A Comparative Assessment of Transfemoral Prosthetic Sockets

Identifiers: NCT04038580

Unique Protocol ID: HUM00140733

Document Date: 10/7/2021

HUM00140733

Title: A comparative assessment of conventional and adjustable transfemoral prosthetic sockets

Principal Investigator: Deanna Gates, Ph.D.

BACKGROUND:

Within the next three decades, well over one million Americans are expected to be living with an amputation of the lower limb (Ziegler-Graham et al. 2008) yet many will not wear them due to discomfort. Nearly 40% of individuals with lower limb amputation report that their biggest concern when receiving a prosthesis is comfort and fit (Seaman 2010), and, in a study of 78 traumatic-amputees, 57% reported dissatisfaction with prosthetic comfort (Dillingham et al. 2001). Discomfort is one of the leading factors limiting prosthetic use and the amount of time spent in weight-bearing activity (Ali et al., 2012), in turn limiting physical activity. Inactivity resulting from prosthetic disuse may potentially contribute to reductions in residual limb muscle mass and strength (Sherk et al. 2010) and, inactivity is a well-recognized pathway to increased morbidity and mortality. Thus, for individuals with lower limb amputation, prosthetic comfort is vital to the maintenance of a healthy life style. The primary cause of this discomfort is the prosthetic socket - the portion of the prosthesis that fits snugly over the residual limb. Indeed, a 2001 clinical review on current and future developments in the field stated that: "The single most critical aspect of any prosthesis is the quality of the interface between the limb …and… prosthesis. The …socket determines the amputee's comfort and ability to control the artificial limb" (Marks and Michael 2001).

Even in a well-suspended, well-fitting socket, diurnal fluctuations in the volume of the residual limb can limit the extent to which prosthesis users are able to maintain fit throughout the day. During an average work day, the residual limb may lose between 6-7% of its volume (Board et al. 2001) due to fluid imbalance during loading and unloading. To accommodate for changes in limb volume throughout the day, prosthesis users are instructed to add or remove prosthetic socks for a traditional socket (Fig 1D) or to adjust the size of the socket using an adjustable socket system. There are several adjustable socket systems that have recently come on the market, including the The Quatro Socket (Quorum Prosthetics, Windsor, CO, USA), Infinite Socket (LIM Innovations, San Francisco, CA, USA), and CJ Socket (CJ Sockets Technologies, Beverly, MA, USA).

The patented Quatro Socket design (Joseph Johnson, Quorum Prosthetics, Windsor, CO) has 4 opposing zones of compression based on the patented HiFi interface (Randall Alley, biodesigns, inc., Westlake Village, CA). The original design has three independently adjustable zones (2 longitudinal compression, 1 circumferential brim) which allow for macro and micro adjustments throughout the users day. These adjustments can improve the ease and time to don and doff the prosthesis, account for volume fluctuations from -5% to 11%, and change the amount of compression that the user feels most comfortable in. The wearer can quickly loosen, tighten and modify the compression by simply adjusting one of the three Boa dials located on the socket.

The LIM Infinite socket (Fig. 1B) consists of a heat moldable textile brim, carbon fiber struts, flexible plastic inner cup, a lanyard suspension unit, and anodised alignment base plate. The CJ socket system (Fig 1C) consists of a rigid J-shaped frame, a non-elastic garment referred to as the 'sail' and an adjustable closure. While implemented differently, each allow the user to adjust the

fit of the socket manually while it is donned. Each socket system claims to improve socket comfort and fit and some also claim to improve mobility and walking endurance. However, as they are so new to the market, there is no objective outcomes research to support these claims.

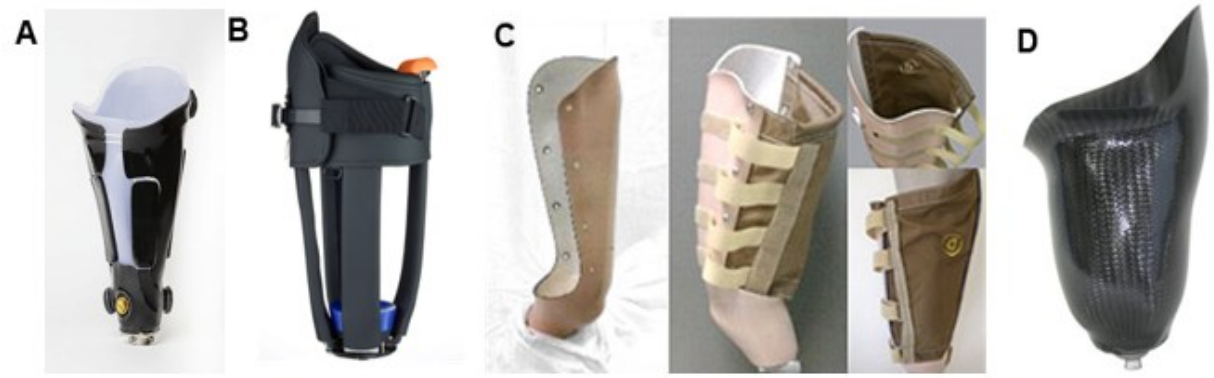

Figure 1. New prosthetic socket options. A) Quorum Prosthetics ' "The Quatro" (opquorum.com/) B) LiM's "Infinite Socket" (liminnovations.com), C) CJ Socket Technologies' "CJ Socket" (image from www.pvopinc.com/products_services/). D) Conventional, laminated socket (image from www.blatchford.co.uk/endolite/one-shot-socket/)

