JRRD Volume 49, Number 4, 2012
Pages 597–612

Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet

Robert S. Gailey, PhD, PT;[1–2*] Ignacio Gaunaurd, PhD, MSPT;[2] Vibhor Agrawal, PhD, MS (BioE);[1–2] Adam Finnieston, CPO, LPO;[3] Christopher O'Toole, MS (BioE);[2] Ronald Tolchin, DO[4]

[1]Department of Physical Therapy, Miller School of Medicine, University of Miami, Coral Gables, FL; [2]Functional Outcomes Research and Evaluation Center, Miami Department of Veterans Affairs (VA) Healthcare System, Miami, FL; [3]Arthur Finnieston Prosthetics + Orthotics, Miami, FL; [4]Physical Medicine and Rehabilitation, Miami VA Healthcare System, Miami, FL

Abstract—We examined the application of outcome measures to determine changes in function caused by standardized functional prosthetic gait training and the use of four different prosthetic feet in people with unilateral transtibial limb loss. Two self-report measures (Prosthetic Evaluation Questionnaire-Mobility Scale [PEQ-13] and Locomotor Capabilities Index [LCI]), and three performance-based measures (Amputee Mobility Predictor with a prosthesis [AMPPRO], 6-minute walk test [6MWT] and step activity monitor [SAM]) were used. Ten people with unilateral transtibial limb loss, five with peripheral vascular disease (PVD) and five without PVD, completed testing. Subjects were tested at baseline and after receiving training with their existing prosthesis and with the study socket and four prosthetic feet, i.e., SACH (solid ankle cushion heel), SAFE (stationary attachment flexible endoskeletal), Talux, and Proprio feet, over 8 to 10 weeks. Training was administered between testing sessions. No differences were detected by the PEQ-13, LCI, 6MWT, or SAM following training and after fitting with test feet. The AMPPRO demonstrated differences following training with the existing prosthesis in the PVD group and between selected feet from baseline testing (p </= 0.05). Significant differences were found between the PVD and the non-PVD groups (p </= 0.05) in the AMPPRO and 6MWT when using the Proprio foot. Self-report measures were unable to detect differences between prosthetic feet.

Clinical Trial Registration: ClinicalTrials.gov; NCT01340807, "A Comparison of External Mechanical Work Between Different Prosthetic Feet"; **http://www.clinicaltrials.gov**.

Key words: functional outcomes, gait training, lower-limb amputation, Medicare Functional Classification Level, microprocessor ankle, mobility, performance-based outcome measures, prosthetic feet comparison, self-report outcome measures, transtibial amputation.

INTRODUCTION

A paradox may exist today regarding the prosthetic care of people with lower-limb loss. In a climate of comparative effectiveness healthcare where there is a need to demonstrate differences between selected interventions,

Abbreviations: 6MWT = 6-minute walk test, AMP = Amputee Mobility Predictor, AMPPRO = AMP with a prosthesis, ANOVA = analysis of variance, IRB = institutional review board, LCI = Locomotor Capabilities Index, MFCL = Medicare Functional Classification Level, MPA = microprocessor ankle, PEQ = Prosthesis Evaluation Questionnaire, PEQ-13 = PEQ-Mobility Scale, PVD = peripheral vascular disease, SACH = solid ankle cushion heel, SAFE = stationary attachment flexible endoskeletal, SAM = step activity monitor, SD = standard deviation, VA = Department of Veterans Affairs.

***Address all correspondence to Robert S. Gailey, PhD, PT; University of Miami, Physical Therapy, 5915 Ponce de Leon Blvd, 5th floor, Coral Gables, FL 33146; 305-284-4535; fax: 305-575-3248. Email: rgailey@umail.miami.edu**

http://dx.doi.org/10.1682/JRRD.2011.04.0077

there is currently no known means to discriminate between the functional differences of prosthetic foot components in the field of prosthetic rehabilitation.

When prosthetic feet have been compared, few statistically significant differences have been consistently reported, with the possible exception of the Flex-Foot, which demonstrates greater peak ankle moments [1–3] and maximum dorsiflexion [1,4–6] than the solid ankle cushion heel (SACH) foot (Kingsley Mfg. Co; Costa Mesa, California). Studies indicate a lack of consistency in quantitative gait measures in prosthetic users, even with similar populations walking with comparable prosthetic configurations. It appears to be difficult to readily identify specific gait abnormalities using temporal-spatial, kinematic, or kinetic data; thus, the value of using these measures for outcomes is questionable [7]. However, a number of trends have been detected between prosthetic feet with such variables as self-selected walking velocity, stride length, sound-side weight acceptance force, prosthetic-side propulsive force, and total ankle range of motion [8]. It is often frustrating to the clinician and the prosthetic user that they perceive differences between prosthetic foot designs without any clear evidence to support their notions.

While most studies describe in the methodology that a certified prosthetist fit and aligned the prosthesis, very few describe prosthetic gait training by a physical therapist. The irony is that if a design or material difference exists between prosthetic feet, the prosthetic user should be educated in the proper use of every unique attribute to fully appreciate differences between each specific foot. Furthermore, if residual gait deviations exist because of lack of training or habit, then traditional instrumented measures would be more likely to quantify the physical gait deviations than to identify the differences between prosthetic feet. To eliminate such error, each prosthetic user should be trained to reduce existing gait deviations and maximize the performance of each prosthetic foot, which enables evaluative tools to assess the prosthesis and not the existing gait deviations.

When clinically significant differences using objective data are not found between prosthetic feet, investigators will frequently use results from questionnaires administered to subjects describing their subjective comparisons between prosthetic feet [9–12]. The questionnaires typically are customized to each study without being validated and lack clinical or statistical significance [8]. This is not to say that the prosthetic user's perception is not a suitable measure, but investigators would be well served if a universal self-report instrument capable of detecting differences between selected prosthetic feet could be identified.

The basic premise for differentiating prosthetic components revolves around the context of functional capabilities. If one prosthetic foot has significantly different attributes than another, then it must in some capacity improve function measured either objectively or subjectively by the prosthetic user. Clinicians who prescribe to, evaluate, and treat people with lower-limb loss are interested in obtaining an instrument(s) that will help determine the clinical effectiveness of and discriminate between prosthetic foot choices. Moreover, within the United States there exists a system of categorizing prosthetic feet based on the functional capabilities of people with limb loss; however, the functional differences between categories of feet have never been established.

Outcome measures are quantifiable instruments used to determine functional capabilities in relation to an intervention or other influencing variables. Outcome measures can be used to evaluate progress, establish goals, or simply determine functional capabilities of individuals [13]. These measurement tools are classified as self-report, professional report, or performance-based measures [14]. Performance-based measurement instruments can be the most objective and accurate outcome measures to determine physical capabilities, while the self-report measures are easy to administer and require minimal resources. A majority of measurement tools have been used to quantify functional and mobility limitations or quality of life in people with limb loss [15–16]. To date, no instrument has been identified to detect functional differences between prosthetic components.

