the volitional motor control [14,24-26].

In the upper leg muscles, our data show that amputee subjects had greater inter-subject variability in their *biceps femoris* and *gluteus medius* muscle activation profiles compared to control subjects during walking (Table 2, Figure 6). In addition, our data show that amputee subjects had a different *biceps femoris* activation profile shape than control subjects (Table 2, Figure 6). Previous studies have suggested that transtibial amputees walk with greater residual leg *biceps femoris* activation during early stance compared to the intact *biceps femoris* to stabilize the knee joint [27-29] and/or increase propulsion of the residual leg [30,31]. In normal walking, the primary function of the *gluteus medius* is to provide support during early stance to midstance and the *biceps femoris* has the potential for generating support from early stance to midstance. Ankle dorsiflexors provide support during early stance and ankle plantar flexors provide support during late stance [32]. It is likely that transtibial amputees compensate for the loss of support from ankle muscles by recruiting muscles above the knee to increase walking stability during stance. The inter-subject variability in the *biceps femoris* and *gluteus medius* activation shape observed in our amputee subjects suggests that there are differences in compensatory muscle recruitment patterns used by transtibial amputees during walking.

One limitation of our study is that we did not present data from overground walking. Past studies have shown that lower limb EMG patterns and kinematics can be different during treadmill walking compared to overground walking [33,34]. Biomechanically, treadmill gait and overground gait is identical if the treadmill belt speed is constant [35]. The differences in biological gait measurements occur primarily due to two aspects: differences in visual flow [36] and treadmill speed fluctuations [37]. We did not include overground walking in this study because our primary focus was to quantify differences in signal patterns and variability between amputee and non-amputee groups and within groups. Now that we have demonstrated that reliable signals can be recorded from residual muscles of transtibial amputees during treadmill walking at constant speeds, we plan to expand our study to include lower limb EMG patterns of transtibial amputees and non-amputees during overground walking at self-selected walking speeds. This will provide a better understanding of how signals recorded from residual muscles in transtibial amputees can be utilized to control robotic lower limb prostheses. Another limitation of our study is that the mean age of our amputee

Table 4 EMG median frequencies

	Maximum voluntary activation		Treadmill walking (1.0 m/s)	
	Controls mean (sd)	Amputees mean (sd)	Controls mean (sd)	Amputees mean (sd)
Tibialis Anterior	153 (14) *°	127 (23) *	115 (22) °	121 (18)
Gastrocnemius Medial Head	174 (23) *°	137 (26) *	131 (18) °	124 (49)
Gastrocnemius Lateral Head	166 (23) *°	124 (34) *	122 (14) °	119 (40)
Vastus Lateralis			97 (24)	88 (17)
Rectus Femoris			156 (62)	123 (42)
Biceps Femoris			113 (18)	101 (15)
Gluteus Medius			102 (18)	109 (30)

*p < 0.001 for controls vs. amputees; °p < 0.001 for maximum voluntary activation vs. treadmill walking.

