Robotic Emulation of Candidate Prosthetic Foot Designs May Enable Efficient, Evidence-Based, and Individualized Prescriptions

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ABSTRACT

Introduction: The design and selection of lower-limb prosthetic devices is currently hampered by a shortage of evidence to drive the choice of prosthetic foot parameters. We propose a new approach wherein prostheses could be designed, specified, and provided based on individualized measurements of the benefits provided by candidate feet. In this manuscript, we present a pilot test of this evidence-based and personalized process.

Methods: We previously developed a “prosthetic foot emulator,” a wearable robotic system that provides users with the physical sensation of trying on different prosthetic feet before definitive fitting. Here we detail preliminary demonstrations of two possible approaches to personalizing foot design: 1) an emulation and test-drive strategy of representative commercial foot models, and 2) a prosthetist-driven tuning procedure to optimize foot parameters.

Results: The first experiment demonstrated large and sometimes surprising differences in optimal prosthetic foot parameters across a variety of subjects, walking conditions, and outcome measures. The second experiment demonstrated a quick and effective simple manual tuning procedure for identifying preferred prosthetic foot parameters.

Conclusions: Emulator-based approaches could improve individualization of prosthetic foot prescription. The present results motivate future clinical studies of the validity, efficacy, and economics of the approach across larger and more diverse subject populations.

Clinical Relevance: Today, emulator technology is being used to accelerate research and development of novel prosthetic and orthotic devices. In the future, after further refinement and validation, this technology could benefit clinical practice by providing a means for rapid test-driving and optimal selection of clinically available prosthetic feet. (J Prosthet Orthot. 2022;34:202–212)

KEY INDEXING TERMS: emulator, test-drive, prosthesis, ankle, amputation, walking

The principles of evidence-based practice and personalized medicine are transforming modern-day health care.1,2 Within the field of prosthetics, however, the selection, prescription, and provision of prosthetic feet rely on craftsmanship3,4 despite a growing body of scientific literature, which provides some evidence that could be used to support clinical decision-making.5 Evidence-based practice calls for “integrating individual clinical expertise and patient values with the best available evidence from systematic research, to provide the best clinical care,”6 and personalized medicine calls for this evidence to be valid.

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interpreted in light of both qualitative characteristics and quantitative test results from individual patients. However, when patients with lower-limb amputation are evaluated for the prescription of a prosthetic foot, current processes allow minimal opportunities to collect the data necessary to make such individualized assessments and decisions.7 Producing the evidence required for objective decision-making is challenging given the complexity of patients' needs and the broad spectrum of prosthetic foot functionalities, which is rapidly expanding due to technological advancement. Although recent advancements in advanced robotic prosthetic foot design suggest that it is possible to normalize gait for persons with lower-limb amputation,8–11 results have been inconsistent across studies and individuals,12 have been limited to relatively young and mobile patients, and have not addressed how comorbidities and other functional limitations impact gait performance.13 Furthermore, there are many different prosthetic feet available, each with variations in size, stiffness, and other parameters, and the cost of these feet varies across three orders of magnitude. As a result, persons with lower-limb amputation continue to be disadvantaged as compared with persons without amputation,14,15 and cost/benefit tradeoffs for prosthetic design remain poorly understood.16

In conventional prosthetic foot prescription, patients are evaluated and prosthetic feet are selected primarily by subjective means through observations and patient interviews assessing current abilities and goals, as well as previous life experience and prosthetic usage. Clinicians, such as physiatrists or prosthetists, refer to published evidence, experience with prior patients and prostheses, and professional judgment to determine which foot to select. In some cases, a functional performance evaluation is also performed to add limited objective data.17 Although both observations and functional evaluations can be interpreted in light of evidence and best practice guidelines, this approach remains unable to answer critical questions affecting the ideal prescription for a specific individual, such as how a patient's abilities, confidence, and satisfaction will change when fitted with a new prosthetic foot, especially one with advanced functionality.3–5,7 In some cases, practitioners order multiple candidate prosthetic feet, fit each in sequence for a trial period, gather feedback from the patient, and return unwanted ones. This can provide valuable individualized empirical information to inform decision-making but is a cumbersome and financially risky process given the time involved in fitting multiple feet and the need to manage returns of unwanted feet back to suppliers.

