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Effects of Socket Size on Metrics of Socket Fit in Trans-Tibial Prosthesis Users

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Abstract

The purpose of this research was to conduct a preliminary effort to identify quantitative metrics to distinguish a good socket from an oversized socket in people with trans-tibial amputation. Results could be used to inform clinical practices related to socket replacement. A cross-over study was conducted on community ambulators (K-level 3 or 4) with good residual limb sensation.

Participants were each provided with two sockets, a duplicate of their as-prescribed socket and a modified socket that was enlarged or reduced by 1.8 mm (~6% of the socket volume) based on the fit quality of the as-prescribed socket. The two sockets were termed a larger socket and a smaller socket. Activity was monitored while participants wore each socket for 4wk. Participants' gait; self-reported satisfaction, quality of fit, and performance; socket comfort; and morning-to-afternoon limb fluid volume changes were assessed. Visual analysis of plots and estimated effect sizes (measure as mean difference divided by standard deviation) showed largest effects for step time asymmetry, step width asymmetry, anterior and anterior-distal morning-to-afternoon fluid volume change, socket comfort scores, and self-reported measures of utility, satisfaction, and residual limb health. These variables may be viable metrics for early detection of deterioration in socket fit, and should be tested in a larger clinical study.

INTRODUCTION

Residual limb fluid volume loss commonly causes prosthetic fit problems for people with trans-tibial amputation^[1]. Prosthesis users report socket fit is the single-most important issue related to use of a prosthesis^[2]. Sockets oversized as little as 1.0% have been shown to be clinically distinguishable from properly-sized sockets^[3]. While oversized sockets can be

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compensated with the addition of prosthetic socks^[4,5], socks create a soft layer that weakens the mechanical coupling between the limb and socket. The prosthesis user's gait and capability to ambulate may be compromised, increasing the risk of falling and serious injury. Excessively large sockets may also be responsible for the modest proportion of users who report being dissatisfied, uncomfortable, or unable to use their prostheses due to socket fit^[2,6,7]. Current clinical practices for evaluating a prosthesis user's need for a new socket are based primarily upon subjective methods, including clinical judgment and user feedback. Rarely are quantitative metrics used to determine when socket replacement is required^[8]. A typical socket evaluation consists of the practitioner asking the user about his or her limb pain, activity, and sock use. The practitioner then inspects the residual limb for signs of excessive pressure and performs a visual assessment of the user's gait to identify deviations that may be caused by poor socket fit. Along with an understanding of the user's pathology, results of these assessments are used to determine if socket changes or replacement are necessary.

Current practices for evaluating socket fit may be unfavorable for people with limb loss because changes in comfort and activity may be imperceptible to users if they develop slowly over time. Further, people with poor sensation might not be able to determine if they need a socket replaced until symptoms of poor fit develop.

Scientific evidence to inform timely changes of prosthetic sockets is limited. Fernie and Holliday^[9] suggested that socket fit might be related to the prosthesis user's sock ply. Using a water displacement method, the investigators measured limb volume in 32 active prosthesis users (72% trans-tibial) with lower limb amputation for a period of approximately 20 months. Based on findings of their study, Fernie and Holliday estimated that a sock ply that was 10% or more of the patient's residual limb volume was an indicator for a new, smaller socket. They suggested that sock ply between 5% and 10% of the residual limb volume indicated an "acceptable" socket, while a sock ply between 0% and 5% of the limb volume was considered a "good" fit. These ranges have provided generalized clinical guidelines, but they have not been shown to be accurate metrics for characterizing socket fit or deciding socket replacement because sock ply is not a sensitive or specific enough measure.

The purpose of this research was to extend Fernie and Holliday's efforts to identify quantitative metrics of acceptable socket fit in people with trans-tibial amputation. This objective was accomplished by studying if a known change in prosthetic socket size was reflected in objective and subjective measures of fit, comfort, and performance. We sought to identify metrics that would be sensitive enough to distinguish a good socket from an oversized socket. Results could then be used to inform clinical practices related to socket replacement. Socket replacement standards based upon quantitative evidence, rather than subjective evaluation, may improve early detection of socket fit issues, improve the quality of patient care, and enhance overall patient satisfaction with the prosthesis prescription.

METHODS

We conducted a cross-over study where participants were provided with and evaluated in two sockets, differing in size.