A search of company websites and scientific databases (e.g. Pubmed and GoogleScholar) revealed only patents for device design and two published case studies on the LIM Infinite Socket. Mitton et al. (2017) found that an LiM Infinite socket enabled a 38-year old female with transfemoral amputation and large residual limb volume fluctuations to wear a prosthesis for at least 8 hours a day. Previously, she had only been able to wear the prosthesis for up to an hour and was otherwise wheelchair bound. The patient's socket comfort score improved from a 4 in a conventional laminated socket to an 8 (of 10) and her Special Interest Group in Amputee Medicine (SIGAM) mobility score (Ryall et al. 2003) rose from grade C to E with the new dynamic socket fit (Mitton et al. 2017). In a second case study, a 24-year old male with transfemoral amputation wore an Infinite Socket and an ischial ramus containment (IRC) laminated socket with his standard prosthetic componentry. The patient had a 37% improvement in socket comfort score with the adjustable socket. He also improved on timed tests of functional mobility (L-Test improved 21%, Four Square Step Test improved 19%) but his 2 minute walk test did not differ between conditions (Kahle et al. 2016). Additionally, the researchers simulated volume loss by removing his five-ply sock from the residual limb, resulting in a 2-cm circumferential volume reduction. Under this condition, his socket comfort score improved 93%, the L-test improved 22%, the four-square step test improved 25% and the 2 minute walk test improved 25% with the Infinite socket compared to conventional (Kahle et al. 2016).

While the results of these case studies are promising, there is a critical need to better understand patient outcomes with adjustable prosthetic sockets through larger clinical trials. In fact, there is an overall scarcity of literature regarding the impact of the different interfaces on movement in people with lower limb amputation. A recent literature review found only four clinical trials and two systematic reviews on prosthetic interface and suspension systems (Highsmith et al. 2016). Collectively, they found that the use of gel liners compared with specific weight-bearing sockets improved load distribution (Baars and Geertzen 2005, Klute et al. 2010), comfort (Baars and Geertzen 2005, Klute et al. 2010), and ambulatory independence (Baars and Geertzen).

Additionally, use of a vacuum-assisted suspension system (VASS) relative to total surface bearing suspension reduced pistoning (Klute et al. 2011) and time to prosthetic fitting (Traballesi et al. 2012), but also reduced step activity (Klute et al. 2011).

OBJECTIVE AND SPECIFIC AIMS:

The **objective** of the proposed work is to enhance understanding of the potential benefits of adjustable sockets and inform clinical decision making. We will explore a range of outcomes that have been found to be important for prostheses users and specifically assess the claims made by device manufacturers. Thirty adults with a transfemoral amputation will participate in four test sessions; one with their clinically prescribed socket, and three with different test sockets. Participants with prescribed laminated sockets will be fitted for three different adjustable sockets. Participants with a prescribed adjustable socket will be fitted with two different adjustable sockets and one laminated socket. We will test the following aims:

Aim 1: Compare socket comfort and prosthetic satisfaction between prosthetic sockets. Participants will complete three self-report surveys to assess comfort and condition-specific quality of life with each socket tested. Additionally, participants will complete several activities in the lab including sitting, standing, and walking. After each task, we will ask the user to rate their socket comfort and pain in their residual limb. Based on published case studies, we hypothesize:

H1: Participants will report greater satisfaction and comfort when using adjustable sockets compared to conventional, laminated sockets.

Aim 2: Determine the impact of prosthetic socket on patient mobility and confidence. Mobility will be assessed using several tests that are easy to perform in a clinic: 10-m walk test, timed-up-and-go (TUG), the L-Test, narrow beam-walking, and five times sit-to-stand (FTSTS) (described in Research Strategy). We will also ask participants about their confidence performing different activities in the home using the Activities specific balance confidence (ABC) scale, and their self-reported mobility using the Plus-M and mobility sub-section of the Prosthetic Evaluation Questionnaire (PEQ). Based on published case studies, we propose the following hypotheses:

H2a: Mobility, as measured by the 10-m walk test, TUG, L-Test and FTSTS, will be improved when wearing adjustable sockets compared to conventional, laminated sockets.

H2b: Participants will self-report greater mobility on the PLUS-M and mobility subscale of the PEQ and greater confidence when wearing adjustable sockets compared to laminated sockets.

Aim 3: Determine if prosthetic socket design influences prosthetic use in the home. Each adjustable sockets should enable the user to tighten manually to maintain fit while donned. In contrast, with a conventional, non-adjustable socket, users would need to remove the prosthesis to add or remove socks. Here we will monitor how many times the participants don and doff the prosthesis during the day while using each socket using a sensor in the socket. We will also measure how long it takes to don and doff the prosthesis (in the lab) to quantify the time devoted to this process. Finally, we will monitor the participants' step activities during the last week of accommodation to determine it the socket design influences what they actually do in daily life. We will test the hypothesis:

H1a: The number of times donned and doffed will be fewer and overall wear time will increase for all adjustable sockets compared to conventional, laminated sockets.

H1b: The time to don and doff the prosthesis will be less for adjustable sockets versus conventional per device manufacturer claims.

H1c: Participants will be more active in daily life when wearing an adjustable socket.

Aim 4: Determine individual characteristics that are associated with benefits of specific socket designs. If adjustable sockets are successful in improving comfort and performance, our secondary goal will be to identify which patients are the best candidate for which specific socket system. Therefore, we will also collect basic demographic information including residual limb length, age, BMI, K-level, time since amputation, and prosthesis type. We will determine if any of these demographic characteristics or personal factors (taken from the PEQ) are associated with whether the participant benefited from a specific device (over standard-of-care).