To address the unmet clinical need for more and better evidence to drive prosthetic foot prescription, we propose a novel empirical approach that informs the selection of prosthetic feet in an individualized manner. Using our previously designed prosthetic foot emulator,18,19 we developed an approach that enables rapid side-by-side trialing of prosthetic feet.20,21 In this novel approach, clinicians can select from a variety of prosthetic foot categories, product models, and/or product configurations with differing mechanical characteristics to evaluate, which might be most appropriate and satisfactory for an individual patient. The mechanical characteristics of each candidate foot are programmed into the robotic emulator system, which then replays those characteristics for patients to test drive. This provides patients with the physical sensations of wearing the actual prosthetic feet, but without having to purchase and fit each physical foot. Implementing new foot emulations into the program using the mechanical characteristics of prosthetic feet is straightforward, and even hypothetical designs can be considered. Patients are then guided through a series of mobility tests where clinicians can evaluate functional performance, movement aesthetics, patient preference, and/or patient reported outcomes (e.g., balance confidence, pain, perceived exertion). Objective biomechanical measurements can be taken to evaluate outcomes such as balance, range of motion, symmetry, compensations that might put the patient at risk, or even energy consumption. Clinicians can consider broad differences in movement behavior, for example, observing that an individual could advance from a K2 Medicare Functional Classification Level (MFCL; K2 indicating limited community ambulation)3 to a K3 MFCL (indicating broad community ambulation with variable cadence capability) if provided with the appropriate prosthesis. Clinicians also could tune more subtle effects with variations in foot parameters, for example, specifying a 10% change in keel stiffness to individualize foot stiffness category selection. Changes in outcomes could then be weighed against practical constraints, such as the patient's health coverage and ability to pay, across a spectrum of different foot options.

Using emulation, patient outcomes that would result from using various candidate prosthetic feet can be predicted. Such a process, if validated, could be used clinically—before prescription—to drive evidence-based and individualized prosthetic foot prescriptions. Evidence could include patient-specific subjective and/or objective measures. The two studies described within this manuscript serve as an initial demonstration of such emulator-based approaches.

We describe here two experiments conducted to investigate the feasibility of emulator-based approaches to prosthetic foot prescription. First, we assessed the emulator's ability to mimic the behavior of different categories of feet during use by persons with transtibial amputation, while measuring a variety of outcome metrics to understand the importance of individualized prescription approaches. We hypothesized that the “best” foot would vary across subjects, inclines, and outcome measures. Second, we tested a proof-of-concept preference optimization protocol for selecting among a variety of candidate foot parameters. We hypothesized that for relatively simple parameterizations of prosthetic foot behavior (here, three parameters), manually exploring and tuning the parameters would result in near-optimal settings within 5 minutes. We present comprehensive results for individuals from a convenience sample in each study to explore the strengths and weaknesses of the proposed emulation-based prescription approach.

**METHODS**

**TECHNICAL DESCRIPTION OF THE PROSTHETIC FOOT EMULATOR**

The prosthetic foot emulator (Figure 1) consists of an off-board electric motor, a real-time controller, a flexible tether transmitting sensor signals and mechanical power, and a prosthetic foot end-effector (Figure 2). The user wears the prosthetic foot as they would a conventional prosthetic foot, except that they are constrained by the tether. The tether does not interfere
with natural leg swing, but does limit the distance the user can travel relative to the actuation system, which we accounted for by having subjects walk on a treadmill.

A complete description of the emulator hardware is provided in a previously published manuscript. The motor is a 1.61-kW servomotor driven by a 3-phase industrial motor controller. A real-time controller reads sensor signals and computes motor commands to track the desired emulation profiles. The flexible tether consists of sensor transmission lines and a steel coil Bowden conduit that houses a 3-mm Vectran synthetic rope. A prosthetic foot end-effector provides a passive compliant heel and an articulated forefoot with control of forefoot plantarflexion torque about the ankle, achieving closed-loop bandwidth of 17 Hz and worn mass of less than 1 kg. Torque control parameters were hand-tuned to provide good torque-tracking performance while being robust to changes in walking speeds and gait styles.