Participants

Inclusion criteria for study participants included having had a trans-tibial amputation at least 18 months prior, Medicare Functional Classification Level (K-level) 2 (limited community ambulator) or higher, currently wearing a definitive prosthesis with an acceptable socket fit for at least 4h/d, and current socket not undergoing active revision during the data collection period. Exclusion criteria included use of an assistive device (e.g., cane, walker), injuries or skin breakdown on the residual limb, or presence of peripheral neuropathy. Inclusion and exclusion criteria were verified by the research prosthetist. Evaluation included a verbal history of limb health, an examination of the residual limb to characterize pressures and verify no unusual areas of redness were present. The prosthesis was inspected to determine recent modifications and sock ply use.

Participants were recruited via flyers placed in practitioner offices and through contacts from participation in a previous research study. All procedures were reviewed and approved by a University of Washington Institutional Review Board, and informed consent was obtained from the participants before test procedures were initiated.

Socket Fabrication

Two sockets were fabricated for each participant. One socket was identical to the participant's as-prescribed socket shape and the other was modified (i.e., either enlarged or reduced) based on the fit quality of the as-prescribed socket. To determine the design for the modified sockets, the research practitioner established a sock thickness threshold based on sock thickness measurements under stance-phase weight-bearing conditions (measured using the apparatus described below with a 101.2kPa applied pressure). An as-prescribed socket normally worn with a sock thickness less than 3.0mm was considered clinically safe to enlarge, while one with a sock thickness more than 3.0mm was considered not safe to enlarge and instead was reduced. The basis for using a 3.0mm threshold was the research practitioner's clinical judgement that 3.0mm allowed a reasonable margin of safety when reducing a socket 1.8mm (corresponding to a volume change of ~6%). The procedure ensured that participants were not given a test socket that would compromise their safety or limb health by being too large or too small.

To create the test sockets, we made a positive mold of the participant's as-prescribed socket using deformable, low-shrinkage polymers. The low-shrinkage polymers minimized error in mold shape while still allowing the mold to be removed without damaging the socket. A low-shrinkage platinum cure silicone (Rebound 25, Smooth-On, Inc., Easton, Pennsylvania) with a few drops of thickening agent (Thi-Vex Silicone Thickener) was applied in a 1–2mm thick layer on the inside surface of the socket. A stiffer, second silicone polymer (Rebound 40) was used to fill the mold. The mold, including the distal end, was scanned using a tabletop laser scanner (3D ScannerHD, Next Engine, Santa Monica, California), and the data

imported into a commercial CAD software package (TracerCAD, Ohio Willow Wood, Mt. Sterling, Ohio). Measurement error using this technique for mold-fabrication was acceptable, averaging 0.10mm mean radial error.

The CAD software was used to apply a uniform 1.80mm radial adjustment (i.e., enlargement or reduction based on clinical assessment as described above) and create a new shape file. We sent two shape files, one for the as-prescribed socket and one for the modified socket, to a central fabrication facility to make foam positive molds. We then fabricated sockets over the molds using an epoxy-acrylic resin (EAR1, Acsys Orthopedics, Vista, California) and a double bias carbon fiber weave (American Prosthetic Components, Green Bay, Wisconsin). If the participant normally wore a lock and pin suspension, then the sockets were fit with a lock and pin suspension system (Icelock 600-series, Ossur, Foothill Ranch, California) with the pin mounted into the participant's regular prosthetic liner.

We evaluated shape quality of the sockets by comparing the fabricated socket shapes with the digital file shapes used to create them. To measure the fabricated socket shapes we used a custom digitizer described in detail elsewhere^[10]. Measured socket shapes were aligned with the digital files from which they were created using custom software that was minimally sensitive to the distribution of shape error^[11]. A relative weight of 0.8 mean absolute distance and 0.2 shape similarity (mean negative hyperbolic arc tangent of the surface-normal dot product) was used^[3]. We calculated the mean radial error and volume error for the fabricated socket vs. digital file to characterize the fabrication error.

We also calculated the volume differences between the larger and smaller sockets. The digital shape files were used. The alignment algorithm used above was implemented but an alternate weighting, 0.2 mean absolute distance and 0.8 shape similarity, was used so as to heavily weight shape differences over volume difference in the optimization. This selection was necessary to ensure the shapes were compared instead of socket volumes. Results were expressed as percentage volume change relative to the smaller socket.