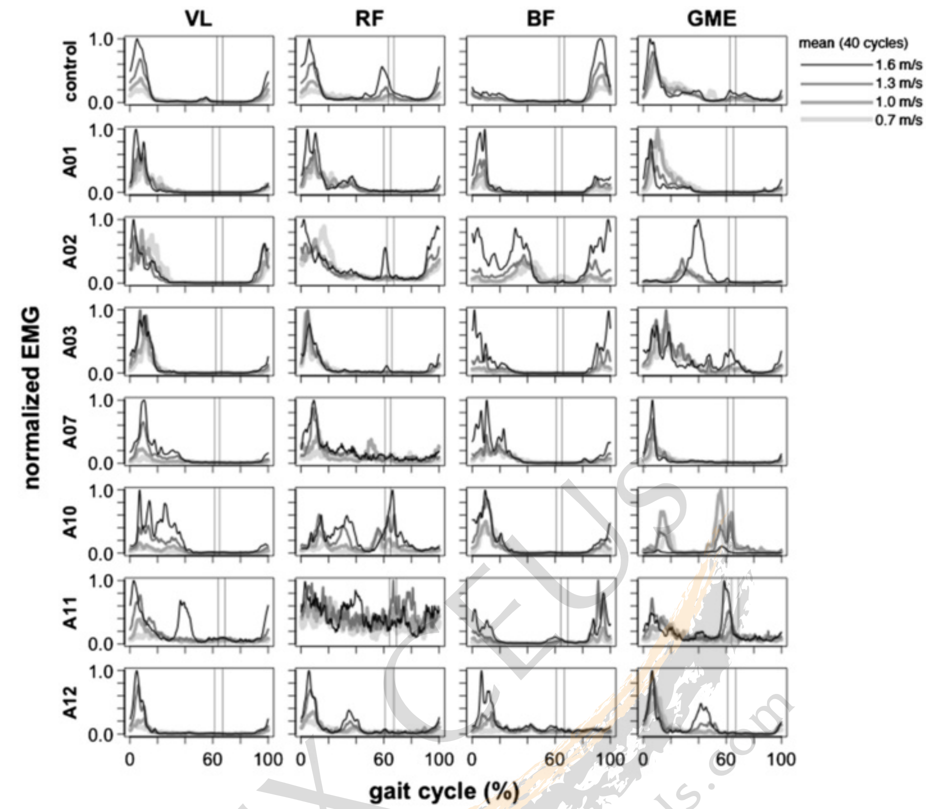

Figure 8 Upper leg EMG activation profiles during walking. *Vastus Lateralis* (VL), *Rectus Femoris* (RF), *Biceps Femoris* (BF), *Gluteus Medius* (GME). Mean EMG intensity curves of upper leg muscles for control group and seven amputee subjects during 0.7, 1.0, 1.3, and 1.6 m/s treadmill walking. Mean curves are calculated from 40 consecutive cycles. The grand mean curve is shown for the control group. Vertical lines show average toe-off events for the fastest and slowest walking speeds. In amputee subjects, the trend of increasing EMG amplitude with walking speed was not seen across amputee subjects. In amputee subject *A11*, activation of the VL increased with walking speed at 0-20% of the gait cycle and also a phase shift (max activation appears to occur earlier). There was also activation of the VL around 40% of the gait cycle, but only at the fastest walking speed. There was no distinct activation pattern of the RF at any speed. There was GME activation around 60% of the gait cycle and amplitude increased with walking speed and also a phase shift (max activation appears to occur earlier). In subject *A10*, GME activation decreased with walking speed at 0-20% and 40-80% of the gait cycle. In subject *A03*, there was similar activation of the VL and RD across all walking speeds. In subject *A02*, activation of GME increased dramatically at 20-60% gait cycle for the fastest walking speed with a significant phase shift (peak activation occurs later). There was also a large increase in BF activation at the fastest walking speed.

group was greater than our non-amputee group. We do not believe that the results presented in this study would change significantly given more similar ages between groups, but further data could support or refute this assumption.

Several previous studies have presented EMG data from the amputated limb of transtibial amputees during walking [27,28,30,38], but they did not record EMG from residual limb muscles inside the socket. It has traditionally been thought that the mechanics of the socket-limb interface prevent reliable measurements of EMG from the residual limb muscles during walking with surface electrodes. Au et al. recorded EMG from residual limb muscles within the socket, but were only able to get a reliable signal during swing [1]. We were able to record robust and reliable EMG during both stance and swing by using active EMG electrodes to maximize signal-to-noise ratio and using silicone putty to minimize movement and discomfort at the electrode sites.