SUBJECT RECRUITMENT

In each study, we recruited six able-bodied individuals with unilateral transtibial amputation to test the efficacy of the prosthetic foot emulator. Convention sampling was used, given the preliminary and exploratory nature of these pilot studies. All subjects were determined by their physician to be of a K3 functional level, although significant differences in gait ability were observed. Subjects were screened for their ability to walk comfortably with their prescribed prosthesis for several minutes at a time without a walking aid. Good socket fit, as determined by each subject's clinical care team, was a necessary condition for inclusion in the study. Experience with prosthetic use varied from less than 1-year postoperation to 46 years. Treadmill speed was set to either 1.25 m/s or the subject's preferred walking speed if it was less than 1.25 m/s. Preferred walking speed was measured overground in a timed walk down a 50-m hallway using the subject's daily-use prosthesis. Subjects weighing in excess of 210 lb were not recruited for the study given the hardware limitations, although higher-capacity versions of the prosthetic foot end-effector have now been developed. All subjects completed the protocol twice to ensure familiarity with all conditions, with data reported for the second repetition. Some subjects had additional prior experience with the emulator hardware. All subjects provided written informed consent before completing the protocol, which was approved by the Carnegie Mellon University Institutional Review Board.

EMULATOR FITTING

Subjects wore the prosthetic foot emulator as they would a standard prosthetic foot: a pylon with universal prosthetic foot adapters at each end was sized according to each subject's leg length and used to attach the prosthetic foot emulator to each subject's socket. Subjects used the socket provided by their clinical prosthetist for normal daily use. Subjects were fitted with the prosthetic foot emulator by a certified prosthetist who set the physical alignment of the foot, which was then retained throughout each study. Fitting was performed using a standing mode, which held motor position constant, providing a passive spring-like behavior to the user. In study 1, the sagittal alignment of the foot (plantar/dorsiflexion 0° position) was set to match the reference data of the commercially available prosthetic foot categories, whereas in study 2 it was optimized along with other prosthetic foot parameters.

STUDY 1: COMPARING PROSTHETIC FOOT CATEGORIES

For our first proof-of-concept study, hypothetical behaviors were programmed to demonstrate the system's flexibility and ability to emulate experimental designs for testing before standalone implementation. We assessed the emulator's ability to differentiate individual physiological response to different prosthetic foot features for a range of individuals, walking conditions, and outcome measures. Emulated behavior was switched using controls in a software interface, without mechanically modifying emulator hardware. Six subjects participated in the experiment (Table 1).

The experimental protocol consisted of 2 days of walking: 1 day walking on a level treadmill and the other on an inclined (5°) treadmill. Each subject walked with his prescribed prosthetic foot (PRES) and with the emulator in four modes (Figure 3): SACH, emulating a traditional solid ankle cushioned heel foot, which consists of a rigid ankle and compliant foam foot; DER, emulating a dynamic elastic response foot, which consists of compliant carbon fiber ankle and foot members; BiOM, emulating the BiOM T2, which is a modern powered robotic ankle with a compliant foot; and HIPOW, a custom mode designed to...
maximize torque during plantarflexion, resulting in a high-power output. SACH and DER modes exhibited net negative work during each step (energy absorption), whereas BiOM and HIPOW conditions provided net positive work (powered propulsion). Foot behavior is emulated by rendering the ankle torque versus angle relationships of commercially available and hypothetical prostheses. Reference data for the commercial-foot modes were sourced from previously published inverse dynamics analyses of persons with amputation walking with a typical specimen of each respective foot category normalized by subject weight. HIPOW was designed to maximize torque during plantarflexion, with the expectation that torque would not be tracked precisely. Conditions were presented in random order. Subjects walked for 7 minutes in each condition and were required to rest for 5 minutes between conditions. To switch the emulator from one mode to another, the experimenter selected a different ankle torque versus angle reference trajectory, scaled for each subject’s weight.

