Mobility analysis of AmpuTees (MAAT 5): Impact of five common prosthetic ankle-foot categories for individuals with diabetic/dysvascular amputation

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Abstract

Introduction: Diabetes and vascular disease represent the most common etiologies for lower limb amputations. In lower limb loss rehabilitation, the prosthetic ankle-foot mechanism is the most common major component needed to restore function. The purpose of this study was to examine the impact of five common prosthetic ankle-foot mechanisms on functional mobility in a large sample of individuals with amputation due to diabetes/dysvascular disease.

Methods: A retrospective analysis of the Prosthetic Limb Users' Survey of Mobility (PLUS-M®) captured in the patient care setting. A total of 738 individuals were included and subsequently subdivided into five groups based on the ankle-foot mechanism of their current prosthesis. Groups were compared using a general linear univariate model with age, body mass index, comorbid health status, time since amputation, and amputation level entered as covariates.

Results: The microprocessor ankle-foot group had the highest mobility ($F_{4,728} = 3.845$, $p = 0.004$), which was followed by the vertical loading pylon type ankle-foot, the hydraulic ankle-foot, the flex-walk-type ankle-foot, and lastly the flex-foot-type ankle-foot.

Conclusion: These results demonstrate that the selection of different prosthetic ankle-foot technology directly impacts functional mobility for the patient with an amputation due to diabetes and/or vascular disease.

Introduction

Lower limb amputation is estimated to account for 65% of all extremity amputations, with the ratio of major lower limb amputation to major upper limb amputation (i.e. excluding digit amputations) estimated to be as high as approximately 15:1.[1] As all individuals that experience a lower limb amputation at or proximal to the ankle joint will require a prosthetic ankle-foot mechanism, this component category impacts the lives of more individuals with amputation than any other prosthetic technology.

Despite the prevalence and importance of ankle-foot design and function to prosthetic rehabilitation, the most recent Cochrane review on the prescription of prosthetic ankle-foot mechanisms noted a further need for studies demonstrating differences in performance between various prosthetic ankle-foot mechanisms.[2] Subsequent to the updating of the Cochrane review in 2009, there have been several studies that have examined differences in prosthetic ankle-foot mechanisms. For example, recent studies have demonstrated improved functionality for certain measures associated with a new design of ankle-foot

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mechanisms labeled as "crossover feet," which comprise of an ankle-foot mechanism designed to be more versatile for walking as well as low-level running, compared to more common energy-storage-and return (ESAR) feet.[3–5] Another series of studies demonstrated differences in function between four different specific ankle-foot models, each from a different ankle-foot category.[6–8] Raschke et al. compared prosthetic feet with varying levels of quantified forefoot stiffness and showed differences in ankle moments.[9] Alternatively, another study found a lack of differences between the conventional solid-ankle-cushioned-heel foot and ESAR-type feet in step activity and six-minute walk test.[10]

Despite the value of these studies, the strength of their findings is limited based on sample size, with additional potential concerns related to optimal adaptation periods and limited testing environments. While evidence-based clinical practice guidelines have concluded that "Neither patient age nor amputation etiology should be viewed as primary considerations in prosthetic foot type [selection],"[11] policy makers have implied a need for studies specific to the Medicare population, described as those with "a relatively large percentage of participants with dysvascular etiologies for their lower limb amputations (also including diabetes)."[12] Thus, the purpose of this study was to examine the impact of different types of prosthetic ankle-foot mechanisms on functional mobility for lower limb prosthesis users with an amputation due to diabetes, with or without vascular disease. This study attempted to address potential limitations such as sample size and real-world environment through a retrospective analysis of outcomes collected on patients seen in the clinic to assess differences noted with prosthetic ankle-foot type. There are currently five categories of prosthetic ankle-foot mechanisms for the unlimited community ambulator[13,14] tracked within the outcomes database available for analysis. Among the five categories, it was hypothesized that the microprocessor ankle-foot (MPF) would result in greater mobility than the other four categories. This was hypothesized due to MPF being the only category of ankle-foot that utilizes sensors to read and subsequent motors to respond to various tasks faced by the user, given it is the most analogous function to the human neuromuscular system.