Commonly assessed measures of function include walking speed, walking distance, rising from or sitting in a chair, ascending or descending stairs or inclines, and walking outside on a variety of surfaces. Two of the most widely investigated self-report measures that assess the aforementioned elements and have also been shown to offer good reliability with prosthetic users are the Prosthesis Evaluation Questionnaire-Mobility Scale (PEQ-13) and the Locomotor Capabilities Index (LCI). Two clinically friendly performance-based measures that have been shown to discriminate between functional capabilities are the Amputee Mobility Predictor (AMP) and the 6-minute walk test (6MWT) [17].

The Prosthesis Evaluation Questionnaire (PEQ) and LCI have been used to describe the perception of difficulty

in performing prosthetic function and mobility. The PEQ is a self-report, 82-item questionnaire developed to assess prosthetic function, mobility, psychosocial aspects, and well-being [18]. The PEQ-13 is the 13-question subset prosthetic mobility scale that focuses on the perceived potential for mobility, ambulation, and transfers while using a prosthetic device [19]. The PEQ-13 uses a 100-point formatted visual analog scale with a scoring range of 0 to 130, with a higher score indicating higher functioning [19]. The PEQ-13 has high internal consistency, excellent test-retest reliability, and good convergent validity with the LCI [19–21]. Although the concurrent validity of the PEQ-13 has been reported with respect to other self-report measures, its ability to discriminate between Medicare Functional Classification Level (MFCL) or different prosthetic components remains unknown [21].

The LCI is a component of the measurement tool called the Prosthetic Profile of the Amputee and is designed as a self-report measure of prosthetic mobility that evaluates ambulatory abilities with or without different levels of ambulation aides and assistance [22–25]. The LCI consists of 14 activity-based items, ranging from walking in the house to carrying an object, which are divided into two subscales: Basic Abilities and Advanced Abilities [23]. The LCI-5 is a modified version of the LCI with a 5-point ordinal scale that maintains the LCI's original psychometric properties while incorporating a lower ceiling effect and a larger effect size [23]. Overall, the LCI-5 has demonstrated good test-retest reliability and internal construct validity, which was established with the PEQ, in elderly and middle-aged populations with amputation [20–21,23]. Like the PEQ-13, the LCI-5's ability to determine a person with amputation's perception of prosthetic mobility when using different categories of prosthetic ankle and/or foot assemblies is unknown.

The AMP is a performance-based outcome measure of current and future functional capabilities that can estimate the MFCL of people with lower-limb amputation. The AMP can be administered in 10 to 15 min, either with a prosthesis (AMPPRO) or without. The AMPPRO has been determined to have excellent reliability and validity in measuring functional capabilities with a prosthesis [26].

The 6MWT has become one of the most widely used performance-based outcome measures of functional mobility and exercise capacity in a wide variety of populations because of its construct, low cost, and convenience to administer [27]. The 6MWT has been found to be effective in determining functional capacity using peak oxygen uptake [27–28]; predicting community ambulation capacity [29]; and assessing overall performance, mobility, and cardiovascular fitness [30]. More recently, contributing variables such as hip extensor strength, age, single-limb balance time, and symmetry of step length have been found to correlate with 6MWT performance in people with amputation [31]. The 6MWT distance has been shown to be responsive to functional training interventions in people with lower-limb amputation [29].

Maintaining a certain level of activity is important for overall health. Many methods can be implemented to monitor activity level, such as daily logs, pedometers, heart rate monitors, questionnaires, and accelerometers [32]. The step activity monitor (SAM), which is a device that measures long-term step activity, has demonstrated good reliability when measuring continuous activity [33] with varied surfaces and terrains [32]; footwear; body types [34]; gait styles [33]; and medical interventions and conditions, e.g., joint arthroplasty, lower-limb amputation, and diabetes mellitus [33–34].

The MFCL is a 5-level classification system that uses code modifiers (K-levels 0, 1, 2, 3, and 4) from the Health Care Financing Administration. The MFCL describes the functional abilities of people with lower-limb amputation. The classification levels are determined by the patient's past medical history, current health, residual-limb status, associated medical problems, and desire to ambulate. The MFCL has a wide range in function, from those who are bedbound (K0) to fully functioning people with amputation with the potential to participate in high-level activities (K4) (**Table 1**). Based on a Centers for Medicare and Medicaid Services committee review, most prosthetic feet in the United States were assigned to a specific MFCL K-level. The categorization of prosthetic feet—K1, K2, or K3—is used by government and private healthcare payers to determine a patients' eligibility for a prosthetic foot.

The purpose of this study was to determine the ability of commonly used self-report and performance-based measurement instruments to detect functional differences between four categories of prosthetic feet in people with unilateral transtibial limb loss and whether differences with the selected measures exist between cohorts with and without peripheral vascular disease (PVD). We selected the test prosthetic feet to represent each of the categories of feet, i.e., SACH foot (K1); stationary attachment flexible endoskeleton (SAFE) foot (Campbell-Childs Inc; White City, Oregon) (K2); Talux foot (Ossur; Reykjavik, Iceland)

Table 1.
Definitions for Medicare Functional Classification Level.

K-Level*	Functional Description	Foot Description
0	Does not have ability or potential to ambulate or transfer safely with or without assistance, and prosthesis does not enhance quality of life or mobility.	Not eligible for prosthesis.
1	Has ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of limited and unlimited household ambulator.	External keel, SACH foot, or single-axis ankle/foot.
2	Has ability or potential for ambulation with ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of limited community ambulator.	Flexible-keel foot and multi-axial ankle/foot.
3	Has ability or potential for ambulation with variable cadence. Typical of community ambulator who has ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.	Flex-foot system, energy storing foot, multi-axial ankle/foot, dynamic response, or flex-walk system or equal.
4	Has ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of prosthetic demands of child, active adult, or athlete.	Any ankle/foot system appropriate.

*K is arbitrary letter assigned by Health Care Financing Administration to this classification system.
SACH = solid ankle cushion heel.

(K3); and Proprio foot (Ossur), which is the first commercially available microprocessor ankle (MPA) (no assigned K-level). We hypothesized that the selected self-report and performance-based instruments would be able to detect differences between the MFCL categories of prosthetic feet following standardization of prosthetic socket and gait training and that subjects without PVD would demonstrate a higher level of function with the different prosthetic feet, as measured by selected self-report and performance-based measures, than subjects with PVD.

METHODS

Study Design

The investigation was a randomized crossover study (**Figure**). Subjects underwent a total of six testing sessions and were asked for a time commitment of 40 h over a 10 to 12 wk period. Subjects were recruited from the Miami Department of Veterans Affairs (VA) Healthcare System, Jackson Memorial Hospital clinics, and local prosthetic clinics providing services to people with amputation.