Subjects’ walking performance was measured in each emulator mode using a variety of techniques that could inform foot prescription. Four different metrics were used: two objective measures of steady-state walking economy (metabolic energy consumption rate and heart rate), a functional performance measure (maximum walking speed), and a subjective measure (subject-reported ease of walking). Metabolic energy consumption rate was estimated from oxygen and carbon dioxide concentrations and flow rates of expired breaths, measured by a commercial respirometry system (Oxycon Mobile), and averaged over the last 3 minutes of each trial. Heart rate was measured by the same respirometry system using pulse oximetry and averaged over the last 3 minutes of each trial. Net metabolic energy consumption and net heart rate were computed as the average measurement in each condition, minus the average measurement during a quiet standing trial before any conditions. Maximum sustainable walking speed was established at the end of each walking trial by progressively increasing the speed of the treadmill in 0.05 m/s increments every 10 strides until the subject indicated they felt they could no longer sustain walking at the set speed for 5 more minutes. Subject-reported ease of walking was assessed by asking the subjects to rate each of the emulated modes on a Likert scale that ranged from −10 to 10, where −10 indicated “walking is impossible,” 0 indicated “similar to walking with my prescribed prosthesis,” and +10 indicated “walking is effortless.” Subjects were also given the option to

![Figure 3](image-url)

**Figure 3.** Emulating ankle torque versus angle behavior of candidate prostheses for a representative user. Demonstrated emulations include the following: A, solid ankle cushioned heel (SACH); B, dynamic elastic response (DER); C, an active robotic foot, the BiOM T2 (BiOM); and D, a conceptual high-powered robotic foot design (HIPOW). Top, Prosthetic foot ankle torque plotted versus % stance of the prosthesis-side step. Shaded region indicates root mean squared error (RMSE) about the mean measured trajectory. Bottom, Prosthetic foot ankle torque plotted versus prosthetic foot ankle angle.

| No. | TS, m/s² | Cause       | TSA, y | Age, y | BW, lb | Prescribed Foot                  |
|-----|----------|-------------|--------|--------|--------|----------------------------------|
| 1   | 1.25     | Traumatic   | 9      | 42     | 176    | Fillauer Wave                    |
| 2   | 1.25     | Traumatic   | 6      | 57     | 183    | Ottobock Triton VS              |
| 3   | 1.25     | Traumatic   | 1      | 45     | 180    | Össur Vari-Flex                 |
| 4   | 1.25     | Traumatic   | 12     | 48     | 210    | BiOM T2                         |
| 5   | 1.25     | Congenital  | 46     | 49     | 165    | Freedom Inovations Renegade AT   |
| 6   | 0.90     | Deep vein thrombosis | 18 | 53   | 189    | Össur Vari-Flex TS               |

*Refers to each subject’s deidentified subject ID, TS refers to treadmill speed used for each subject throughout the study, Cause is the cause of amputation as indicated by each subject, TSA refers to the approximate time that the study was conducted after each subject’s amputation, Age is each subject’s age, BW refers to each subject’s bodyweight, and Prescribed Foot refers to the make and model of foot that each subject was most recently prescribed for their normal daily use.
write down their subjective impressions on how the emulations felt compared with feet they had experienced previously. Subjects recorded their subjective feedback immediately after each trial and were blinded to the name and parameters of each condition.

Measures of ankle torque and angle were calculated using onboard encoders (torque was inferred by measuring the deflection of a calibrated series elastic spring situated between these encoders).\textsuperscript{18} Emulation accuracy was assessed by computing the root mean squared error (RMSE) between the desired and measured trajectories of ankle torque versus time. The net work was computed as the integral of ankle power, which was calculated as ankle torque multiplied by ankle angular velocity, over the course of the stance period.

STUDY 2: OPTIMIZING FOR SUBJECTIVE PREFERENCE

For our second proof-of-concept study, we assessed the emulator's utility as a tool for optimizing passive prosthetic foot parameters using a simple manual tuning procedure. Subjects walked on a level treadmill at a steady speed, whereas a certified prosthetist adjusted the three parameter settings that controlled keel behavior. The prosthetist tuned these three parameters during testing through slider bars in a simple software interface on a desktop computer. Six subjects participated in the experiment (Table 2).