Methods

Study design

A retrospective cohort review of a multi-center outcomes database was performed. A convenience sample taken from multiple clinics located in various regions within the continental United States was extracted for the time period of April 2016 through February 2018. Importantly, the database tracks patients longitudinally but will only require certain data inputs at various time points within the care pathway. As such, there are many patients with incomplete data depending on the point within the care pathway that they have been seen and their outcomes submitted. For example, comorbidities are only verified during evaluation appointments consistent with the start of a new device or major componentry. As such, those patients seen only for follow-up appointments would not have verified comorbid health on record. For those patients who may have had multiple measures of mobility, only the outcomes entry and data at the time of greatest mobility were retained. This was consistent with the purpose of this study to assess potential mobility in patients with amputation due to vascular disease and/or diabetes. It was decided a priori that the greatest mobility was most representative of that patient's potential. This database review was approved by the Western Investigational Review Board (Protocol #20170059) and conforms to Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.

Participants

As part of the inclusion criteria, individuals must have had an amputation with vascular disease and/or diabetes. Only major amputations are submitted to the outcomes database, thereby preventing inclusion of any minor amputation (e.g. digit amputations). In order to be included, patients must have presented to their prosthetist for either a new device or a follow-up appointment during the noted time period. Additionally, individuals were included if the following had been verified within the outcomes database: comorbid health,[15] body mass index (BMI), Medicare Functional Classification Level (i.e. K-level),[13,14] mobility score captured via Prosthetic Limb Users Survey of Mobility (PLUS-M[TM16,17]), and patient wears one of the K3 prosthetic feet categories tracked within the database. The PLUS-M[TM] has only been validated for patients 18 years and older; thus, the inclusion age criterion was 18 years and older. There was no maximum age limit as function was given priority over age whereby any individual who met functional potential criteria to receive K3 prosthetic foot should be considered to have functional level appropriate for inclusion.

Procedure

During routine standard of care, patients are asked to complete the 12-item PLUS-M[TM] questionnaire.[16,17]

The questionnaire consists of 12 questions developed to assess functional mobility.[18] Questions vary in task difficulty, with patients responding to questions on a scale ranging with responses of "unable to do," "with much difficulty," "with some difficulty," "with a little difficulty," and "without any difficulty." Responses have weighted values of 1 to 5 which are summed and converted to a T-score.[18] For cases where a question may have been either purposely or inadvertently skipped, the raw score and T-score were calculated using the procedures outlined by the instrument developers.[18]

For analyses, only the T-score is used as denoted by instrument instructions.[18] Mobility outcomes are only collected for patients who have a prosthesis. The PLUS-M[TM] is only administered at the time of evaluation for a new device or major component, and then at a two-week follow-up and every six months thereafter when the patient returns. Comorbidities are only reviewed for the database at the time of an evaluation appointment. Reviewed comorbidities include the 18 that comprise the Functional Comorbidity Index (FCI) with the exception of obesity which is determined through calculation of BMI and denoted as greater than 30.0.[19] Additionally, clinicians review hypertension and hypercholesterolemia.

Prosthetic ankle-foot mechanisms

There are five categories of K3-level prosthetic ankle-foot mechanisms currently tracked within the prosthetics users' outcomes database. The categories include MPF mechanisms and four that are classified as non-microprocessor (i.e. non-MPF). The MPF utilizes a microprocessor and series of sensors to measure the patient's gait cycle and then respond according to the required output for optimal stepping.[20] With the exception of two currently available commercial MPF, these feet are primarily adaptive in nature, using small motors to adjust hydraulic or pneumatic resistance to forces but do not generate power at the ankle. The Ossur® Proprio[TM] and Ottobock® Empower[TM] are similar to the adaptive MPF but also generate ankle power in swing phase (Proprio[TM]) or swing and stance phase (Empower[TM]).[20]

The four non-MPF ankle-foot categories include feet that deflect and return stored energy to assist walking to varying degrees.[21,22] There are certain mechanical qualifiers for prosthetic foot categories established by the American Orthotics and Prosthetics Association through the *AOPA Foot Project*.[22] The categories are denoted by descriptors and their Healthcare Common Procedure Coding System L-code. The first category is the L5987 or shank-foot system with vertical loading pylon (VL5987). To qualify in this category, the ankle-foot mechanism must have "dynamic keel" rating in the