Eligibility Criteria

We recruited healthy males and females between the ages of 40 and 65 with unilateral transtibial amputations caused by diabetes, PVD, trauma, or tumor. The inclusion criteria required that the subjects be able to use a prosthesis for ambulation on level surfaces with a consistent cadence, comfortably fit with a prosthesis for a period of at least 6 mo, and able to tolerate the testing protocol. We excluded individuals if, at the time of enrollment, they weighed >115.67 kg (manufacturer weight limitation for the MPA) at baseline visit; were receiving renal dialysis; had severe cardiac or pulmonary disease that limited their ability to exercise, including angina or poorly controlled hypertension; had neurological disorders affecting their ability to ambulate; had severe lower-limb arthritis; currently had an open wound on their intact lower limb; had problems with prosthetic fit; or had poor glucose control of diabetes mellitus.

Study Procedures

We interviewed 55 subjects by telephone and scheduled 18 potential subjects who satisfied the inclusion criteria, described verbally, for the formal screening process. During the formal screening process, each candidate underwent the informed consent process and participated in the personal interview, physical evaluation, and baseline testing. Of the subjects, 13 received medical clearance (1 presented with neurological involvement, 2 were found to have extensive comorbidities not passing the physical examination, and 2 were unable to attend all testing sessions). Ten subjects completed the study as per

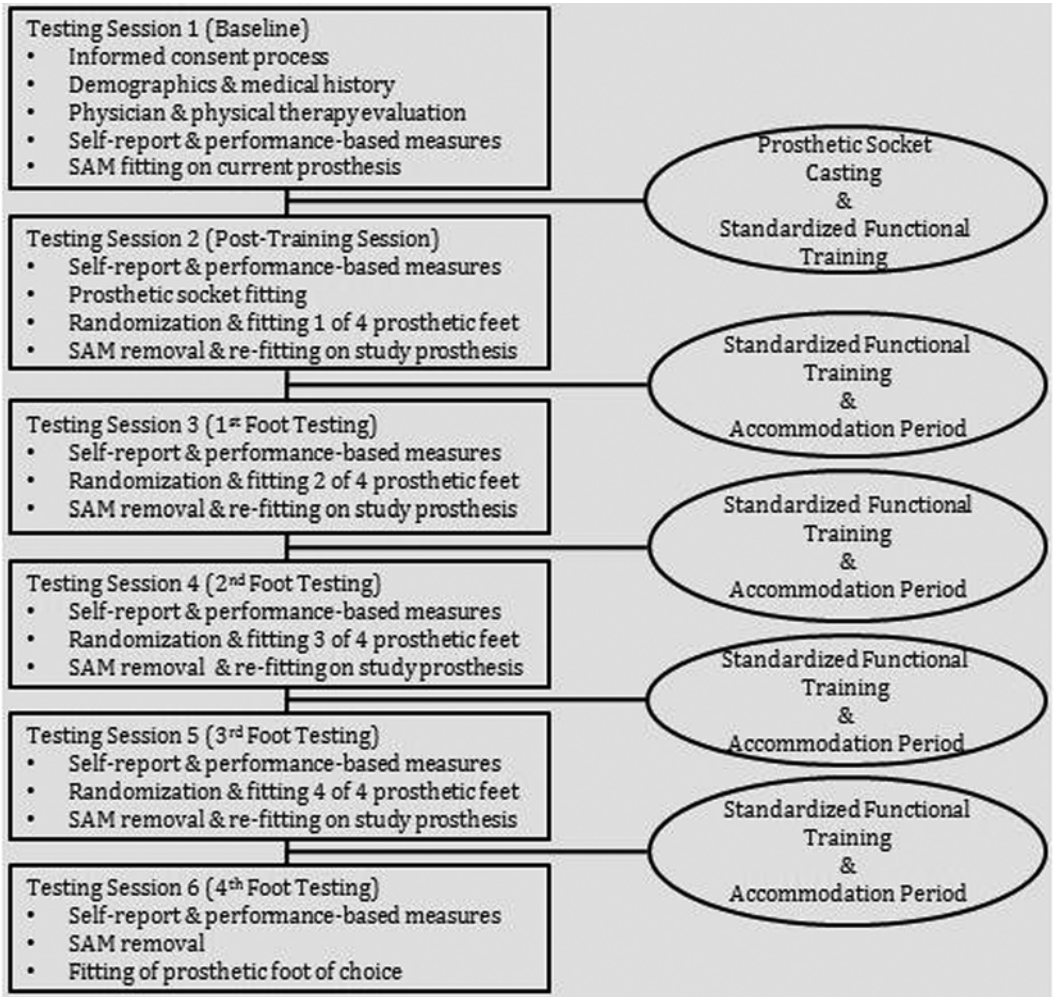

Figure.
Study design. SAM = step activity monitor.

the protocol. Two subjects were excused for noncompliance with appointments and testing procedures and a third withdrew because of medical reasons. The examiner gathered demographic information at the baseline visit. Subjects received a comprehensive physical evaluation by a physician prior to testing, which included past medical history; cause of amputation; inspection of residual limb; comorbidities as per the Melchiorre Comorbidity Scale [35]; current medications; vascular and sensation assessment; smoking and alcohol history; and other appropriate history, including previous treatments. Following medical approval, a licensed physical therapist performed upper- and lower-quarter screenings to examine subjects' limb range of motion, general strength, and length of residual limb. The study prosthetist assessed and documented that the subjects' existing prosthetic sockets and components were well fit, pain-free, and working properly before the first two testing trials.

Outcome Measures

Subjects completed the following two self-report questionnaires at each testing session: PEQ-13 and LCI-5. They then completed two performance-based measures: AMPPRO and 6MWT, which was performed on a 55 m level indoor rectangular walkway with a nonslip surface. We used the 6MWT instructions from the American Thoracic Society guidelines for the test [35]. We collected the speed and distance ambulated from the 6MWT. All measures were administered by the same licensed physical therapist who was a member of the research team. The test

administrators were blinded to the total scores for all measures for every subject until the conclusion of the study.

At the conclusion of testing session 1, we fit subjects with the SAM around the prosthetic ankle. The SAM data were downloaded at the beginning of each testing session and refit on the prosthetic limb at the end of testing sessions. We collected data on steps per day (steps/day) and hours of daily activity during the period between two testing sessions.