Additional Case Study Participants and Sockets—Three additional people with trans-tibial limb loss were tested as case studies. Case study participants entered the study wearing as-prescribed sockets that were of acceptable but not optimal fit. They were imminently being fit (within ~1 month) with a new socket by their regular practitioner. We tested the case study participants using the same protocol as the others, except that their as-prescribed socket was the “larger” socket, and their newly-fitted socket was the “smaller” socket. The intent of these case studies was to determine if results were consistent with the main study. We term these individuals “case study participants” and the others as “main study participants.”

Sock Thickness Measurement

Sock thickness was measured to determine if participants increased sock thickness when wearing the larger socket compared with the smaller socket. A custom tabletop instrument that applied controlled pressures during measurement was used^[12]. Thickness was recorded under four different pressure conditions to reflect the following clinical activities: donned (6.3kPa); donned-conditioned (subject to compressive loading cycles before testing)

(6.3kPa); equal weight-bearing (50.6kPa); and stance phase weight-bearing (101.2kPa)^[13]. Differences in the thickness of socks worn with the larger socket compared to the smaller socket were calculated.

Gait Analysis

A 4.9m×0.9m electronic walkway (GaitRITE, CIR Systems, Sparta, New Jersey) was used to assess participants' walking performance and gait stability. The pressure-sensitive electronic walkway provided measurement of walking speed, step length, and step time (spatial resolution of 1.27cm; walking speed error within $\pm 3\%$). It has demonstrated good-to-excellent test-retest reliability in longitudinal applications^[14,15]. Electronic walkways have been used extensively to measure spatiotemporal gait parameters in studies that included people with lower limb amputation^[16–21].

The walkway was placed midway along an 18.3m level hallway and was set to sample at 80Hz. Participants began walking 1.5m in front of the walkway to achieve a constant speed. Participants made five passes over the walkway, with four complete steps of each leg typically recorded during each pass. Data collected included mean walking speed; cadence; step length, width and time; and affected leg/non-affected leg symmetry. Symmetry was calculated by subtracting values measured for the prosthetic leg from the non-prosthetic leg and then dividing by the sum for both legs. These variables were selected because they were previously determined to be indicative of stability, falling, and fear of falling in elderly adults^[22,23].

Activity Monitor

Activity (h/d) was measured with an Actigraph GT3X+ activity monitor (ActiLife, Pensacola, Florida). The GT3X+ is a light-weight (19g) triaxial micro-electro-mechanical(MEM) accelerometer^[24, 25]. Actigraph MEMs-based activity monitors have been used previously to assess activity in people with lower limb amputation^[26,27].

The GT3X+ was attached to the lateral aspect of each participant's prosthetic ankle (pylon) using double-sided tape and VetRap adhesive bandage (3M, St. Paul, Minnesota) to minimize movement relative to the prosthesis. The activity monitor was set to sample at 40Hz for the entire 4-wk data collection period. Activity was determined using a classification algorithm described previously^[26]. The algorithm calculated the duration of active windows in hours over the entire the data collection period. That value was divided by the total number of days of data collection to determine active hours/day. Daily activity was selected as an outcome as it has been used previously to evaluate effectiveness of prosthetic interventions including pylons^[28], knees^[28–30], and feet^[31].

Limb Fluid Volume Measurement

Limb fluid volume was measured using a custom bioimpedance analysis system and custom electrodes^[32]. The bioimpedance system was an embedded PC (Innovative Integration, Simi Valley, California) with peripherals (X3-25M and X3-10M XMC IO modules) configured into a multi-frequency bioimpedance instrument. Measurements from the anterior and posterior surfaces, both proximally and distally, were monitored in this study.

Custom skin electrodes were fabricated using conductive tape (ARCare8881, Adhesives Research Inc., Glen Rock, Pennsylvania), multi-stranded silver-plated copper wire with an aramid core and poly vinyl chloride insulation (New England Wire, Lisbon, New Hampshire), a flattened metal crimp to strain relieve wires as they exited the insulation within the electrode, and a thin layer of hydrogel (KM10B, Katecho, Des Moines, Iowa) between the electrode and skin. This electrode configuration was used successfully in previous studies^[33–36].

Current-injection electrodes were positioned on the proximal thigh and the distal aspect of the residual limb. Voltage-sensing electrodes (FIGURE 1) were positioned anteriorly (over the anterior lateral muscle group) and posteriorly (over the central posterior muscle group).