RESEARCH STRATEGY:

Thirty (30) adults with transfemoral amputation will be recruited over two sites. Participants will be recruited from personal interaction with the clinical collaborators involved in this study, including Tony Gutierrez, C.P.O. (Bionic Prosthetics and Orthotics) and Bharathi Swaminathan, M.D. (Captain James A. Lovell Federal Health Care Center) in Chicago, Illinois and Jeffrey Wensman, C.P.O. (UM Orthotics and Prosthetics Center), Brian Kelly, D.O. (Dept. of Physical Medicine and Rehabilitation, Michigan Medicine), and Lisa DiPonio, M.D. (Ann Arbor VA Medical Center) in Ann Arbor, Michigan.

Potential participants will be screened to ensure that they meet the following inclusion criteria:

- Unilateral lower-limb amputation
- Two months of independent ambulation with a prosthesis
- Minimum functional level of K2 on the Medicare Functional Classification Level (MFCL): corresponding to "the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator"

Potential participants will be excluded if they meet any of the following exclusion criteria:

- Pathology or injury of the intact limb that significantly affects walking
- Medication that affects their ability to walk
- Neurologic disease that affects ability to walk
- Significant and/or recent cardiovascular history
- Significant vision problems
- Suffer from an impaired mental capacity that negatively impacts verbal communication with the clinicians and research team, or requires a Legally Authorized Representative to facilitate communication

Potential participants will be screened via phone call prior to enrollment using an IRB approved health history questionnaire developed at the University of Michigan and used in several on-going studies.

STUDY DESIGN:

We propose a randomized crossover study of four prosthetic sockets. Patients will come to the lab for four separate testing visits (**Fig. 5**), one in each of four sockets. First they will come to the clinic where they will be consented and screened to ensure eligibility in the study. At this interview, participants will be enrolled if the prosthetist and/or physician can medically justify the prescription of at least two of the types of sockets used in the study. The three adjustable sockets to be tested are the The Quatro™, Infinite Socket™, and CJ Socket^{TM}. Participants will complete all testing first in their currently prescribed socket and then in each of the three adjustable sockets (or two adjustable sockets and one laminated socket depending on participant's currently prescribed socket). The order of testing will be randomized by a computer and a staff member not involved in this study will place the order in sealed envelopes with the subject number on the outside of the envelope. This envelope will be opened by the prosthetist once the participant enrolls.

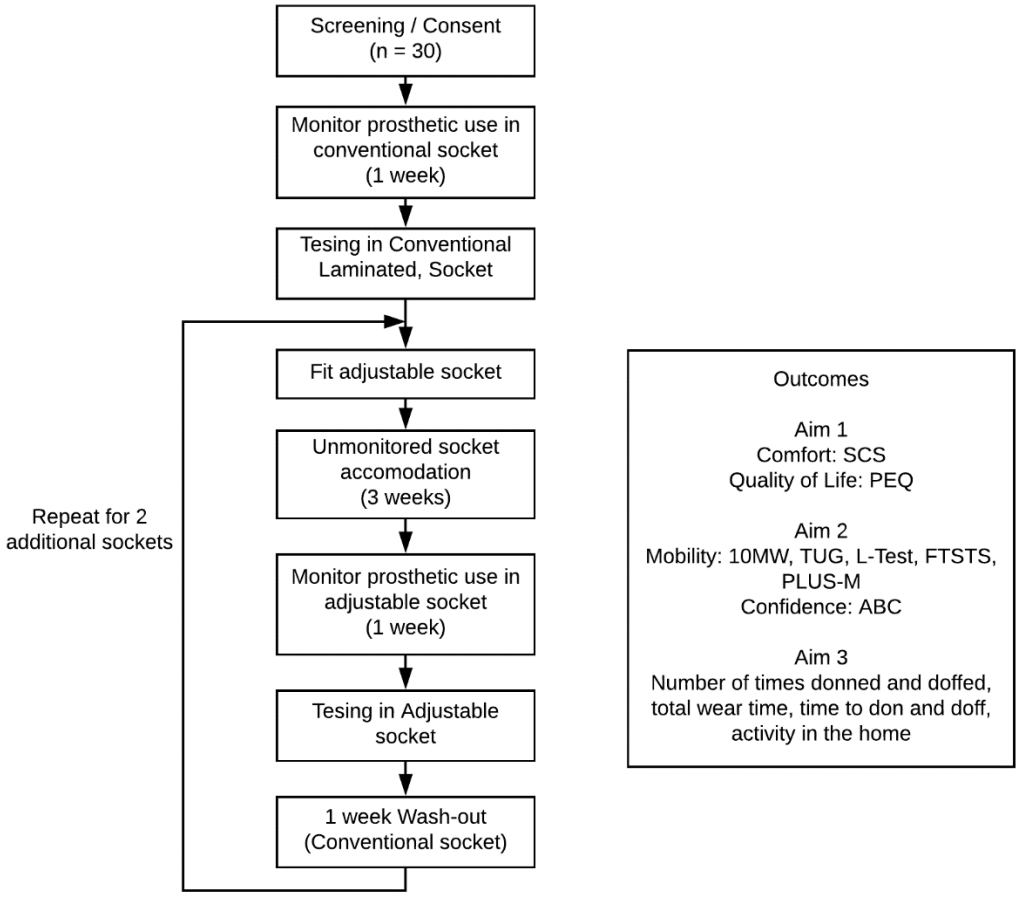

Figure 5. Example flow diagram illustrating the study design. Participants will complete the same clinical tests (Outcomes) in each of four prosthetic sockets (prescribed + 3 experimental).