Standardized Functional Prosthetic Gait Training

Subjects completed baseline measures with their existing prosthesis. Over the next 10 to 14 d, participants received 1 to 4 h of training, depending on their individual needs. All subjects were required to attend at least one training session and had to demonstrate proficiency of four gait-related movement patterns; review two home exercises; and negotiate sitting, standing, ramps, and stairs prior to being discharged from the training program. At the conclusion of testing session 2, participants were fit with their new prosthetic socket, which was to be worn continually throughout the study, and were randomly fit with the first of four prosthetic feet. Following testing session 2, each subject received 1 to 4 h of standardized prosthetic gait training focusing on the design characteristics of each particular test foot and were given specific instruction on how to maximize the performance of each foot. The training was administered at the onset of the accommodation period for each of the four test feet. Each subject was given a 2-week (10–14 d) accommodation period with each prosthetic foot. The intention of training was to assist subjects in achieving a consistent level of mobility and maximizing performance with their existing prosthesis. It was performed with the intention of reducing gait deviations related to superfluous physical movement patterns that would influence the ability to properly take advantage of the design characteristics of each category of prosthetic foot. The training is a standard protocol that has been previously published [17,36–39] combined with specific instructions for using the characteristics of each prosthetic foot. We used a standardized socket design and alignment procedure for all subjects. The goal of the training and prosthetic fitting was to reduce the number of confounding variables that would influence prosthetic foot performance and ascertain whether the differences between categories of prosthetic feet could be assessed without bias. Therefore, any differences determined by the outcome measures would be attributable to differences in prosthetic feet.

The training was consistent between each subject and each test foot and included the following exercises: (1) stool stepping to improve single-limb standing balance on the prosthetic foot; (2) resistive gait training to ensure transverse pelvic rotation and symmetry of movement during ambulation; (3) resistive ambulation to promote dynamic balance and proper toe-load over the prosthetic foot during late stance with the intention of maximizing the benefits of the prosthetic foot; (4) ball rolls in three planes to increase the speed of hip muscular contraction and to encourage single-limb balance over the prosthetic limb; (5) trunk rotation to assist with balance and symmetry of movement over both feet; and (6) change of direction and turning skills [17,36–40]. We offered no generalized strengthening, stretching, or cardiovascular endurance training to improve the general fitness of the subject.

In addition, we instructed the participants on how to maximize the use of each of the different prosthetic feet according to design characteristics when ascending and descending stairs, ascending and descending a ramp, and performing sit-to-stand and stand-to-sit progressions. One example of the specific prosthetic foot training for one task, such as descending a ramp, would be as follows:

- SACH foot: Subjects would be taught to compress the cushion heel, slowly moving their body weight over the keel of the foot. The nondisabled limb should rapidly step, preparing for initial contact.
- SAFE foot: Subjects would be asked to compress the cushion heel, slowly moving their body weight over the longer flexible keel and allowing for late stance balance.
- Talux foot: Subjects would compress the heel, feeling the foot move to the floor and ride over the foot, allowing the J-shaped pylon to advance over the stationary foot. As the body progresses forward, subjects balance over the toe, deflecting the footplate.
- Proprio foot: Subjects compress the heel, feeling the foot move into plantar flexion. As the body progresses over the stationary foot, subjects balance over the toe, deflecting the footplate. During the swing phase, the MPA dorsiflexes to increase ground clearance.

For all prosthetic feet, the physical therapist used a gait belt to restrain the subjects while they descended the ramp, giving them time to feel the described motions and to balance over each foot. We encouraged subjects to take symmetrical step lengths between limbs; however, step

length with specific feet was related to each foot's keel or footplate design and ankle characteristics. The SACH foot has a shorter keel and solid ankle and the SAFE foot has a flexible keel and solid ankle, while the Talux and Proprio feet have a heel-to-toe footplate with a J-shaped pylon or MPA, respectively. The prosthetic foot design characteristic variations highlighted by the physical therapist are reflected in the descriptors that Durable Medical Equipment Regional Carriers use to determine the differences between the MFCL foot K-levels. All training was limited to those foot design characteristics included in the MFCL K-level descriptors, with the exception of the Proprio foot because, to date, MPAs have not been described because of their relative novelty.

A licensed physical therapist employed observational assessment and clinical judgments to ensure that all participants were able to perform all training activities without difficulty. During each 1 h training session, the subject's progress was assessed on predefined criteria. Subjects were trained only in areas in which training was needed. When they satisfactorily met the predefined criteria, training was concluded.

Prosthetic Socket

Between testing sessions 1 and 2, the prosthetic limb was fabricated and fitted. A single prosthetist who performed all socket fittings and prosthetic alignment used a computer-aided design/computer-aided manufacturing imaging and modification system. A thermoplastic suction socket design was used with either the Iceross Seal-In X5 transtibial liner (Ossur) or Iceross Synergy Cushion liner (Ossur) with external suspension sleeve, depending on fit and subject preference. A detachable coupling system was used in an effort to standardize the connection between the socket and the prosthetic feet.

Prosthetic Feet

We selected the four prosthetic feet for this study based on representation of the MFCL K-level descriptors (**Table 1**). The SACH foot (K1: external keel, SACH foot or single-axis ankle and/or foot) is a nonarticulating foot that has a molded high-density foam rubber cushioned heel and wooden keel. The SAFE foot (K2: flexible-keel foot and multi-axial ankle and/or foot) is a nonarticulating foot with a foam rubber cushioned heel, wooden bolt-block, and polyurethane elastomer flexible-keel foot. The Talux foot (K3: Flex-Foot system, energy storing foot, multi-axial ankle and/or foot, dynamic response, or flex-walk system or equal) is a carbon-fiber Flex-Foot system with a J-shape–designed dynamic response foot that incorporates an elastomer rubber block for multi-axial ankle movements. The Proprio foot is the first MPA to contain an accelerometer capable of measuring ankle motion at 1,600 Hz. It actively provides up to 10° of dorsiflexion and 18° of plantar flexion.

For each test foot, we performed the bench alignment according to the manufacturer's specifications, followed by a dynamic alignment session with the goal of achieving consensus between the prosthetist and subject regarding optimal alignment for each foot before testing. If at any time during the training or accommodation period the subject requested that the socket or foot alignment be re-examined, the prosthetist would meet with subject as soon as possible (always within 48 h). Prior to every testing session, the subjects were asked and stated that they were comfortably fit and had accommodated well to the new test foot.

At the conclusion of testing session 6, we fit subjects with one of the four study feet of their choice on their study prosthetic socket. We offered follow-up prosthetic services for an additional 90 d after the study for the prosthetic socket and foot of choice.

Data Analysis

We performed statistical analysis using SAS version 9.1 (SAS Institute Inc; Cary, North Carolina). We used descriptive statistics to describe the subjects. For analysis of subject characteristics and outcome measures, we divided subjects into two groups: those with amputations caused by diabetes and PVD (PVD group) and those caused by trauma and cancer (non-PVD group). We used an independent sample *t*-test to determine characteristic differences between the two groups. For each outcome measure, we performed a repeated-measures analysis of variance (ANOVA) to compare the six testing sessions. When the ANOVA revealed significant differences ($p < 0.05$), we applied pairwise comparisons using related pairs *t*-tests to identify the source of differences ($p < 0.05$). We computed the difference between a given pair of sessions for the subject groups and determined the mean difference for subject groups. We used a Student *t*-test to determine whether the mean difference was significantly different from zero.