Limb fluid volume measurements were taken in a morning test session and an afternoon test session. In each session, the participant underwent an approximately 30-minute protocol that included 5 cycles of: sitting for 90s with the prosthesis donned; standing for 90s; walking on a treadmill at a self-selected walking speed for 90s; and standing for 5–10s.

Collected bioimpedance data were post-processed using de Lorenzo's form of the Cole model^[37] to determine extracellular fluid impedance. A limb segment model^[38,39] was then used to convert extracellular fluid impedances to extracellular fluid volumes. In this study, we investigated only extracellular fluid volume changes and not intracellular changes because extracellular changes were expected to be most relevant to the relatively short-term limb fluid volume fluctuations of interest in this study.

The rate of limb fluid volume change between morning and afternoon sessions expressed in %/h was calculated for each test day for each of the four channels. Residual limb fluid volumes measured during the brief 5–10s stand after the 5th walk cycle during the morning and afternoon test sessions were used ($V_{mL,1st\ session}$). Residual limb fluid volume change was expressed as a percentage difference:

$$V_{\text{between \% / h}} = 100 \times \frac{V_{mL,PM\ session,cycle\ 5} - V_{mL,AM\ session,cycle\ 5}}{V_{mL,AM\ session,cycle\ 5} * t_{h,between\ sessions}}$$

Self-Report Survey

Participants' perceptions of socket fit were evaluated with a standardized, self-report survey. The survey contained select items from the Prosthesis Evaluation Questionnaire (PEQ)^[40], and the single-item Socket Comfort Score (SCS)^[41]. PEQ questions included one question on general satisfaction and questions required to derive Ambulation, Residual Limb Health, Utility, and Well-Being subscale scores (TABLE 1). Survey questions and response options were presented as recommended by the developers (i.e., a 10cm visual analog scale [VAS] for the PEQ and an 11-item numeric scale for the SCS). Item-level scores were derived for the PEQ-Satisfaction and SCS items (i.e., 0–100 and 0–10, respectively). Subscale scores (0–100) for the remaining PEQ questions were derived according to the developers' instructions.

Testing Procedure

Each participant began the study using the duplicate of the as-prescribed socket. We did not randomize ordering because the modified socket was more likely to cause irritation, which could have carried over to the as-prescribed socket if the modified socket were used first. The participant came to the lab, the research prosthetist attached the socket to the participant's existing prosthesis (i.e., foot and pylon) and confirmed an acceptable fit. Research staff attached the activity monitor on the ankle of the prosthesis. The participant was asked to conduct normal activities, and return to the lab after 1wk for clinical evaluation. If the research prosthetist deemed the fit unacceptable for continued use, the participant was returned to his or her own prosthesis and referred to his or her regular practitioner for care. If the prosthesis was deemed acceptable for continued use, the participant wore it for an additional 3wk.

The participant then returned to the lab after a total 4wk of socket use for morning and afternoon test sessions. In the morning session, the participant was administered the self-report survey, their sock thickness was measured, and their limb fluid volume was measured during the 30-minute test protocol. The afternoon session was conducted approximately 3 hours after the morning test session. Upon returning for the afternoon session, the participant was queried about their between-session activities. Limb fluid volume was assessed using the same protocols as in the morning session. Gait analysis using the electronic walkway was conducted.

After the afternoon test session was completed, we removed the activity monitor from the participant's prosthesis and downloaded the data. The as-prescribed socket was then replaced with the participant's modified socket, and the activity monitor was reattached. The research practitioner again evaluated the participant's limb and gait to ensure socket fit was acceptable.

Testing procedures were repeated for the modified socket, including clinical evaluation after 1wk and the morning and afternoon data collection sessions after 4wk. The participant was encouraged to conduct the same between-session activities both test days. Participants were not informed of their test results during the study.

Case study participants went through comparable testing protocols. They used their as-prescribed socket first and their newly-fit socket second.

Data Processing and Analysis

The larger socket was compared to the smaller socket by tabulating gait results for each participant, generating visual plots, and by calculating the mean difference for each measure (larger-smaller socket conditions), a 95% confidence interval for the mean difference, and the effect size (mean difference/standard deviation). Measures included gait analysis; activity duration; morning-to-afternoon limb fluid volume change; self-reported measures of the PEQ; and socket comfort.