Participants' level of amputation, cause of amputation, prosthetic history and functional level (i.e., Medicare Functional Classification Level (MFCL) or K-Level) will be obtained from

medical records. Sociodemographic characteristics (e.g. sex, race, ethnicity, veteran status), will be obtained via a self-report. The presence of comorbidities will be assessed using the Charlson Comorbity Index (Charlson et al. 1994). Additionally, while we will not control for it, prosthetists will document participants' prosthetic ankle and knee types and all components used. We will also document whether the individual is in physical therapy. Individuals may also utilize different types of suspension. Based on a review of medical records, we expect that this will be predominantly elevated vacuum suspension in Illinois and predominantly lanyard suspension at the University of Michigan. We chose not to standardize prosthetic componentry as it takes time to accommodate to each change made to the prosthetic system. Therefore, the only variable that will change within each participant will be their socket and the results therefore, indicate this effect of this change alone. This choice also enables us to determine if any specific componentry is related with patient outcomes (Aim 4).

Participants will be fitted with an adjustable socket by Jeffrey Wensman, C.P.O. (Michigan) or Tony Gutierrez, C.P. (Illinois), who are certified by the American Board for Certification in Orthotics, Prosthetics and Pedorthics, and will be trained in each fitting process by the socket manufacturer. Manufacturers' representatives will be consulted as needed to ensure that each patient fitting meets the design specifications for each design. Representatives will not be allowed to meet independently with any subjects or allowed to question them about their socket design, except as needed to aid in the fitting of the socket.

The participant will be given one week to accommodate and make adjustments and then four weeks of accommodation once the patient and prosthetist agree that the patient is comfortable and stable. If stable, comfortable gait is not achieved after 3 weeks, the socket will be removed and the patient will be excluded from that condition. This adverse event will be reported in all publications arising from this work.

Surveys will be given in the third week of accommodation to reduce potential bias for the end of conditions when participants anticipate a change to a different socket (Coleman et al. 2004). At that time, participants will be given a device to measure how many times the socket is donned and doffed (see description below) and an activity monitor (ActiGraph Link, Pensacola, FL) to monitor activity during the last week of wear. This session will be conducted by the Clinical Coordinator, who will be blind to the condition the participant is assigned to. Participants will then come to the clinic (Chicago or Ann Arbor) where they will perform a series of clinical assessments (described below). After each new socket, the participant will return to their initial socket for a one-week 'wash-out' before trying the subsequent socket. At the end of testing, participants will be able to keep whatever socket they choose, and this choice will be documented.

OUTCOME MEASURES:

Comfort: Participants will report their comfort with each socket using The Socket Fit Comfort Score (SCS). This is a single question in which subjects are asked: "On a scale from 0-10, if 0 represents the most uncomfortable socket fit you can imagine and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb at the moment?" (Hanspal et al. 2003). This question will be asked in the third week of accommodation. Additionally, during the lab visit, participants will be asked their SCS after brief

periods (2 minutes) of standing, sitting, and walking. Participants will also report comfort using the Comprehensive Lower Limb Amputee Socket Survey (CLASS) in which subjects are asked questions utilizing a likert scale. The questionnaire is divided into 4 sections including Stability, Suspension, Comfort, and Appearance (Gailey, et al., 2019).

Satisfaction & Quality of Life: Surveys will be administered after each thee week home use period when the participants return the monitoring devices. Condition-specific quality of life will be measured with the Prosthetic Evaluation Questionnaire (PEQ) (Legro et al. 1998). The PEQ consists of 82 questions that describe the function of a lower-limb prosthesis and assess prosthesis-related quality of life. The questionnaire is divided into ten functional scales, addressing four major domains: prosthetic function, mobility, psychosocial experience, and well-being. Finally, participants will complete Prosthetic Socket Preference Questionnaire after each socket which asks which device they prefer on a 100 mm visual analog scale from their prescribed laminated socket to the test socket (Ferris et al. 2012). A score of 0 would be 100% preference for their prescribed socket while 100 mm represents 100% preference for the socket tested in that condition.

Confidence: Confidence performing different activities in the home will be assessed using the Activities specific balance confidence (ABC) scale (Powell and Myers 1995). The ABC scale is a 16-item self-reported measure scored on a rating scale from 0 to 100, with higher scores indicate greater balance confidence. An average score is calculated by adding all item scores and dividing by the total number of items. The ABC scale has demonstrate high internal consistency, good test-retest validity, and good construct validity in people with lower limb amputation (Miller et al. 2003). It can be administered in 10 to 20 min.

Figure 6. Top) Illustration of the L-Test from (Kim et al. 2015), Bottom) Illustration of the LEGSys system for assessing gait

Mobility: Participants will complete several standard clinical tests designed to measure mobility. The 10-m walk test measures elapsed time over 10 m from a standing start (Datta et al. 1996). This measure uses customary walking speed as a measure of walking ability/capacity and has shown content and metric reliability and validity (Deathe et al. 2009). The timed-up-and-go (TUG) assesses several aspects of mobility including getting out of a chair, walking 3 m, turning, and sitting down (Schoppen et al. 1999). The outcome is the time from buttocks off the chair to buttocks down. The L-test (Deathe and Miller 2005) is a modified version of the TUG which incorporates two transfers and four turns of which at least one would be to the opposite side (Fig 6). We will complete both tasks as the TUG has ceiling effects in fit individuals and the L-Test can be too difficult for some amputees (Deathe and Miller 2005). For the narrow-beam walking test, the participant will attempt to walk the length of a narrowing beam five times. The beam is 7.32 m in length and 1.5 inches in height with four segments of varying widths (wide = 18.6 cm, intermediate = 8.6 cm, narrow = 4.0 cm, and very narrow = 2.0 cm). The mean distance walked across each trial, relative to overall beam length, is recorded for the outcome (Sawers and Hafner, 2018).Finally, participants will complete a five-times-sit-to-stand (FTSTS) test, which is measure of functional mobility, lower limb strength, and dynamic balance (Whitney et al. 2005, Goldberg et al. 2012). During each of these tasks, participant will wear a portable device consisting of five