RESULTS

Table 2 gives the descriptive characteristics of the five PVD group subjects and the five non-PVD group subjects. The PVD group consisted of five males and the non-PVD group of four males and one female. We found significant differences in age, height, and weight between the PVD and non-PVD groups.

The most common comorbidities of the PVD group subjects were hypertension, cataracts, type 2 diabetes mellitus for ≥4 years, and neuropathy of the nondisabled lower limb. The PVD group had 2.20 ± 2.17 comorbidities (mean ± standard deviation [SD]). The most common comorbidity of the non-PVD group subjects was hypertension. The non-PVD group had 0.60 ± 0.89 comorbidities. The mean ± SD time the subjects had used their existing prosthesis was 1.6 ± 1.4 yr, with a range from 0.6 to 6.0 yr. **Table 3** describes the details of the subjects' existing prostheses.

The median time the subjects received initial standardized prosthetic gait training with their existing prosthesis was 2 h, with a range of 1 to 4 h. We asked subjects to return for a second session to ensure that they maintained the gait pattern and remembered their home exercises. The Proprio foot was the only prosthetic foot that required up to 3 h of training because of its advanced technology and user training. All subjects completed the study in 10 to 12 weeks.

Table 4 describes the results for the self-report and performance-based outcome measures for the PVD group at baseline, after initial training, and after each prosthetic foot was fitted and worn for 10 to 14 d. The PVD group's baseline PEQ-13 and LCI-5 results revealed that their mobility would be considered to be at a high functioning level with little difficulty [19,23]. Prior work determined that the mean scores for the AMPPRO with respect to K2, K3, and K4 are 35, 41, and 45 points, respectively [13], with a minimal detectable change value of 3.3 [23]. The PVD group's baseline AMPPRO score (37) confirmed that they were functioning between K2 and K3 as per the MFCL classification (**Table 1**) [26]. The baseline 6MWT performance of 410.53 ± 66.30 m for the PVD group demonstrated that they have the potential to exceed basic prosthetic ambulation skills by approaching the K4 level [26]. We found no significant differences between the self-report measures (PEQ-13 and LCI-5) when comparing results at baseline, following initial training, and after fitting with four different prosthetic feet. The AMPPRO was the only performance-based outcome measure that demonstrated differences between baseline, initial training, and

Table 2.
Characteristics of peripheral vascular disease (PVD) group (n = 5) and non-PVD group (n = 5), their differences, and corresponding 95 percent confidence interval (CI).

Characteristic	PVD Group	Non-PVD Group	Difference Between Groups (p-value)	95% CI
Age			0.02*	2.48 to 16.71
Mean ± SD	60.60 ± 2.30	51 ± 5.83		
Range	58–64	43–57		
Height (cm)			0.049*	0.03 to 19.27
Mean ± SD	179.58 ± 8.50	169.92 ± 3.85		
Range	167.64–189.23	166.37–175.26		
Weight (kg)			0.03*	1.44 to 25.43
Mean ± SD	105.53 ± 6.42	92.09 ± 9.69		
Range	99.79–115.53	77.47–101.60		
Time Since Amputation (yr)			0.17	8.60 to 35.00
Mean ± SD	2.90 ± 1.84	16.10 ± 17.60		
Range	1.50–5.92	1.33–37.33		
Melchiorre Comorbidity Scale (points)			0.17	–0.82 to 4.02
Mean ± SD	2.20 ± 2.17	0.60 ± 0.89		
Range	1–6	0–2		

*Statistically significant ($p \leq 0.05$).
SD = standard deviation.

Table 3.
Socket design, suspension system, ankle and foot assembly, and time with existing prosthesis for each subject.

Subject	Socket Design	Suspension System	Ankle/Foot Assembly	Time with Existing Prosthesis (yr)
1	PTB	Pelite Liner with External Sleeve	Otto Bock Dynamic Motion	1.6
2	PTB	Pin and Lock	Seattle Litefoot	1.0
3	PTB	Pelite Liner	Endolite Multiflex	2.0
4	PTB	Pin and Lock	Seattle Catalyst	1.0
5	PTB	Pin and Lock	Otto Bock Dynamic Motion	2.0
6	PTB	Pelite Liner	SACH	0.7
7	PTB	Pelite Liner with External Sleeve	Otto Bock Dynamic Motion	0.7
8	PTB	Pelite Liner	SACH	1.0
9	PTB	Pelite Liner	Endolite Multiflex	2.0
10	PTB	Pin and Lock	Otto Bock Springlite	6.0

PTB = patellar tendon bearing, SACH = solid ankle cushion heel.

Table 4.
Self-report and performance-based outcome measure results for peripheral vascular disease group for each testing session ($n = 5$).

Outcome Measure	Baseline	Training	SACH Foot	SAFE Foot	Talux Foot	Proprio Foot
LCI-5 (score)						
Mean ± SD	53.6 ± 4.8	54.6 ± 1.9	54.2 ± 2.5	52.6 ± 5.5	54.6 ± 1.5	54.8 ± 1.8
Range	45–56	52–56	51–56	43–56	53–56	52–56
PEQ-13 (score)						
Mean ± SD	111.02±17.40	111.80±14.80	102.60±24.40	92.94±34.70	115.14±10.80	110.96±16.40
Range	87.8–130.0	94.9–129.8	68.4–129.8	41.6–129.8	101.5–129.8	87.3–128.7
AMPPRO (score)						
Mean ± SD	37.0 ± 2.0	40.4 ± 3.2*	41.8 ± 3.3†	40.6 ± 3.6	42.2 ± 2.6‡	41.0 ± 3.5§
Range	35–39	37–45	38–45	35–43	38–45	35–44
6MWT (m)						
Mean ± SD	410.53±66.30	432.65±42.80	463.83±57.90	439.96±38.90	456.39±44.90	437.07±54.70
Range	298.24–463.29	388.35–493.77	411.48–561.96	391.48–499.17	416.08–533.40	389.56–525.43
6MWT Speed (m/min)						
Mean ± SD	68.30±11.05	72.10±7.13	77.03±9.65	73.30±6.48	76.10±7.48	72.80±9.12
Range	49.71–77.22	64.73–82.30	68.58–93.66	65.25–83.20	69.35–88.90	64.93–87.57
Steps/Day (mean)						
Mean ± SD	—	4,336 ± 1,830	3,230 ± 1,194	3,094 ± 1,285	2,702 ± 914	2,735 ± 448
Range	—	2,302–5,971	1,927–4,473	2,001–4,982	1,656–3,686	2,210–3,247
Hours of Daily Activity (mean)						
Mean ± SD	—	3.65±1.30	3.69±1.50	3.26±1.10	3.14±0.90	3.28±0.90
Range	—	2.0–5.0	2.4–5.7	2.6–5.2	2.3–4.5	2.4–4.7

*Significant difference ($p < 0.05$) between baseline and training.
†Significant difference ($p < 0.05$) between baseline and SACH foot.
‡Significant difference ($p < 0.05$) between baseline and Talux foot.
§Significant difference ($p < 0.05$) between baseline and Proprio foot.
6MWT = 6-minute walk test, AMPPRO = Amputee Mobility Predictor with a prosthesis, LCI-5 = Locomotor Capabilities Index, PEQ-13 = Prosthesis Evaluation Questionnaire-Mobility Scale, SACH = solid ankle cushion heel, SAFE = stationary attachment flexible endoskeletal, SD = standard deviation.

between the prosthetic feet for the PVD group. The PVD group had significant improvements in functional ambulation (AMPPRO scores) following initial training with their existing prosthesis. After initial training, they were functioning at the K3 level (**Table 1**) [26]. We observed improvements in AMPPRO scores when comparing the baseline results with performance with the SACH, Talux, and Proprio feet. We found no differences between the

6MWT performance for the PVD group when comparing baseline, after initial standardized prosthetic gait training, and fitting with the different prosthetic feet. We did not see differences in steps/day and hours of daily activity between testing sessions for the PVD group.