The study was exploratory in nature, with the objective of identifying potential variables to be further studied, and therefore, it was an estimation effort instead of a hypothesis-testing

effort. The tables and plots were visually inspected to identify variables that displayed differences between larger and smaller sockets, and trends across participants. To characterize socket size differences and sock thickness differences between the larger and smaller sockets, which helped to characterize the shape quality of the sockets we fabricated, we used the Wilcoxon Sign Rank Test. This test was chosen due to the small sample size, which precluded us from testing reliably if the data were from a Gaussian distribution. Results from case study participants were inspected individually and compared with findings from the participant group.

RESULTS

Participants

Main study data were collected from 9 participants, 7 male and 2 female. Participants averaged 54.1yr(SD15.9yr) in age and the median was 52.0yr. Time since amputation at the outset of the study averaged 19.7yr(SD13.4yr) and the median was 20.3yr. Other demographic data plus participant prosthesis information are provided in TABLES 2a,2b.

The morning and afternoon data collection sessions started at approximately the same time during each of the two days for each participant (i.e., 9:06AM–11:38AM and 1:04PM–3:41PM, respectively). The time between sessions averaged 3h and 20min (SD18min) with a median of 3h and 18min across all test days. The number of days between the beginnings of each 4-wk test period average 29d(SD5d) and the median was 28d.

Socket Fabrication

Shape quality testing of the 18 fabricated sockets (2 for each participant) showed that sockets tended to be slightly oversized. Mean radial error for the actual socket shape compared with the digital socket shape ranged from –0.10mm to 0.46mm with a mean of 0.11mm(SD 0.16mm) and median of 0.07mm.

For the nine pairs of sockets (larger/smaller), mean radial differences between the larger and smaller socket averaged 1.83mm(SD 0.05mm); the median was 1.80mm. Volume differences ranged from 4.5% to 7.0% with a mean of 5.8%(SD 0.7%) and median of 5.9%.

Sock Thickness

Participants' selected sock thickness was significantly greater while wearing the larger socket compared with the smaller socket for each loading condition ($p<0.01$ for all comparisons) (FIGURE 2). The mean difference in stance phase weight bearing sock thickness between the larger and smaller socket was 1.85mm(SD 0.59mm) and the median difference was 2.06mm, which well matched the mean measured socket radial difference of 1.83mm(SD 0.05mm) and median of 1.80mm.

Gait Analysis

Visual inspection of tabulated gait data identified no substantial and consistent differences in spatiotemporal variables between the larger and smaller sockets (TABLE 3), and relatively low effect sizes except for Step Time Asymmetry(0.591) and Step Width Asymmetry(0.562)

(TABLE 4). We noted that differences among participants for distance measures but not time measures tended to be greater for the larger socket than the smaller socket.

Activity

Participants' activity duration over the course of each 4-wk test period (hours/day) when wearing the larger socket was greater than the smaller socket for 5 of the 9 participants, but differences were modest (FIGURE 3) and effect size was small (0.106) (TABLE 4). Participants averaged 3.14(SD 0.70) hours/day (median 3.26 hours/day) with the larger sockets and 3.13(SD 0.62) hours/day (median 3.20 hours/day) with the smaller sockets.

Limb Fluid Volume

Most of the participants experienced a strong dependence of limb fluid volume loss on socket size at the anterior-distal and anterior regions, with greater percentage fluid volume loss per hour (a more negative change) in the larger socket than in the smaller socket (FIGURE 4a,b). The effect sizes were large, -0.580 and -0.593 , respectively (TABLE 4). Absolute differences in mean rate change between the two sockets were 0.77%/h and 2.17%/h (medians 0.75%/h and 0.33%/h) for the anterior and anterior-distal locations, respectively. The posterior and posterior distal regions showed smaller absolute mean rate change differences, 0.10%/h and 0.26%/h (medians 0.13%/h and 0.72%/h), respectively.

Two participants were not included in anterior-distal and posterior-distal volume measurements since their relatively short residual limbs did not accommodate mid-limb electrodes; thus, no distal volume measurements were available. Only anterior and posterior region measurements were taken for these two participants.