sensors that analyzes gait (LEGSys+, Biosensics, Watertown, MA). This system measures temporal-spatial parameters such as stride length, time, cadence, and velocity. It also measures knee and hip angles and motion of the pelvis (Fig. 3). This system is already available in the amputee clinics in both Michigan and Illinois.

We will also ask participants about their self-reported mobility using the mobility sub-scale of the PEQ (described above) and the Prosthetic Limb Users Survey of Mobility (PLUMS-M) (Hafner et al. 2017). The full PLUS-M survey has 44 items and there are two short-forms (12 and 7 items each). Here we will use the 12-item short form as it has shown excellent agreement with the 44-item score and good construct validity (Hafner et al. 2017). Additionally, normative data for 1019 people with lower limb amputation is available at (http://www.plus-m.org) to aid in interpretation of the findings.

Activity in Daily Life: Our study will employ accelerometers to objectively measure physical activity levels and step count, as has been done previously in subjects with prostheses (Chou et al. 2009, Albert et al. 2013). Specifically, an ActiGraph Link accelerometer (ActiGraph, Pensacola, FL, USA) will be secured to the participant's prosthesis during the last week of accommodation. The ActiGraph Link is a waterproof device that measures 3.5 x 3.5 x 1 cm and weighs 14 grams. The sampling frequency will be set to 80 Hz, which will allow for 10 days of raw data collection without need to charge the batter (See Preliminary Study 3). The average acceleration per day and the average acceleration during the participant's most active 5 hours per day will be calculated in R using the GGIR package, an open source R-package for analysis of raw accelerometer data (http://cran.r-project.org/web/packages/GGIR/GGIR.pdf). The GGIR program 1) detects and corrects for: calibration error using local gravity as a reference (van Hees et al. 2014); unusually high sustained values (an indication of device malfunction); and non-wear and 2) calculates activity-related acceleration using all three axes (i.e., $\sqrt{(x^2+ y^2+ z^2)}$-1g). Step counts will be determined using the ActiLife Software package, ActiGraph's data analysis and management software program.

Ease and number of times donned and doffed: Based on a prior case report (Mitton et al. 2017), we expect that total wear time will increase for adjustable sockets. To test this, we will monitor how many times the participants don and doff the prosthesis during the day using a TCRT5000 Reflective Optical Sensor in the base of the socket. This device will be connected to a small data logger (Arduino Nano: 7.62x1.27x3.05cm) which will be attached to the socket. The Nano will record the time when it detects a sharp change in proximity corresponding with the donning or doffing of the prosthetic. On a 10,000 mAh battery we expect this system to maintain functionality for 233 hours. This data will be collected continuously during the last week of the accommodation period.

STATISTICAL PLAN AND DATA ANALYSIS:

We will recruit 30 people with unilateral transfemoral amputation (TFA). Half of the participants will be recruited at University of Michigan and the other half will be recruited at Rosalind Franklin University. We anticipate about a third of our participants will not complete all aspects of the

study based on a prior literature review (Highsmith et al. 2016). Sample size estimates are described by Aim. All power calculations were performed in G*Power Version 3.0 (Universitat Keil, Germany). With the given sample we should be sufficiently powered to detect differences across all four Aims. In some cases, this means we are overpowered for a particular comparison, but all participants need to complete earlier aims to be included in Aim 4, requiring the largest sample size.

Aim 1: Compare socket comfort and prosthetic satisfaction between prosthetic sockets. To test the hypothesis that

H1: Participants will report greater satisfaction and comfort when using adjustable sockets compared to conventional, laminated sockets.

We will compare PEQ scores, socket comfort scores, patient preference, and quality of life measues between conventional and adjustable prosthetic sockets using a linear mixed model with subjects as a random variable, and socket type (conventional, CJ Socket, Infinite Socket, Quatro) as repeated, fixed factor. Significant effects of socket type will be explored using post-hoc testing with LSD corrections. The minimal detectable change (MDC) will be used to assess the clinical significance of this difference. The MDC for subscales of the PEQ range between 0.8 and 1.7 (Resnik and Borgia 2011) while the MDC of the socket comfort score is 2.73 (Hafner et al. 2016).

Power Analysis: Power calculations were done using a repeated-measures ANOVA, as G*Power cannot calculate power for linear mixed models. These analyses are similar, except that in the multivariate approach, if a subject is missing data for one socket, they will be dropped from the entire analysis. In the mixed approach, only that one socket will be dropped and the remaining data will be retained. With 30 participants, we have 72% power to detect a small effect ($f = 0.2$), and 100% power to detect a medium effect ($f = 0.5$, $\alpha = 0.05$). With 20 participants (full model, 33% attrition), we have 51% power to detect a small effect ($f = 0.2$), and 99% power to detect a medium effect.

Aim 2: Determine the impact of prosthetic socket on patient mobility and confidence. The primary dependent measures for mobility are time in seconds for the 10-m walk test, timed-up-and-go (TUG), L-Test and five times sit-to-stand (FTSTS) (described in Research Strategy). To test the hypothesis:

H2a: Mobility, as measured by the 10-m walk, TUG, L-Test and FTSTS, will improve when wearing adjustable sockets compared to conventional, laminated sockets.