"Keel Test" (≥ 25 mm displacement at 1230 N and $\geq 75\%$ energy return), "dynamic heel" rating in the "Heel Test" (≥ 13 mm displacement at 1230 N, OR $\geq 82\%$ energy return), and either pass the "Vertical Loading Test" (≥ 10 mm deflection) or the "Horizontal Displacement Test" (horizontal toe keel motion ≥ 25 mm and horizontal heel motion ≥ 5 mm). The next category is the L5981 or flex-walk system (FW5981). To qualify, this ankle-foot mechanism also has a "dynamic keel" rating, "dynamic heel" rating, and then has separate deflecting heel and keel. The L5980, flex-foot system (FF5980), requires "dynamic keel" and "dynamic heel" ratings as well as >10 mm net displacement with the "Dynamic Pylon" test. The last category is the L5968 which describes ankle-foot mechanisms that utilize a hydraulic ankle mechanism (HA5968).[20,23–26]

Analysis

Individuals were stratified according to prosthetic foot type. These five groups were then compared through a general linear univariate model with mobility (i.e. PLUS-M[TM] T-score), the dependent variable, and prosthetic foot type as grouping variable. In the event of a significant difference, Fisher's least significant difference post hoc test was used to determine specific group differences. Age, BMI, FCI, time since amputation, and amputation level were entered as covariates. In this manner, the influence from factors that may impact functional mobility to varying extents such as age, body morphology, comorbid health, prosthetic experience, and mechanical lever arm were accounted for within the analysis.[15,27–29] In light of the study purposes to assess prosthetic foot function in K3 ambulators with amputation due to diabetes/dysvascular disease, entering these factors as covariates allowed for results to better reflect the impact of prosthetic ankle-foot function. All analyses were performed within SPSS® v20.0 (IBM, Armonk, New York, USA).

Results

The database extraction yielded 7071 patients with lower limb amputation. After applying inclusion/exclusion criteria, there were 738 individuals included for analysis (Figure 1; Table 1). The average group size was 147.6 ± 118.4 patients.

When comparing groups with different ankle-foot mechanisms, prior to entering any covariates into the model, there was a significant difference between groups ($F_{4,733} = 3.482$, p=0.008), with an observed power of 0.862. Individuals with MPF had the greatest mobility ($52.82 \pm$ SE 1.97). Individuals with the FW5981 reported the lowest mobility ($47.08 \pm$ SE 0.57), although
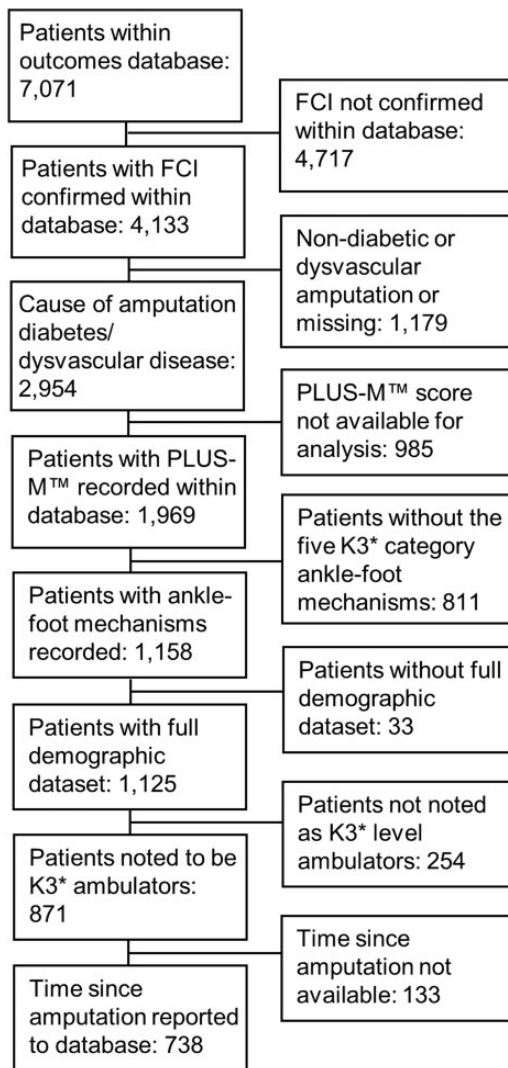
power of 0.897. Individuals with MPF continued to have the greatest mobility after adjustments ($52.06 \pm$ SE 1.95). Individuals with FF5980 reported the lowest mobility ($47.13 \pm$ SE 0.93), although this was still on average similar to FW5981 ($47.14 \pm$ SE 0.56). Post hoc tests revealed that MPF had significantly greater functional mobility than both FF5980 (p=0.023) and FW5981 (p=0.015). The VL5987 group continued to have the greatest mobility after the MPF group ($50.20 \pm$ SE 0.83), while not statistically less than the MPF (p=0.377), it resulted in greater functional mobility than FF5980 (p=0.014) and FW5981 (p=0.002). The HA5968 group had the third highest mobility ($49.08 \pm$ SE 1.10).