Although there was the possibility for mechanical artifacts in our EMG recordings, data of EMG median frequencies suggest that we measured muscle activity from the residual limb muscles with little to no motion artifact. The EMG median frequencies recorded from the residual limb muscles during walking were similar to the EMG median frequencies recorded from the residual limb muscles during seated maximum voluntary activation trials (Table 4). In addition, the EMG median frequencies recorded from residual lower leg muscles in amputee subjects during treadmill walking were similar to the EMG median frequencies of the intact lower leg muscles in control subjects during treadmill walking (Table 4). Some of the amputee subjects demonstrated abnormal EMG patterns that had rhythmic, short-duration, and high-amplitude bursts (e.g., Figure 3, subjects *A06* and *A09*). We do not believe that these bursts resulted from mechanical perturbations to the electrodes because of the filtering we used and the frequency content of the resulting signals. Similar EMG patterns have been demonstrated in individuals with spinal cord injury that have had long-term disuse atrophy of the muscles [39,40]. The short-duration, high-amplitude EMG bursts that occurred around heel-strike and toe-off events may have been a result of reflex activation from muscle fiber stretch (Ia and II afferents) or rapid loading/unloading (Ib afferents).

The unique residual muscle activation patterns seen in our amputee subjects during gait suggest that neural plasticity may have occurred following amputation. Previous studies have demonstrated that neural plasticity in lower limb amputees occurs predominantly at the cortical level [41,42]. Neural plasticity can be affected by cause of amputation (e.g. traumatic, cancer-related, dysvascular-related), age at amputation, surgical procedure, muscle atrophy, and degeneration of nerves. The long-term cortical reorganization that occurs following injury is also highly use-dependent [43]. Changes in gait-related muscle activity following amputation would have a major impact on use-dependent cortical plasticity. Some amputees may learn to activate their residual muscles to improve stability at the limb-socket interface or to minimize socket discomfort/pain associated with impulsive prosthetic forces. This could alter the activation patterns away from the normal functional pattern seen in intact subjects and could contribute to increased inter-subject variability in amputees.

The results of this study are encouraging for the development of powered lower limb prosthesis under myoelectric control. Coupling an amputee's nervous system to a robotic prosthesis should provide a strong stimulus for learning to modify residual muscle activation patterns. In past studies, we have found that subjects with intact musculoskeletal systems can quickly adapt their muscle activation patterns to control powered lower-limb orthoses under proportional myoelectric control [44-47]. It seems likely that amputees could also learn to modify their muscle activation patterns to control powered lower-limb prostheses, though it may take longer due to the motor plasticity that has occurred since the amputation. Residual limb muscle activation patterns during dynamic tasks such as walking may function to improve fit and/or minimize discomfort at the socket-limb interface. Learning new residual activation patterns to control lower-limb prostheses may compete with this. Future studies should investigate why amputees adopt specific residual limb muscle activation patterns in order to assess the feasibility of myoelectric control using residual limb muscles during walking. Continued technological advances in intramuscular electrodes that could transmit control EMG signals through the prosthetic socket-limb interface without breaking the skin [17-19] would provide a means for generating feedforward control signals to a robotic prosthesis from the nervous system. Another option is recent technological advances in flexible epidermal electronics that could be mounted directly on the skin within the prosthetic socket-limb interface [48]. Either of these options could provide a long-term means for improving the control of powered lower limb prosthesis using EMG from the residual limb muscles.

Conclusions

It is possible to record artifact-free muscle activation patterns from residual limb muscles within the prosthetic socket-limb interface with surface electromyography electrodes. There is high inter-subject variability in recruitment patterns in amputees, but for each subject EMG patterns are consistent from stride to stride. Our results support the potential use of myoelectric controllers for direct feedforward control of robotic lower limb prostheses.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

SH recruited human subjects and collected data. SH processed and analyzed data, performed statistical analyses, and drafted the manuscript. DF conceived of the study and helped to draft the manuscript. DF and SH participated in the study design and contributed to interpretation of findings. Both authors read and approved the final manuscript.

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