We will use a linear mixed model with subjects as a random variable, and socket type as a repeated, fixed factor. Significant effects of socket type will be explored using post-hoc testing with LSD corrections. Results will also be compared to published measurement errors, where they exist, to establish their clinical relevance. The standard error of the measure (SEM) for the L-test is 3 s (Deathe and Miller 2005) The MDC for the TUG in people with lower limb amputation is 3.6 s (SEM = 1.6 s) (Resnik and Borgia 2011).

Participants confidence performing different activities in the home will be assessed using the Activities specific balance confidence (ABC) scale (scored 1-100) (Powell and Myers 1995) and self-reported mobility using the Plus-M (Hafner et al. 2017) . The PLUS-M 12-Item Short Form provides T-scores that range from 21.8 to 71.4 where higher scores indicate better mobility.

Survey scores will be compared using a linear mixed model with subjects as a random variable, and socket type (conventional, CJ Socket, Infinite Socket, Limitless Socket) as repeated, fixed factor to test the hypothesis:

H2b: Participants will self-report equal or greater mobility on the PLUS-M and mobility subscale of the PEQ and equal or greater confidence when wearing adjustable sockets compared to laminated sockets.

Significant effects of socket type will be explored using post-hoc testing with LSD corrections. If mobility changes between sockets, we will perform secondary analyses to understand why this change occurred. For example, if we see improved 10-m walk test times, we will compare joint kinematics and temporal-spatial measures from the LegSys+ system. Here, we might expect that the altered trimlines of some of the adjustable sockets enable individuals to increase their hip flexion/extension, enabling a longer step length.

Power Analysis: Although there is not sufficient data in the adjustable sockets tested to estimate standard deviations, we can draw from existing literature assessing a different type of socket, the High-Fidelity Interface™ (HiFi, biodesigns, inc., Westlake Village, CA, USA), which is unique in that it has areas of tissue compression and release. In an experimental study of people with a transfemoral amputation (n = 11), the HiFi improved ABC score from 77.2±16.8 with a standard-of-care ischial ramus containment socket to 90.7±5.7 (Kahle et al. 2016). This indicates that the socket has a strong effect (effect size = 0.92) on balance confidence. Thus with 30, we are 100% powered to detect a difference in ABC scores.

Aim 3: Determine if prosthetic socket design influences prosthetic use in the home. We will monitor the participant in their daily life for a one-week period. We calculate the average number of times the prosthesis is taken on and off during the day for a seven-day period. Wear time will be determined as the total time from donning to doffing for a 24-hr period. This will then be averaged over the seven-day monitoring period. Finally, we will time how long it takes the participant to don and doff their prosthesis at a comfortable pace. We will first determine whether the resulting data is normally distributed by visual inspection of the sample frequency distribution and the Kolmogorov-Smirnov test. We will appropriately transform the data if is not normally distributed (Myles et al. 1999). Data will then be compared using a linear mixed model (as described above) to test the hypothesis:

H1a: The number of times donned and doffed will be fewer and overall wear time will increase for all adjustable sockets compared to conventional, laminated sockets.

H1b: The time to don and doff the prosthesis will be less for adjustable sockets versus conventional per device manufacturer claims.

Physical activity measures (i.e., average acceleration, step counts, number of bouts, steps per bout) will be calculated for each day within the one-week period. Since we are attaching the accelerometer to the prosthetic device, we do not need to specify a minimum threshold of wear time for a valid day (i.e., we do not need to require a specific number of hours and a minimum number of days of accelerometer wear time for a day to be considered valid). Daily activity levels will be averaged across all days in the one-week period for an average activity level per day.

Comparisons between prosthetic sockets will be made using a linear mixed model with sockets as fixed effect and subjects as a random effect. We will use these results to test the hypothesis:

H1c: Participants will be more active in daily life when wearing an adjustable socket.

Aim 4: Determine individual characteristics that are associated with benefits of specific socket designs. If adjustable sockets are successful in improving comfort and performance, our secondary goal will be to identify which patients are the best candidate for which specific socket system. We will determine if any of these demographic characteristics or personal factors (taken from the PEQ, SF-36) are associated with whether the participant benefited from a specific socket (over standard-of-care non-adjustable sockets). To do this, we will first determine which outcome measure demonstrates the strongest effect of socket design. We will then perform correlation analysis to determine which participant characteristics correlate with this outcome measure (as describe in Preliminary Study 2). As this is the first large study on adjustable sockets, this analysis will be exploratory. However, based on two case studies, we expect the strongest effect will be in socket comfort score (SCS). We also believe that BMI, residual limb length, and K-Level will be strong predictors of SCS. We need 29 participants to detect a large-effect size ($r \geq 0.50$, $\alpha = 0.05$, $\beta = 0.8$). The results of this exploratory analysis can be used in the design of future studies to assess outcomes in the patients most likely to benefit from adjustable socket technologies.

Confidentiality and Security

All data will be stored in a locked file cabinet or password protected computer. Only members of the study team will have access to this data. These data will have no identifiable information, only participant ID numbers. All identifiable information will be destroyed once the study is complete.