Survey (PEQ & SCS)

Socket comfort score (SCS) was strongly dependent upon socket size as evidenced by data shown visually in FIGURE 5 and the large effect size (-0.587) (TABLE 4). Mean SCSs were 6.7(SD2.7) for the larger socket and 8.2(SD1.3) for the smaller socket (medians 7.0 and 9.0). Satisfaction scores and PEQ subscale scores for most participants were higher for smaller than larger sockets for each variable (FIGURE 6), though three participants showed opposites results. Mean scores for the Satisfaction, Ambulation, Residual Limb Health, Utility, and Well-Being subscales were 67(SD33), 78(SD26), 79(SD21), 77(SD26), and 82(SD23) for the larger socket and 82(SD13), 88(SD11), 83(SD17), 87(SD12), and 88(SD16) for the smaller socket. Medians were 69, 87, 90, 91, 97 and 85, 90, 92, 90, and 96, respectively. There was a greater range of scores for the larger socket than the smaller socket for all survey variables. All domains of the PEQ had effect sizes ranging from -0.526 to -0.389 , which are relatively large effects.

Case Study Participant Results—Case study participants, on average, had their amputation more recently than main study participants (time since amputation ranged from 0.8 to 7.7 years). They also had larger residual limbs than main study participants with a mid-length circumference ranging from 31.6 to 33.2 cm. The number of days between the beginnings of each 4-wk test period average was considerably longer than the main study

participants, ranging from 128 to 335 days. Reasons for high number of days included delays in optimizing new socket fit and participant health issues.

Sock thicknesses ranged from 1.30 to 5.77 mm for case study participants entering the study (old socket), which were, in general, greater than sock thicknesses of main study participants when they wore the larger sockets.

All case study participants (shown using dashed lines in FIGURES 3 to 6) were more active wearing their new (smaller) socket compared with their old (larger) socket. Differences in activity between larger and smaller sockets were generally greater than those experienced by main study participants (FIGURE 3). Consistent with most of the main study participants, all three case study participants experienced higher morning-to-afternoon limb fluid volume loss rates at anterior-distal regions when wearing the larger socket compared with the smaller socket (FIGURE 4a,b). Results from other regions showed mixed results.

Two of the case study participants (B,C) showed self-report results consistent with main study participants, i.e. lower scores for the larger socket compared with the smaller socket for SCS, Satisfaction, Utility, and Residual Limb Health. One case study participant (A) had higher SCS and Satisfaction scores for the larger socket than for the smaller socket (FIGURES 5,6).

DISCUSSION

The purpose of this research was to identify objective metrics for early identification of deteriorating prosthetic socket fit in people with trans-tibial amputation. If metrics of fit quality could be established, they could be used in clinical practice to monitor users' socket fit, and quantitatively establish when a socket needed to be replaced. Because of the limited number of participants evaluated ($n=9$ in the main study; $n=3$ in the case studies), results from this study should be considered preliminary. Relevant variables identified should be investigated in larger studies.

For the safety of participants in the present study and because our intent was to identify the very early stages of socket fit deterioration, we made participants' larger sockets only about 6% greater in volume than their smaller sockets. According to Fernie and Holliday^[9], a socket that is 5% to 10% oversized is an "acceptable," but not "optimal," socket fit. Thus, we would expect only the most sensitive variables to demonstrate meaningful differences in the present study. Presumably, these variables would demonstrate greater changes as socket fit approached an unacceptable condition.

A limitation of the present study was that gait variables, sock thickness, and morning-to-afternoon limb fluid volume change were measured on one day for each of the two sockets (larger, smaller). Results from the testing day may or may not have reflected typical outcomes the one month of wear. Self-report data were likewise collected on only one day though for the PEQ participants were asked to reflect over the past 4wk when assigning scores. SCS is at the moment the question is asked. Another limitation was that for main study participants, socket size adjustments were applied uniformly over the socket, as opposed to regionally as is usually performed in clinical practice when a socket is replaced.

We made the size change relatively small (~6% socket size) which may have limited clinical impact on socket fit.

Gait Analysis

Mean walking speeds measured in the present study, 1.22–1.23m/s, were comparable to those reported in the literature for trans-tibial prosthesis users^[42]. Highsmith *et al.* reported an average walking speed of 1.21m/s(SD 0.19m/s) in 7 trans-tibial community ambulators, and Berge *et al.* 1.24m/s in 15 “active” community ambulators with trans-tibial amputation. Thus, participants in this study appear to reflect typical, trans-tibial community ambulators of a similar age in regards to walking speed, a variable often considered to be an effective indicator of overall functional status^[44].