Table 5 describes the results for the self-report and performance-based outcome measures for the non-PVD group at baseline, after training, and after each prosthetic foot was fitted and worn for 10 to 14 d. Like the PVD group, the non-PVD group perceived that they were performing mobility tasks at a high functioning level with little difficulty, as reflected by the baseline PEQ-13 and LCI-5 scores. The baseline AMPPRO scores and 6MWT performance indicate that the non-PVD group were functioning at the K4 level, suggesting that their mobility skills far exceeded those of basic ambulation and were considered normal for active adults (**Table 1**) [26]. We found no differences in their perceived ability to perform activities as per the PEQ-13 and LCI-5, functional mobility as per the 6MWT, and steps/day and daily activity as per the SAM, when comparing baseline, after initial standardized prosthetic gait training, and after fitting with the four different prosthetic feet. We found differences in AMPPRO scores for the non-PVD group when comparing differences between baseline results and following fitting with the SAFE, Talux, and Proprio feet. Interestingly, we found significant differences when comparing results following initial training and after fitting with the Proprio foot, suggesting that prosthetic ambulation improved with the Proprio foot.

Table 6 describes the differences in outcome measure results between the PVD and non-PVD groups at baseline, after training, and after each prosthetic foot was fitted and worn for 10 to 14 d. We found significant differences ($p < 0.05$) between the two groups with the AMPPRO such that the non-PVD group exhibited higher scores at baseline and with the SAFE and Proprio feet. The SAFE foot had the lowest AMPPRO score among all the feet with the PVD group, which may account for the statistically significant difference when compared with the non-PVD group. Only the Proprio foot had a significantly greater distance walked

Table 5.
Self-report and performance-based outcome measure results for non-peripheral vascular disease group for each testing session ($n = 5$).

Outcome Measure	Baseline	Training	SACH Foot	SAFE Foot	Talux Foot	Proprio Foot
LCI-5 (score)						
Mean ± SD	55.8 ± 0.4	55.6 ± 0.5	55.2 ± 1.8	55.2 ± 1.8	56.0 ± 0.0	54.4 ± 3.6
Range	55–56	55–56	52–56	52–56	56–56	48–56
PEQ-13 (score)						
Mean ± SD	123.06 ± 6.40	118.74±11.30	112.34±23.30	121.66±10.70	124.94 ± 8.30	124.02 ± 8.60
Range	115.0–130.0	101.7–129.9	74.3–130.0	103.2–130.0	110.2–130.0	109.2–130.0
AMPPRO (score)						
Mean ± SD	43.2 ± 1.3	43.6 ± 1.7*	44.0 ± 1.9	44.6 ± 1.5†	45.0 ± 1.2‡	45.8 ± 0.4§
Range	42–45	41–45	42–46	43–46	43–46	45–46
6MWT (m)						
Mean ± SD	482.14±69.60	485.92±62.20	495.01±70.30	488.18±53.20	507.34±48.10	539.94±79.60
Range	399.56–555.00	409.07–550.38	413.98–604.60	413.35–549.48	434.16–555.30	424.45–621.18
6MWT Speed (m/min)						
Mean ± SD	80.35±11.60	80.98±10.37	82.50±11.71	81.36 ± 8.86	84.55 ± 8.01	89.99±13.27
Range	66.59–92.50	68.18–91.73	68.99–100.77	68.89–91.58	72.36–92.55	70.74–103.53
Steps/Day (mean)						
Mean ± SD	—	7,321 ± 2,237	6,202 ± 1,527	7,465 ± 3,459	6,321 ± 1,598	6,769 ± 1,623
Range	—	5,474–10,423	4,689–8,548	5,023–13,274	4,722–8,930	5,037–9,409
Hours of Daily Activity (mean)						
Mean ± SD	—	5.22 ± 1.10	4.26 ± 1.20	4.94 ± 2.10	4.80 ± 1.10	4.48 ± 1.10
Range	—	4.2–6.9	2.9–6.0	3.1–8.8	2.6–5.7	2.6–6.1

*Significant difference ($p < 0.05$) between training and Proprio foot.
†Significant difference ($p < 0.05$) between baseline and SAFE foot.
‡Significant difference ($p < 0.05$) between baseline and Talux foot.
§Significant difference ($p < 0.05$) between baseline and Proprio foot.
6MWT = 6-minute walk test, AMPPRO = Amputee Mobility Predictor with prosthesis, LCI-5 = Locomotor Capabilities Index, PEQ-13 = Prosthesis Evaluation Questionnaire-Mobility Scale, SACH = solid ankle cushion heel, SAFE = stationary attachment flexible endoskeletal, SD = standard deviation.

Table 6.
Comparison between peripheral vascular disease (PVD) group and non-PVD group for self-report and performance-based outcome measures.

Outcome Measure	Baseline	Training	SACH Foot	SAFE Foot	Talux Foot	Proprio Foot
LCI-5 (score)						
Mean Difference	2.2	1.0	1.0	2.6	1.4	–0.4
p-Value	0.35	0.32	0.48	0.35	0.10	0.82
PEQ-13 (score)						
Mean Difference	12.06	6.94	9.74	28.72	9.80	13.06
p-Value	0.18	0.42	0.53	0.14	0.14	0.15
AMPPRO (score)						
Mean Difference	6.2*	3.2	2.2	4.0*	2.8	4.8*
p-Value	<0.001	0.08	0.22	0.05	0.06	0.03
6MWT (m)						
Mean Difference	71.77	53.27	31.18	48.22	50.94	102.86*
p-Value	0.13	0.15	0.46	0.14	0.12	0.04
6MWT Speed (m/min)						
Mean Difference	11.96	8.87	5.19	8.03	8.49	17.14
p-Value	0.13	0.15	0.46	0.14	0.12	0.04
Steps/Day (mean)						
Mean Difference	—	2,985*	2,972*	4,370*	3,618*	4,033*
p-Value	—	0.04	0.009	0.02	0.02	0.007

*Statistically significant (p 0.05).
6MWT = 6-minute walk test, AMPPRO = Amputee Mobility Predictor with prosthesis, LCI-5 = Locomotor Capabilities Index, PEQ-13 = Prosthesis Evaluation Questionnaire-Mobility Scale, SACH = solid ankle cushion heel, SAFE = stationary attachment flexible endoskeletal, SD = standard deviation.

in the 6MWT when comparing the non-PVD and PVD groups. Although not statistically significant, the Proprio Foot had the highest values for the 6MWT for the non-PVD group and the lowest for the PVD group. The number of steps/day was significantly ($p < 0.05$) higher in the non-PVD group after training and with all four prosthetic feet.