Discussion

This study sought to determine the impact of various prosthetic ankle-foot mechanisms on functional mobility for patients who have undergone amputation due to diabetes and/or vascular disease. We chose to investigate functionality within the patients' real-world environment and to limit the scope of the investigation to the lower limb prosthesis user with amputation due to diabetes/dysvascular disease. Our focus centered on those utilizing K3-level prosthetic feet, as these demographics denote the largest population subject to prosthetic rehabilitation.[1] Our results supported our hypothesis. From the five categories of prosthetic ankle-foot mechanisms investigated, the MPF group had the greatest mobility. The second highest level of mobility, and greatest mobility among any non-MPF ankle-foot mechanism, was the shank-foot system with vertical loading pylon.

It is not entirely surprising that the MPF would result in the greatest mobility given previous smaller studies surrounding MPF functionality.[6,30,31] In particular, the increased adaptive ability of the MPF to adjust its inclination angle, and thereby reduce the typically increased forces associated with these surfaces, seems to provide benefit to patients in their functional mobility. If this is the case, then those who do not frequently encounter slopes may not benefit as much from the increased adaptability and as a result the increased mass of the MPF may prove to outweigh such benefit. Notably, the increased mobility with the MPF over the hydraulic ankle-foot technology would indicate the responsive changes with an MPF increase the adaptability, and this affords improved function over hydraulic control alone. This is analogous to findings for prosthetic knee technology that shows increased functionality of microprocessor knees over conventional hydraulic knee units.[32–34]

A significant contribution from this study was the ability to limit the analysis to a large sample of patients

Figure 1. Eligibility flow chart, from 7071 outcomes entries, 738 met inclusion criteria and were utilized for the current study analysis. FCI: Functional Comorbidity Index; PLUS-M™: Prosthetic Limb Users Survey of Mobility™; *: Medicare functional classification level.

this was on average similar to FF5980 ($47.53 \pm$ SE 0.94). Post hoc tests revealed that MPF had significantly greater functional mobility than both FF5980 (p=0.050) and FW5981 (p=0.021).

The VL5987 group had the greatest mobility after the MPF group ($50.24 \pm$ SE 0.84), while not statistically less than the MPF (p=0.461), it was still greater functional mobility than FF5980 (p=0.032) and FW5981 (p=0.002). The HA5968 group had the third highest mobility ($48.76 \pm$ SE 1.10).

Once the analysis was re-run entering the noted confounding variables, the overall differences persisted. There was a significant difference between groups ($F_{4,728} = 3.845$, p=0.004; Figure 2), with an observed

Table 1. Subject demographics.