We parameterized the behavior of a compliant keel using three parameters we called “alignment,” “stiffness,” and “shape” (Figure 4). The “alignment” parameter adjusted the ankle angle at which the forefoot produced zero torque, which effectively controls the ankle angle at foot-flat (initial toe contact) and toe-off while simultaneously altering stiffness to hold the maximum ankle torque and peak dorsiflexion constant. “Alignment” had units of degrees and was adjusted in 3.75° increments across an allowable range of 0° to 15° plantarflexion. The “stiffness” parameter adjusted the forefoot angle at which maximum torque was achieved, which effectively specified the slope of the torque versus dorsiflexion angle curve; smaller “stiffness” values result in higher physical stiffness. “Stiffness” had units of degrees and was adjusted in 3.75° increments across an allowable range of 5° to 20° dorsiflexion. These increments in stiffness exceeded the “just noticeable difference” identified by other researchers.\textsuperscript{26} The “shape” parameter adjusted the behavior of the ankle throughout midstance to produce a “stiffening” or “softening” nonlinear spring law, without altering the end points of the spring emulation. “Shape” was unitless and was adjusted in increments of 0.35 across an allowable range of −0.7 to 0.7, with 0 corresponding to a linear response (Figure 4).

These parameters defined a Bezier curve that controlled characteristics of the ankle torque versus angle profile. Default settings were roughly similar to the DER mode described in study 1. A “maximum torque” parameter was set to correspond approximately with the maximum ankle torque observed during walking. Upper and lower bounds on parameters were selected empirically through pilot testing to determine ranges that were both wide and tolerable by a variety of subjects. Parameter adjustments were restricted to energy-neutral emulations, such that the prosthetic foot did not significantly absorb or deliver net work on each step. A linear extrapolation determined ankle torque beyond the angle corresponding to the “maximum torque” to avoid extreme curve slopes in situations for high positive or negative values of shape. The MATLAB code used to define the Bezier curve can be found in Supplemental Digital Content 1, http://links.lww.com/JPO/A81.

FORCED EXPLORATION

First, subjects performed a forced exploration trial, in which the prosthetist systematically guided them through a predefined group of parameter combinations to ensure subjects experienced the full range of parameter values the system could achieve. Starting from the default parameter values, each parameter was independently increased to its maximum value, then decreased to its default value, then decreased to its minimum value, then increased back to its default value. Finally, again starting from the default parameter values, “alignment” and “stiffness” were increased in tandem to their maximum values, then decreased to their default values, then decreased to their minimum values, and increased back to their default values. Subjects walked for 15 seconds in each combination of parameters.

PARAMETER TUNING

Second, subjects performed a manual tuning trial, in which the prosthetist tuned the settings to determine the optimal values for the individual subject. The tuning methodology was left up to the prosthetist's discretion. Although the use of the prosthetic foot emulator was new to the prosthetist, the

| No. | TS, m/s\textsuperscript{2} | Cause | TSA, y | Age, y | BW, lb | Prescribed Foot |
|-----|-----------------|--------|-------|-------|-------|----------------|
| 1   | 1.25            | Traumatic | 9     | 42    | 176   | Fillauer Wave  |
| 2   | 1.25            | Traumatic | 23    | 26    | 200   | Freedom I. Thrive |
| 3   | 0.90            | Compart. syndrome | 14   | 37    | 155   | Freedom I. Senator |
| 4   | 0.90            | Deep vein thrombosis | 18   | 53    | 189   | Össur Vari-Flex TS |
| 5   | 0.90            | Traumatic | <1    | 34    | 185   | Ability Rush 87 |
| 6   | 1.00            | Congenital | 46   | 49    | 165   | Freedom I. Renegade AT |

\textsuperscript{*}Refers to each subject’s deidentified subject ID, TS refers to treadmill speed used for each subject throughout the study, Cause is the cause of amputation as indicated by each subject, TSA refers to the approximate time that the study was conducted after each subject’s amputation, Age is each subject’s age, BW refers to each subject’s bodyweight, and Prescribed Foot refers to the make and model of foot that each subject was most recently prescribed for their normal daily use.
prosthetist noted that the experience was quite reminiscent of adjusting a conventional microprocessor-controlled prosthetic knee or ankle. Two bouts of optimization were performed. The subject and prosthetist were instructed to work together to determine the best value for each of the settings. Optimization began from an initial condition that was standardized across subjects: −12.5° for “stiffness,” 7.5° for “alignment,” and 0 for “shape” for the first bout, and values corresponding to the “best” settings from the first bout for the second bout. Each tuning bout ended when the prosthetist and subject determined it was not possible to further improve the behavior of the foot or 5 minutes had elapsed, whichever came first.