DISCUSSION

This study investigated the ability of self-report (PEQ-13 and LCI-5) and performance-based outcome measures to detect differences after standardized functional prosthetic gait training and between four prosthetic feet (SACH, SAFE, Talux, and Proprio) in people with unilateral transtibial amputation. While we discussed selecting a variety of prosthetic feet for this study, the four feet selected are popular designs that fairly represented each MFCL K-level. We hypothesized that after receiving training with their existing prosthesis, the subjects would increase and/or achieve a consistent level of mobility with their existing prosthesis. Also, if we found differences in the selected outcome measures after the initial 2-week training period, we would assume that they were related to differences between prosthetic feet since this was the only change with regards to their prosthesis or training. The PVD and non-PVD subjects' perception of mobility measured by the PEQ-13 and LCI-5 remained constant and at a high level throughout the study. We found no differences in the subjects' perception of mobility after receiving the initial training with their existing prosthesis and different prosthetic feet.

The ability of the PEQ-13 and LCI-5 to detect differences between prosthetic feet has never been examined. The MFCL established community ambulatory or "higher-functioning" individuals as being able to ambulate with variable cadences [9]. At baseline, the PEQ-13 scores for the PVD and non-PVD groups categorized the participants as having little difficulty performing functional activities [6]. The LCI-5 reports higher-functioning individuals as those who score at least 54 out of 60. Because the participants scored within or approached that range for the LCI-5, we suggest that a "ceiling effect" exists for this particular population. We suggest that the LCI-5 could be an ideal measure for people with lower-limb amputation whose perception of mobility is at a low to moderate level, such as those receiving rehabilitative therapy postamputation. The PEQ-13 and LCI-5 may not be appropriate measures of mobility for this study sample or to measure differences between prosthetic feet. The inability of the PEQ-13 and

LCI-5 to detect change in perception of mobility challenges clinicians to create a self-report instrument capable of distinguishing perceptional differences in mobility between prosthetic components.

After receiving the initial training with their existing prosthesis, the PVD group demonstrated improvement in AMPPRO performance and therefore functioned at a higher MFCL. The minimum detectable change value for the AMP has been reported to be 3.3 points, which is consistent with the findings of this study [23]. The PVD group were able to maintain and even improve their function after being fit with different prosthetic feet. These improvements support standardized functional prosthetic gait training as an intervention that can reduce gait deviations and improve ambulation in people with lower-limb amputation. The AMPPRO is an appropriate performance-based measure to determine change in functional capability and/or mobility. The non-PVD group's AMPPRO performance at baseline demonstrated that they were functioning at the highest MFCL for people with lower-limb amputation. They continued to function at that level throughout the study. Similar to the PVD group, the non-PVD group maintained their improvement in function from the initial training period after being fit with three of the four prosthetic feet (SAFE, Talux, and Proprio feet). Interestingly, the non-PVD group demonstrated an improvement in their AMPPRO scores after initial training and with the Proprio foot, which would suggest that the Proprio foot improved the function in a select group. The Proprio foot has been described in the literature as a quasipassive prosthetic ankle that can actively change the ankle angle in swing phase of level walking and ascending and descending ramps and stairs in order to improve the knee kinematics of the amputated limb during late stance and throughout the swing phase of gait [41–43]. Agrawal et al. found that the Proprio foot promoted higher symmetry in level walking between the intact and prosthetic limb than other prosthetic feet [43]. Other benefits of the Proprio foot on functional activities such as ascending and descending stairs and ramps have been described in the literature [27–28].

Even though there were differences in functional mobility, as per the 6MWT, the differences were not statistically significant for the PVD and non-PVD groups after receiving training with their existing prosthesis. Yet, at the study's inception, both groups' ambulation skills were consistent with active adults and athletes with lower-limb loss [26]. The 6MWT performance remained consistent throughout the study even after the subjects were fit with four different prosthetic feet. The walking velocities of this study group were found to be faster than prior studies have reported, especially with the PVD group [44–45]. The non-PVD group was faster than the PVD group but not statistically significant. However, both groups were within the moderate range (61–79 m/min) [31] at baseline. The non-PVD group, when wearing the Talux and Proprio feet, increased their velocities to what is considered moderate to fast walking velocities (80–96 m/min) [46], resulting in a significant difference between groups with the Proprio foot ($p < 0.05$).

Because both groups were considered within normal ranges for nondisabled adults [31] and instructed according to the American Thoracic Society Guideline for the 6MWT to cover as much distance as possible in 6 min, we did not anticipate that a change of foot would significantly increase their self-selected walking speed. All groups had a mean 6MWT distance that was consistent with or slightly higher than previous reports [13]. In short, if a person has reached his or her optimal moderate to fast walking speed, there may not be a significant increase in the walking speed related to prosthetic foot choice because functionally, there is not a need to increase walking speed, and physiologically, the person has achieved his or her optimal economy of effort. The value of walking speed as an instrument to detect differences between prosthetic feet in higher functioning individuals needs to be examined.

The SAM was useful in determining the level of daily activity of the subjects with regards to standardized prosthetic gait training and different prosthetic feet. Steps/day have been used as a measure of daily aerobic activity, with the goal of walking 10,000 steps/day as the target for a healthy lifestyle [47–48]. The average American has been found to take approximately 5,117 steps/day [49]. The participant's steps/day were consistent or higher than what has been reported in previous literature [50–52]. The non-PVD group's average steps were almost twice that of the PVD group and just slightly above the average American's number of steps, again suggesting that the activity level of the non-PVD group was higher than previously published reports. Hours of daily activity reported for the PVD and non-PVD groups were consistent with what has been reported for people with unilateral transtibial amputation with vascular and traumatic lower-limb loss [51]. The question that must be asked is, Would design characteristics actually increase the person's ability to walk more in the course of the day,

or is the greater contributor to steps/day motivation, personality, activity level, vocation, or other factors unrelated to the prosthetic foot choice?