	MPF	VL5987	FW5981	FF5980	HA5968
Sample size (females)	28 (4)	155 (11)	342 (86)	123 (34)	90 (15)
Age (years)	57.1 ± 13.0	57.7 ± 12.1	58.8 ± 10.4	58.6 ± 11.8	61.1 ± 10.2
Height (cm)	179.8 ± 10.1	179.5 ± 10.1	176.1 ± 10.4	174.4 ± 10.1	176.5 ± 9.6
Mass (kg)	98.7 ± 16.8	101.0 ± 23.9	95.1 ± 24.2	89.0 ± 24.8	90.5 ± 18.2
BMI (kg/m^2)	33.5 ± 5.7	33.6 ± 7.3	32.9 ± 7.2	31.4 ± 7.6	31.1 ± 5.1
Multi-morbidity (FCI)	3.5 ± 2.5	3.0 ± 1.8	3.1 ± 1.8	2.9 ± 1.8	3.3 ± 1.9
Months since amputation	128.7 ± 163.3	97.0 ± 132.8	88.2 ± 121.3	103.5 ± 131.4	91.6 ± 140.6
Amputation level					
Below-Knee	14	121	241	80	66
Above-Knee	7	16	67	31	7
Bilateral	7	18	34	12	17

MPF: microprocessor ankle-foot; VL5987: shank-foot system with vertical loading pylon; FW5981: flex-walk system; FF5980: flex-foot system; HA5968: hydraulic ankle-foot system; BMI: body mass index; FCI: functional comorbidity index.
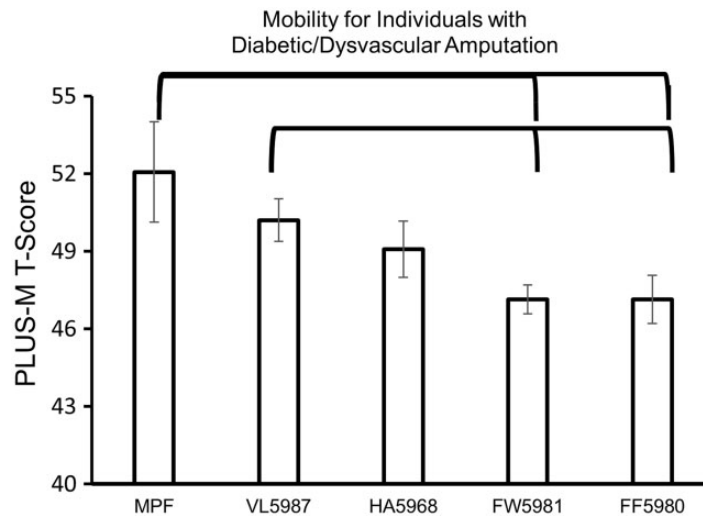

Figure 2. Mobility (PLUS-M T-score) for five different groups of prosthetic ankle-foot users (total sample, n=738). Columns (from left to right) correspond to microprocessor ankle-foot (MPF), shank-foot systems with vertical loading pylons (VL5987), hydraulic ankle-foot systems (HA5968), flex-walk ankle-foot systems (FW5981), and flex-foot type ankle-foot systems (FF5980). Significant differences were noted after removing potential confounding effects of age, body mass index, comorbid health status, time since amputation, and amputation level. Black bars indicate group differences at $p < 0.05$.

with amputation due to diabetic/dysvascular etiology. Recruitment of this patient population is challenging. The available literature focuses primarily on traumatic etiology.[12,30,31] This is problematic in light of the high prevalence of amputation within this population[1] and is emphasized in a recent Agency for Healthcare Research and Quality report noting a lack of studies with patients of diabetic/dysvascular etiology.[35] Additionally, with the large sample available for analysis, it was also possible to enter potentially confounding variables that may impact functional mobility such as age, body morphology, comorbid health, prosthetic experience, and mechanical lever arm,[15,27–29] which is not possible on limited sample sizes. While there may be other factors that impact mobility such as motivation, we were able to determine the impact of foot category on lower limb prosthesis user mobility while accounting for multiple factors.

Clinical implication

It seems reasonable that MPF would have low utilization within the sample as provision of these devices can be restricted by many payer policies (Table 1).

However, given the significant increase in mobility with the shank-foot system with vertical loading pylon (i.e. VL5987), it is odd that the flex-walk system (i.e. FW5981) would have such high representation within the sample. One plausible reason for this may be the clearance requirement of the shank-foot system with vertical loading pylon compared to the flex-walk system. For example, the standard Ossur® Re-flex Rotate™ (i.e. shank-foot system with vertical loading pylon) requires 216 mm of clearance, limiting individuals with long residual limbs or short stature from being able to fit the foot underneath their limb without making their prosthetic side too tall. This, however, is not consistent across all shank-foot systems with vertical loading pylon. The Endolite® Elite2™ (i.e. shank-foot system with vertical loading pylon) requires only 130 mm. The Ossur® LP-Variflex™ (i.e. flex-walk system), for comparison, only requires 68 mm of clearance for the same size 27 cm foot. Thus, the flex-walk system may be utilized more due to physical space demands.