VALIDATION

Finally, we validated that the tuned settings were in fact preferred through a double-blind validation. We compared the tuned settings to a validation set that consisted of five different conditions (A to E). Within the validation set, two of the parameters were held constant (alignment and shape), whereas the third varied across the range of possible values (stiffness). Settings were changed once every 12 seconds, and the subject was instructed to vocalize whether each setting was “better than,” “worse than,” or “about the same as” the setting that preceded it. These patient-reported preferences were scored +1, −1, or 0, respectively. The order of appearance of each set of parameters was randomized such that subjects experienced each of the possible back-to-back comparisons once per validation bout. Three bouts of validation were performed, and subjects received a 2-minute break between bouts. Each condition was scored in comparison against each other condition, counting the number of comparisons in which it was rated better than the alternative. Each condition’s overall score was the sum of these comparisons against each of the others.

RESULTS

STUDY 1

EMULATOR CONTROLLER PERFORMANCE

The quality of the ankle torque versus angle control scheme used in each study was assessed in study 1. The mean desired and measured prosthetic foot ankle torque trajectories during the stance phase of the prosthetic limb are presented for a representative subject in Figure 3, along with the reference data used to design the emulation for comparison. The data presented are from a representative subject walking at 1.25 m/s on level ground for 150 strides. The mean RMSEs in torque tracking across all subjects were 7.8 ± 2.4 Nm, 2.6 ± 0.7 Nm, 3.4 ± 0.9 Nm, and 7.9 ± 1.1 Nm for SACH, DER, BiOM, and HIPOW modes, respectively. These values represent between 2% and 4% of the maximum ankle torque, depending on mode.

VARIABILITY ACROSS SUBJECTS, WALKING CONDITIONS, AND OUTCOME MEASURES

Although some trends in the effects of each foot were observed across subjects, walking conditions, and outcome measures, considerable variability pervaded (Figure 5). Emulation modes, which provided net positive work (i.e., BiOM and HIPOW), often provided a metabolic energy benefit for subjects, particularly during uphill walking, but two of the six subjects consumed the lowest metabolic power in the DER mode on level ground. Heart rate followed a somewhat similar qualitative trend, although heart rate and metabolic rate trends were qualitatively different for two of the six subjects. Maximum walking speed was generally less affected by foot selection, although four of the six subjects were able to achieve considerably higher walking speeds in the net positive work modes. Subject-reported ease of walking was often inconsistent with other outcome measures, and five of the six subjects reported greater ease when net prosthetic foot work was slightly lower than that which maximized other outcomes.

STUDY 2

FEASIBILITY OF PREFERENCE-BASED MANUAL TUNING OPTIMIZATION

Prosthetist-tuned settings always encompassed the best and/or second-best settings determined through the validation tests (Figure 6). Stiffnesses far from the preferred setting resulted in more consistent rejection, resulting in bell-shaped curves for each subject. Considerable variability in each subject’s preferred stiffness setting was observed across subjects.

Tuning times for the first and second bouts of parameter tuning for each subject were 4:03 ± 1:43 and 2:57 ± 1:05 (min: sec; mean ± standard deviation), respectively. During validation,
parameter settings were nominally switched every 12 seconds, for a total of 2:12 (min:sec) per validation bout, although this was not tightly controlled. Tuning parameter selections and measurement accuracy did not systematically vary across bouts, despite increased subject and prosthetist exposure. Only subject 4 reached the 5-minute time limit for tuning, during only the first bout of tuning.

We observed that prosthetist tuning tended to proceed as follows. Starting from the default settings, the prosthetist inquired, “how does this feel?” Based on the response, and upon visual inspection of gait quality, the prosthetist adjusted the settings in the direction expected to improve overall satisfaction. This process was repeated, with pseudorandom parameter changes injected by the prosthetist to elicit a response. The prosthetist stopped when they felt that they were no longer able to improve the behavior of the foot.