In the PVD group, we found the lowest LCI-5, PEQ-13, and AMPPRO scores, along with the minimum distance ambulated, for the SAFE foot, which is classified as a K2 foot. The K3 foot (Talux foot) had higher values than the K2 foot for the same outcome measures in the PVD group. These findings suggest that the current categorization of prosthetic feet may not be consistent with the functional capabilities of people with amputation, because the K3 Talux foot appears to be an appropriate choice for both K2 and K3 people with amputation. These findings suggest that certain prosthetic foot designs may improve balance and mobility in people with amputation who have the physical capabilities to take advantage of the dynamic properties of a foot. When we compared the differences in outcome measure scores between the PVD and non-PVD groups, we found that only two performance-based measures detected differences. The AMPPRO found functional differences between the two groups at baseline and wearing the SAFE foot and the Proprio foot, with the Talux foot approaching statistical significance. Both the SAFE and Proprio feet had greater than the minimal detectable change (3.3) in AMPPRO scores, 4.0 and 4.8, respectively. The number of steps/day was also significantly greater across all conditions in the non-PVD group, confirming that they are more active throughout the day. Since the PVD group had a significant improvement in function with standardized prosthetic gait training, the results imply that functional training can enable lower-functioning people with amputation to enhance their skills to take advantage of feet typically prescribed to higher K-level ambulators.

The PVD group maintained the higher level of function after training as measured with the AMPPRO, 6MWT, and walking speed, suggesting that they retained the elements of the training and, upon observation, were able to maximize the characteristics of each of the prosthetic feet. The non-PVD group also received the training but because they had higher baseline function and were proficient with the use of their prosthetic foot, did not improve in function. Both groups received training with each new foot, focusing on its specific characteristics to ensure each foot would be evaluated without masking its functional properties because of physical gait deviations. For example, we reinforced physical gait abilities that promote optimal use of a prosthetic foot, such as equal stance time on both limbs, single-limb balance over the foot throughout stance, and the ability to balance over the foot during late stance for maximal deflection of the footplate. The intention of the training was to allow each subject to fully appreciate the characteristics of each test foot so that the outcome measures could be fairly and accurately completed based on the subject's performance with the foot.

In summary, none of the self-report or performance-based measures selected for this study was able to detect clinically significant differences between prosthetic feet in either the PVD or non-PVD groups, who had similar scores. After training, the PVD group maintained a higher level of function than the non-PVD group, and again, differences between feet could not be detected. The non-PVD group did walk significantly farther each day than the PVD group and demonstrated significantly better AMPPRO scores and 6MWT distances with the Proprio foot. These results suggest that these measures may not be suitable for detecting functional differences between categories of prosthetic feet or that the MFCL system for categorizing prosthetic feet may be flawed.

Several limitations existed in this study. Limitations related to this study are similar to many studies that examine prosthetic components. For example, the small sample size was not related to recruiting but rather to the cost and time constraints required to train each subject, fabricate the sockets, maintain the prostheses, and buy the prosthetic feet and other prosthesis-related components. A larger study population would certainly increase the power of this study and increase the confidence in the results. Additionally, alternative prosthetic foot designs might demonstrate different results from those feet we selected; because of the constraints previously described, this study was limited to four feet. We hope that this article motivates further research to investigate the use of these and other self-report and performance-based outcome measures in a larger sample of individuals who are functioning at all levels and, in particular, at the lower levels. In addition, we did not evaluate the value of the prosthetic socket and suspension system and this should be incorporated into future studies. Lastly, using instrumented functional gait analysis, such as force distribution, stride length, and step width, could provide objective findings in determining potential differences among different prosthetic feet.

CONCLUSIONS

The purpose of this study was to determine the ability of commonly used self-report and performance-based measurement instruments to detect differences between

categories of prosthetic feet in people with unilateral transtibial amputations. We found that the self-report measures (PEQ-13 and LCI-5) were unable to detect differences in participants' perception of mobility after receiving standardized prosthetic gait training with their existing prosthesis and after fitting with four categories of prosthetic feet. Between the performance-based measures, only the AMPPRO was able to detect differences in function after receiving standardized functional prosthetic gait training and being fit with four prosthetic feet. The training can enable lower-functioning people with limb loss to enhance their skills and thus take advantage of prosthetic feet typically prescribed to higher-functioning people with limb loss. The AMPPRO did not detect differences between prosthetic feet. In the non-PVD group, the Proprio foot had significantly higher AMPPRO scores and 6MWT distance than the PVD group. This study found that current self-report measures are unable to detect differences between prosthetic feet. Further research is needed to determine which selected performance-based measures are most appropriate in determining the functional difference between prosthetic foot designs.

ACKNOWLEDGMENTS

Author Contributions:

Study concept and design: R. S. Gailey, I. Gaunaurd, V. Agrawal, C. O'Toole.

Acquisition of data: R. S. Gailey, I. Gaunaurd, V. Agrawal, A. Finnieston, C. O'Toole.

Analysis and interpretation of data: R. S. Gailey, I. Gaunaurd, V. Agrawal, C. O'Toole.

Drafting of manuscript: R. S. Gailey, I. Gaunaurd, V. Agrawal.

Critical revision of manuscript for important intellectual content: R. S. Gailey, I. Gaunaurd, V. Agrawal.

Obtained funding: R. S. Gailey.

Statistical analysis: R. S. Gailey, V. Agrawal.

Administrative, technical, or material support: I. Gaunaurd, V. Agrawal, A. Finnieston, R. Tolchin.

Study supervision: R. S. Gailey, R. Tolchin.

Financial Contributions: Dr. Gailey is an educational consultant with Ossur Americas, and funding was partially supported by Ossur Americas. Ossur Americas had no role in the design or conduct of the study and collection or analysis of the data. The company reviewed the manuscript, but was not permitted to make editorial changes to the results and conclusions set forth.

Funding/Support: This material was based on work supported in part by Ossur Americas. The research project was administered through the Miami VA Healthcare System and the South Florida VA Foundation for Research and Education (grant Tolchin-01).

Additional Contributions: The authors thank Amanda D. Huckle, DPT; Robin M. McClain, DPT; Jack M. Nunes, DPT; and Meggie A. Safford, DPT, for their assistance with data analysis. Dr. Tolchin is now with the Baptist Center for Spine Care, Miami, Florida, and Mr. O'Toole is now with the Miami Project to Cure Paralysis, Miami, Florida. Dr. Gaunaurd has earned his doctorate since the submission of this article.

Institutional Review: The study protocol was reviewed and approved by the institutional review board and human studies subcommittee at the Miami VA Healthcare System and informed written consent was obtained from each subject prior to study enrollment.

Participant Follow-Up: Participants who have provided their updated contact information will be notified of the publication of this article and encouraged to check the *JRRD* Web site.

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Submitted for publication April 25, 2011. Accepted in revised form October 4, 2011.

This article and any supplementary material should be cited as follows:
Gailey RS, Gaunaurd I, Agrawal V, Finnieston A, O'Toole C, Tolchin R. Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet. J Rehabil Res Dev. 2012;49(4):597–612.
http://dx.doi.org/10.1682/JRRD.2011.04.0077