Surprisingly, the only gait variables to demonstrate a high effect size, step time and step width asymmetries, experienced greater values (further from zero) for the smaller socket. However, this result is consistent with pylon load cell studies showing greater step-to-step variability for an aligned compared with misaligned trans-tibial prosthesis^[45]. Wearing the smaller socket, participants may have had greater confidence in their prosthesis and thus did not focus as intensely on their gait, creating high step-to-step variability and higher asymmetry than while wearing the larger socket. Greater step width asymmetry may indicate a tendency to turn while travelling the length of the gait matt, suggesting proprioception differences between the two sockets.

Activity

Our participants’ activity ranged from 1.8 to 4.4 hours/day. Klute *et al.* measured mean activity rates of 4.2 and 4.7 hours/day on trans-tibial prosthesis users using two different pylons^[28]. Coleman and colleagues reported mean rates of 3.4 and 5.8 hours/day for trans-tibial participants using two different prosthetic liners^[46]. As in the present study, prior studies included middle-aged participants predominantly characterized as community ambulators (K-level 3 or 4). However, because participants’ mean activity rates in the present study (3.13–3.14 hours/day) were lower than in prior studies, they may have been less active than typical prosthesis users.

In the present study, activity measured over a 4-wk period did not differ significantly between the two sockets thus was a poor metric for characterizing socket fit. This result is consistent with similar studies that showed step counts were not sensitive to changes in prosthetic feet^[47], knees^[28,30], or pylons^[28,30,47]. Participants may have had typical daily and weekly routines (e.g., personal, vocational, or recreational activities) that remained constant, regardless of socket fit. They may also have placed artificial activity limits upon their days, limiting their activities once a certain level of total daily activity was reached.

Activity monitoring is sensitive to short-term changes in routine^[48], making changes in activity due to socket fit difficult to distinguish. One participant in the present study stated that he worked longer hours during the month he wore the larger socket compared with the time he wore the smaller socket, accounting for an approximately 19.8% hours/day increase in activity while he wore the larger socket. Monitoring activity for longer time intervals may reduce these problems, as suggested by Halsne *et al.*^[49]. However, towards the goal of a

sensitive variable for early identification of changes in socket fit, long-term activity monitoring may be impractical. Monitoring in more detail, i.e. types and durations of individual activities (e.g., sit, stand, walk, run, doff), may provide insight towards characterization of socket fit, and should be considered in future studies.

Limb Fluid Volume

Anterior or anterior-distal limb fluid volumes may be good metrics for measuring deteriorating socket fit since they demonstrated visible differences and large effect sizes between the larger and smaller sockets. We expect from a biomechanical perspective that anterior-distal differences were more substantial than posterior or posterior-distal ones because the high sagittal plane bending moment of the socket on the limb during gait tended to focus interface normal and shear forces anterior-distally over the relatively small surface area there^[50–53]. An oversized socket, even if accommodated with socks, would be expected to induce greater anterior distal interface stresses on the residual limb than a well-fitting socket because of the looser mechanically coupling between the limb and socket.

It is worth noting that we did not control hydration and diet in this study. Hydration and diet (particularly sodium intake) are known to impact fluid regulation within the body^[54], potentially influencing day-to-day socket fit. The results here suggest that the influence of socket size was larger than the influence of either food/liquid intake or activity.

Self-Reported Outcomes

Of the self-report outcome measured, SCS was the most promising measure to be further studied as a discriminating factor as distinguishing between an oversized and well-fit socket. It should be noted, however, that good residual limb sensation was an inclusion criteria in the present study. SCS may be less effective for prosthesis users who have peripheral neuropathy or other problems that limit sensation. Use of additional socks in the oversized sockets may have mitigated differences in socket comfort. One participant commented that the additional socks in the larger socket added a welcomed cushion to the socket. While socks may provide additional cushioning, too many socks may be detrimental to limb health^[55].

Differences in PEQ scores on all subscales varied considerably (as inferred from the confidence intervals) possibly because participants' perceptions of socket fit issues may have been obscured by the range of questions included in each PEQ subscale. For example, the PEQ Utility subscale includes several questions related to socket fit, but also includes questions related to energy required to use the prosthesis, feel of the prosthesis, and ease of donning the prosthesis^[40] — areas that may not be adversely affected by a slightly oversized socket.