**DISCUSSION**

**STUDY 1**

The emulator exhibited high-quality tracking of the ankle torque versus angle relationships of different categories of commercially available prosthetic feet as well as a hypothetical prosthetic foot. It was successful in eliciting a wide variety of biomechanical and subjective responses from subjects across a range of emulation modes under steady-state level-ground and inclined walking. Future work is needed to validate the accuracy...
The average RMSE of the ankle torque versus angle tracking was below the just-noticeable difference previously reported for people with amputation. Anecdotal commentary from the subjects indicated that the various prosthetic foot emulations matched the respective feet with which subjects had prior experience, with some subtle differences. Two subjects had experience walking with SACH feet and reported that the emulated version felt similar; they noted very high stiffness, causing knee hyperextension and making it difficult to walk quickly, which was deemed consistent with real SACH feet. All subjects had extensive experience walking with DER feet and reported that the DER mode was comfortable and felt similar to their prescribed DER foot. One subject whose prescribed foot was a BiOM T2 reported that the DER mode felt most similar to his prescribed foot; this surprising result could have been caused by tuning of the BiOM to result in low energy output—a phenomenon noted by other researchers. Regardless of whether that was the case, this subject's comment suggests that a fixed ankle torque versus angle reference for BiOM emulation may be too simplistic; a more accurate control architecture should be implemented before clinical use. All subjects found the HIPOW modes compared with the DER and BiOM modes was likely caused by greater deviation of their behavior from the passive compliance of the prosthetic foot end-effector and Bowden cable transmission.

Importantly, none of the subjects experienced optimal outcomes for any one emulation mode across all inclines and walking conditions, highlighting the need to subjectively weigh the relative importance of various outcomes if such data were to be considered in clinical decision-making. In other words, objective outcomes may be secondary to the individual's preference in determining the best prosthetic prescription—an idea that comports with current preference-driven prescription practices. This finding suggests limits for objective outcome measures in an emulator-driven prescription process but supports the potential benefit of a test-drive approach to determining what prosthesis is in fact preferred, as trialed in study 2.

**STUDY 2**

A certified prosthetist with minimal training in the use of a prosthetic foot emulator was able to effectively use this tool to tune three parameters characterizing the mechanical response of an emulated passive prosthetic foot to maximize overall satisfaction. Tuning was consistent with longer structured validation trials and, anecdotally, seemed to be a quick (approximately 3 minutes) and intuitive process for prosthetist and subject. Given the apparent ease and simplicity of the approach and the similarity of the parameter space to conventional prosthetic feet, the clinical relevance of the approach seems promising. In future clinical application, such an approach might help prosthetists select off-the-shelf feet or specify the design of custom feet that more specifically address individual patients' needs. This protocol could be expanded and refined to bring it closer to clinical translation. New algorithms for human-in-the-loop optimization of assistive device function might further speed this process and improve assessment precision. Neither prosthetist nor patient need to know which make or model of foot is being emulated, so this process has the potential to be unbiased by external factors such as cost or prior preference. Objective measures such as socket moments, step counts, and other point-of-care instrumentation could be incorporated into the protocol and weighed against subjective preferences of prosthetist and subject.

We observed that the optimization procedure and validation protocol were sensitive to characteristics of individual subjects. For example, although a discrete change from one parameter value to another may have been clear and significant to one subject, it may have been too subtle for another to discern. It was difficult to tightly control the timing of parameter tuning and validation as subjects would occasionally request extra time to consider a particular set of parameter values before vocalizing...
their preference. Future work could address methods of adapting the step size and range of parameter values to individual users. The prosthetist’s ability to interpret verbal feedback also varied across subjects, which suggests that prosthetists may prefer to spend more time with irresolute patients. Future work should also investigate how the process differs subjectively and in terms of outcomes across different prosthetists of various background, experience, and training.