Albert, M. V., C. McCarthy, J. Valentin, M. Herrmann, K. Kording and A. Jayaraman (2013). "Monitoring functional capability of individuals with lower limb amputations using mobile phones." PLoS One **8**(6): e65340.
Baars, E. C. and J. H. Geertzen (2005). "Literature review of the possible advantages of silicon liner socket use in trans-tibial prostheses." Prosthet Orthot Int **29**(1): 27-37.
Berke, G. M., J. H. L-CPO and V. Nguyen (2010). "Comparison of satisfaction with current prosthetic care in veterans and servicemembers from Vietnam and OIF/OEF conflicts with major traumatic limb loss." Journal of rehabilitation research and development **47**(4): 361.
Board, W. J., G. M. Street and C. Caspers (2001). "A comparison of trans-tibial amputee suction and vacuum socket conditions." Prosthetics and Orthotics International **25**(3): 202-209.
Charlson, M., T. P. Szatrowski, J. Peterson and J. Gold (1994). "Validation of a combined comorbidity index." Journal of Clinical Epidemiology **47**(11): 1245-1251.
Chou, T. G. R., J. B. Webster, M. Shahrebani, T. L. Roberts and R. D. Bloebaum (2009). "Characterization of Step Count Accuracy of Actigraph Activity Monitor in Persons With Lower Limb Amputation." JPO: Journal of Prosthetics and Orthotics **21**(4): 208-214 210.1097/JPO.1090b1013e3181b1084a1066.
Coleman, K. L., D. A. Boone, L. S. Laing, D. E. Mathews and D. G. Smith (2004). "Quantification of prosthetic outcomes: Elastomeric gel liner with locking pin suspension versus polyethylene foam liner with neoprene sleeve suspension." Journal of Rehabilitation Research and Development **41**(4): 591-602.
Couture, M., C. D. Caron and J. Desrosiers (2010). "Leisure activities following a lower limb amputation." Disability and Rehabilitation **32**(1): 57-64.
Datta, D., R. Ariyaratnam and S. Hilton (1996). "Timed walking test—an all-embracing outcome measure for lower-limb amputees?" Clinical rehabilitation **10**(3): 227-232.
Deathe, A. B. and W. C. Miller (2005). "The L test of functional mobility: measurement properties of a modified version of the timed "up & go" test designed for people with lower-limb amputations." Phys Ther **85**(7): 626-635.
Deathe, A. B., D. L. Wolfe, M. Devlin, J. S. Hebert, W. C. Miller and L. Pallaveshi (2009). "Selection of outcome measures in lower extremity amputation rehabilitation: ICF activities." Disabil Rehabil **31**(18): 1455-1473.
Dillingham, T. R., L. E. Pezzin, E. J. MacKenzie and A. R. Burgess (2001). "Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study." American Journal of Physical Medicine & Rehabilitation **80**(8): 563-571.
Ferris, A. E., J. M. Aldridge, C. A. Rabago and J. M. Wilken (2012). "Evaluation of a powered ankle-foot prosthetic system during walking." Arch Phys Med Rehabil **93**(11): 1911-1918.

Fischer, H. and I. Ave (2013). " U. S. Military Casualty Statistics : Operation New Dawn , Operation Iraqi Freedom, and Operation Enduring Freedom.".
Gallagher, P., M. A. O'Donovan, A. Doyle and D. Desmond (2011). "Environmental barriers, activity limitations and participation restrictions experienced by people with major limb amputation." Prosthetics and Orthotics International **35**(3): 278-284.
Gailey, R., Kristal, A., Lucarevic, J., Harris, S., Applegate, B., & Gaunaurd, I. (2019). The development and internal consistency of the comprehensive lower limb amputee socket survey in active lower limb amputees. *Prosthetics and Orthotics International*, *43*(1), 80–87. https://doi.org/10.1177/0309364618791620Gardinier, E. S., B. M. Kelly, J. Wensman and D. H. Gates (2017). "A controlled clinical trial of a clinically-tuned powered ankle prosthesis in people with transtibial amputation." Clin Rehabil: 269215517723054.

Goldberg, A., M. Chavis, J. Watkins and T. Wilson (2012). "The five-times-sit-to-stand test: validity, reliability and detectable change in older females." Aging clinical and experimental research **24**(4): 339-344.
Hafner, B. J., I. A. Gaunaurd, S. J. Morgan, D. Amtmann, R. Salem and R. S. Gailey (2017). "Construct Validity of the Prosthetic Limb Users Survey of Mobility (PLUS-M) in Adults With Lower Limb Amputation." Archives of Physical Medicine and Rehabilitation **98**(2): 277-285.
Hafner, B. J., S. J. Morgan, R. L. Askew and R. Salem (2016). "Psychometric evaluation of self-report outcome measures for prosthetic applications." Journal of rehabilitation research and development **53**(6): 797-812.
Hanspal, R. S., K. Fisher and R. Nieveen (2003). "Prosthetic socket fit comfort score." Disabil Rehabil **25**(22): 1278-1280.
Highsmith, M. J., J. T. Kahle, R. M. Miro, M. S. Orendurff, A. L. Lewandowski, J. J. Orriola, B. Sutton and J. P. Ertl (2016). "Prosthetic interventions for people with transtibial amputation: Systematic review and meta-analysis of high-quality prospective literature and systematic reviews." J Rehabil Res Dev **53**(2): 157-184.
Kahle, J. T., T. D. Klenow and M. J. Highsmith (2016). "Comparative Effectiveness of an Adjustable Transfemoral Prosthetic Interface Accommodating Volume Fluctuation: Case Study." Technol Innov **18**(2-3): 175-183.
Kahle, J. T., T. D. Klenow, W. J. Sampson and M. J. Highsmith (2016). "The Effect of Transfemoral Interface Design on Gait Speed and Risk of Falls." Technol Innov **18**(2-3): 167-173.
Kim, J., A. Davidson and D. H. Gates (2017). Characterizing ambulatory tendencies for lower limb amputees. . 41th Annual Meeting of the American Society of Biomechanics, Boulder, CO.
Kim, J. S., D. Y. Chu and H. S. Jeon (2015). "Reliability and validity of the L test in participants with chronic stroke." Physiotherapy **101**(2): 161-165.
Klute, G. K., J. S. Berge, W. Biggs, S. Pongnumkul, Z. Popovic and B. Curless (2011). "Vacuum-Assisted Socket Suspension Compared With Pin Suspension for Lower Extremity Amputees: Effect on Fit, Activity, and Limb Volume." Archives of Physical Medicine and Rehabilitation **92**(10): 1570-1575.
Klute, G. K., B. C. Glaister and J. S. Berge (2010). "Prosthetic Liners for Lower Limb Amputees: A Review of the Literature." Prosthetics and Orthotics International **34**(2): 146-153.
Legro, M. W., G. D. Reiber, D. G. Smith, M. del Aguila, J. Larsen and D. Boone (1998). "Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life." Arch Phys Med Rehabil **79**(8): 931-938.
Marks, L. J. and J. W. Michael (2001). "Science, medicine, and the future - Artificial limbs." British Medical Journal **323**(7315): 732-735.