The hydraulic ankle-foot mechanism (i.e. HA5968), which in the group mean rank fell only behind the MPF and shank-foot system with vertical loading pylon has a clearance requirement that generally will be taller than many flex-walk system type feet (i.e. FW5981; e.g. Endolite® Echelon™ has a clearance height of only 125 mm). The Endolite® Echelon™ is the most utilized hydraulic ankle-foot mechanism-type foot, and there have been multiple studies reporting benefits of its use.[23–26] However, given only the 5 mm clearance difference in the example Endolite® ankle-foot mechanisms, the findings from this study provide value in guiding the clinical decision process to consider the shank-foot system with vertical loading pylon type foot instead.

Most puzzling may be the findings surrounding the flex-foot system (i.e. FF5980) and its similar utilization/representation within the sample as the shank-foot system with vertical loading pylon. The flex-foot system typically has physical space requirements similar to the shank-foot system with vertical loading pylon, yet it performed lowest in the rank order of group mean for functional mobility and was statistically worse than the shank-foot system with vertical loading pylon. The representation within the sample may be more a reflection of the general lack of clear rank guidance of prosthetic componentry with regard to performance. Further studies are required to determine the reason for the flex-foot system utilization.

As a result of the current study's findings, within the clinical setting, it is proposed that clinicians consider a top-down approach if functional mobility is a primary outcome of interest. In particular, it would seem beneficial to start with the highest rank order for ankle-foot mechanism type (i.e. MPF) and proceed down through group mean ranks (i.e. MPF > shank-foot system with vertical loading pylon > hydraulic ankle-foot mechanism > flex-walk system > flex-foot system) in the event that there are precluding factors, clinical or otherwise, that would discourage an ankle-foot type. In this manner, clinicians will find themselves assured of providing maximum opportunity for functional mobility to their patients.

Study limitations

This study has limitations that should be recognized. First, as part of a retrospective design, representation of device types within the study sample is limited to what is being provided clinically to patients (e.g. payer policies, clinician device familiarity/preference, aggressive marketing from manufacturers). There might be factors beyond age, K-level, amputation etiology, body morphology, comorbid health, amputation level, time since amputation, or even functional mobility that clinicians are utilizing to inform the decision process that are not being captured by the data within the outcomes database and thus unaccounted for within the model. Additionally, while these ankle-foot categories cover the spectrum of prosthetic feet for the K3-level ambulator (i.e. unlimited community ambulator[14]), there are other prosthetic ankle-foot mechanisms available and this analysis also did not investigate those provided to individuals at lower functional levels such as K2 (i.e. limited community ambulator). Future work should expand into lower functional levels, as well as working to gather enough granularity to be able to investigate the impact of some of the more common manufacturer make and model types of ankle-foot mechanisms provided to patients within the care setting.

Conclusions

The most common cause of lower limb amputation is diabetes with or without vascular disease.[1] The prosthetic ankle-foot mechanism represents a significant advancement in engineering and arguably the most crucial assistive technology for patients undergoing prosthetic rehabilitation. This study investigated the impact of five of the most common categories of prosthetic ankle-foot mechanisms on patients' functional mobility. The results found that the MPF yielded the greatest level of mobility, and this was after controlling for numerous factors that may confound the results such as age, BMI, comorbid health status, time since amputation, and even amputation level.[15,27–29] The second highest mobility was found with the shank-foot system with vertical loading pylon. Importantly, the

shank-foot system with vertical loading pylon resulted in highest mobility of any non-MPF ankle-foot mechanism (i.e. not requiring electric energy source to operate). When considering these results for purposes of prosthetic rehabilitation, it is important to note that there may be factors that were not captured within the analysis such as patient preference and willingness to charge a device, or physical space requirements for a taller ankle-foot mechanism, that should be accounted for in the clinical decision process.

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