LIMITATIONS OF THE STUDIES AND FUTURE WORK

In study 1, we demonstrated emulation across different categories of prosthetic feet. DER feet are among the most often prescribed; therefore, in study 2, we focused on optimizing variations of prosthetic foot parameters within this category. Different brands, models, and configurations, including variations in stiffness, damping, geometry, and weight, are known to alter foot behavior in subtle yet meaningful ways. Our study results were consistent with these findings and demonstrate that it is possible to both select across broad foot categories and optimize within a specific category on the basis of various quantitative outcomes of interest. In clinical prosthetic foot prescription, once a candidate prosthetic foot model is selected, it is then customized to best suit an individual’s needs. All clinically available feet incorporate pylons and pyramidal adapters, which are adjusted to set the position and orientation of the prosthetic foot relative to the individual’s residual limb. Some foot parameters are typically specified according to an individual’s shoe size, body weight, and activity level. Some feet have additional features that can be adjusted, such as damping or bumper placement. The complexity of the possible adjustments grows further with robotic feet that have software parameters that can be tuned. These types of adjustments were not considered in study 1 but were the focus of study 2. When comparing different feet clinically, all adjustable parameters are ideally optimized to ensure the best solution is provided to the patient, so one can imagine that a combination of our study 1 and study 2 methods would be most appropriate for eventual translation of an emulator-based approach.

For future studies, we will obtain candidate prosthetic feet and systematically characterize their torque versus angle relationships using benchtop methods based on industry-standard test methods to design emulation modes that more detailed, more accurate, and unaffected by individuals’ gait styles.

In future work, we plan to validate the approach by comparing it to the conventional prescription process in a double-blind experimental protocol. The ease of blinding the user and the prosthetist to the type, brand, and cost of the prosthetic foot being tested is an important advantage of an emulator-based evaluation. Emulator systems with additional degrees of freedom are in development to emulate additional prosthetic foot features, such as split-toes for inversion-eversion compliance. Simple mechanically adjustable elements are also in development, such as swappable forefoot levers to adjust the emulator to the user’s foot size and swappable heel springs to investigate and emulate the effects of varying heel stiffness. The assessment protocol we demonstrated could be refined, simplified, or expanded depending on the clinical use case. We believe the incorporation of clinically validated self-reported mobility measures as well as balance-related outcomes to be of particular interest for future work.

The prosthetic foot emulator cannot be used during community ambulation because of its tethered actuation and control system, so it is limited to use in a clinical laboratory setting. To better simulate real-world prosthetic foot use, the experimental protocol could be expanded to include a variety of different gait conditions including stairs (by use of a stairmill), uneven ground (by use of an uneven ground treadmill), standing or running, and including pushes, pulls, or trips. We are also developing more portable versions of the off-board actuation and control systems.

Laboratory-based emulation approaches cannot account for long-term adaptation effects that are expected to occur over the course of hours, weeks, months, or years of use of the various modes in daily life, but we expect even a few minutes of exposure to provide valuable insights to clinicians about the degree to which different foot designs will benefit their patients. The appropriateness of any given accommodation period for trialing prosthetic feet will likely depend on the specifics of both the user and the device and the nature of the comparisons being made. In future work, we will test the degree to which short in-lab exposure is predictive of longer-term outcomes. In practice, the benefits of longer duration of exposure to each emulation mode (i.e., confidence in the real-world relevance of in-lab outcomes data) would need to be weighed against the benefits of breadth of exposure to many different emulation modes (i.e., increasing the potential to discover “better” prosthetic foot mechanics).

Although our subjects varied greatly in time since amputation and in make and model of prescribed foot, they were relatively homogeneous in K-level, cause of amputation, and weight. We expect that users with lower K-level, dysvascular amputation, and/or significantly higher or lower body weight could have different needs from the subjects tested here. Future studies should recruit a larger sample, including individuals with more diverse medical histories.

Additional discussion of results, limitations, and future work can be found in Supplemental Digital Content 1, http://links.lww.com/JPO/A81. Topics covered include ongoing development of benchtop mechanical characterization methods for prosthetic foot emulation (as an alternative to inverse dynamics described in study 1), various opportunities to expand the scope of emulation such as variable mass and viscoelasticity, and alternative tuning procedures (motivated by study 2).

CONCLUSIONS

These proof-of-concept studies suggest that a prosthetic foot emulator could feasibly be used to inform evidenced-based practice and individualized care in prosthetic prescription. Preliminary results of the approach from these studies demonstrate the potential utility of a prosthetic foot emulator as a tool for 1) test-driving candidate prosthetic foot designs and 2) developing a clinically relevant protocol for optimizing prosthetic foot behavior. Additional studies should focus on refining this approach and investigating its long-term outcomes and clinical translation.
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