Miller, W. C., A. B. Deathe and M. Speechley (2003). "Psychometric properties of the Activities-specific Balance Confidence Scale among individuals with a lower-limb amputation." Arch Phys Med Rehabil **84**(5): 656-661.
Mitton, K., J. Kulkarni, K. W. Dunn and A. H. Ung (2017). "Fluctuating residual limb volume accommodated with an adjustable, modular socket design: A novel case report." Prosthet Orthot Int **41**(5): 527-531.
PDAC. (2016). "Medicare Pricing, Data Analysis and Coding." Retrieved 12/29/17, from https://www.dmepdac.com/resources/articles/2016/06_16_16b.html.
Powell, L. E. and A. M. Myers (1995). "The activities-specific balance confidence (ABC) scale." The Journals of Gerontology Series A: Biological Sciences and Medical Sciences **50**(1): M28-M34.
Reiber, G. E., L. V. McFarland, S. Hubbard, C. Maynard, D. K. Blough, J. M. Gambel and D. G. Smith (2010). "Servicemembers and veterans with major traumatic limb loss from Vietnam war and OIF/OEF conflicts: survey methods, participants, and summary findings." J Rehabil Res Dev **47**(4): 275-297.
Resnik, L. and M. Borgia (2011). "Reliability of outcome measures for people with lower-limb amputations: distinguishing true change from statistical error." Phys Ther **91**(4): 555-565.
Rosenblatt, N. J., T. Ehrhardt, R. Fergus, A. Bauer and R. Caldwell (2017). "Effects of Vacuum-Assisted Socket Suspension on Energetic Costs of Walking, Functional Mobility, and Prosthesis-Related Quality of Life." JPO: Journal of Prosthetics and Orthotics **29**(2): 65-72.
Ryall, N., S. Eyres, V. Neumann, B. Bhakta and A. Tennant (2003). "The SIGAM mobility grades: a new population-specific measure for lower limb amputees." Disability and rehabilitation **25**(15): 833-844.
Sawers, A., & Hafner, B. J. (2018)." Narrowing beam-walking is a clinically feasible approach for assessing balance ability in lower-limb prosthesis users." Journal of Rehabilitation Medicine, **50**(5), 457–464. https://doi.org/10.2340/16501977-2329
Schoppen, T., A. Boonstra, J. W. Groothoff, J. de Vries, L. N. Göeken and W. H. Eisma (1999). "The Timed “up and go” test: reliability and validity in persons with unilateral lower limb amputation." Archives of physical medicine and rehabilitation **80**(7): 825-828.
Seaman, J. P. (2010). "Survey of Individuals Wearing Lower Limb Prostheses." JPO: Journal of Prosthetics and Orthotics **22**(4): 257-265.
Sherk, V. D., M. G. Bemben and D. A. Bemben (2010). "Inter limb Muscle and Fat Comparisons in Persons With Lower-Limb Amputation." Archives of Physical Medicine and Rehabilitation **91**(7): 1077-1081.
Traballesi, M., A. S. Delussu, A. Fusco, M. Iosa, T. Averna, R. Pellegrini and S. Brunelli (2012). "Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study." Eur J Phys Rehabil Med **48**(4): 613-623.
VA/DoD (2017). VA/DoD Clinical Practice Guideline for the Rehabilitation of Individuals with Lower Limb Amputation. V. A. D. o. Defense.
van Hees, V. T., Z. Fang, J. Langford, F. Assah, A. Mohammad, I. C. da Silva, M. I. Trenell, T. White, N. J. Wareham and S. Brage (2014). "Autocalibration of accelerometer data for free-living physical activity assessment using local gravity and temperature: an evaluation on four continents." J Appl Physiol (1985) **117**(7): 738-744.
Whitney, S. L., D. M. Wrisley, G. F. Marchetti, M. A. Gee, M. S. Redfern and J. M. Furman (2005). "Clinical measurement of sit-to-stand performance in people with balance disorders: validity of data for the Five-Times-Sit-to-Stand Test." Physical therapy **85**(10): 1034-1045.
Ziegler-Graham, K., E. J. MacKenzie, P. L. Ephraim, T. G. Travison and R. Brookmeyer (2008). "Estimating the prevalence of limb loss in the United States: 2005 to 2050." Arch Phys Med Rehabil **89**(3): 422-429.