Sock Thickness

Data from the literature indicates that mean sock thickness under stance phase walking conditions is 0.5mm for 1-ply socks, 0.9mm for 3-ply socks, and 1.2mm for 5-ply socks^[56]. Thus within resolution limits for adding socks, participants well-perceived socket size differences between the two sockets; they added sock thickness approximately equal to the

radial size difference between the sockets when wearing the larger socket. This result reflected the participants' good sensation, an eligibility criterion for this study. In general, participants chose to overcompensate rather than undercompensate for the size difference between the larger and smaller socket, consistent with clinical experience.

Quantifying sock thickness under moderate compression (101.2kPa) may be a useful clinical technique for prosthetists to estimate the degree of socket oversizing in prosthesis users with good sensation. Since relationships between ply and thickness vary by sock model and because sock thickness changes over time^[12,13,56], use of a sock thickness caliper may facilitate measurement.

Case study participants—Some results for all three case study participants were consistent with trends observed in the main study: activity was higher for the smaller than the larger socket; morning-to-afternoon anterior-distal limb fluid volume changes were greater for the larger than smaller socket; and self-report PEQ Utility and Residual Limb Health were higher for the smaller than the larger socket. Other measures showed mixed results, including step width asymmetry, morning-to-afternoon anterior region limb fluid volume change, and self-report scores for SCS and PEQ Satisfaction, Well-Being, and Ambulation.

It is reasonable to suspect that the long time period between test days for case study participants affected results, but how and to what degree is unclear. Further investigation is needed.

CONCLUSION

A number of gait, activity, limb fluid volume, and self-reported outcome variables were investigated for their ability to serve as objective metrics for early identification of deteriorating prosthetic socket fit in people with trans-tibial amputation. Results suggest that step time and width asymmetry, anterior and anterior-distal morning-to-afternoon limb fluid volume change, SCS, and subscales of the PEQ were the most promising variables. Evaluation in a larger group of participants should be pursued.

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Highlights

- Step time asymmetry, step width asymmetry, anterior and anterior-distal morning-to-afternoon fluid volume change, socket comfort scores, and self-reported measures of utility, satisfaction, well-being, residual limb health, and ambulation may be viable metrics for early detection of deterioration in socket fit
- Use of a sock thickness caliper with an applied pressure of 101.2 kPa may allow a practitioner to easily measure sock thickness and assess socket oversizing

FIGURE 1. Participant's residual limb with electrodes for monitoring residual limb fluid volume

The proximal current-injection (PCI) electrodes were placed on the upper thigh, and the distal current-injection (DCI) electrode (not visible) was placed on the distal residual limb. The proximal voltage-sensing electrodes were positioned at the level of the patellar tendon distal to the fibular head. The distal voltage-sensing electrodes were positioned such that their lower edges were at the level of the distal tibia. The mid-limb voltage-sensing electrodes were positioned half way between the proximal and distal voltage-sensing electrodes. Voltage was sensed from four channels: 1: anterior-distal channel; 2: anterior channel; 3: posterior-distal channel; 4: posterior channel.

FIGURE 2. Sock thickness differences between the larger and smaller sockets for different loading conditions

Loading conditions reflect applied pressure magnitudes described in the text. Circles are sock thicknesses measured for each participant. Box surrounds 25th and 75th quartile (Inter-quartile range). Line within box is median. Whiskers outside of the box represent the mean. The dashed horizontal line is the radial socket change of 1.8 mm. W-B = weight-bearing.

FIGURE 3. Activity during the 4-week wear periods

Left end points are results from the smaller socket; right end points are results from the larger socket. Participant identifiers shown with numbers and letters. Solid lines are main study participants; dashed lines are case study participants.

FIGURE 4a. Morning-to-afternoon fluid volume change in anterior regions

Left ends points are results from the smaller socket; right end points are results from the larger socket. Participant identifiers shown with numbers and letters. Solid lines are main study participants; dashed lines are case study participants.

FIGURE 4b. Morning-to-afternoon fluid volume change in posterior regions

Left ends points are results from the smaller socket; right end points are results from the larger socket. Participant identifiers shown with numbers and letters. Solid lines are main study participants; dashed lines are case study participants.

FIGURE 5. Socket Comfort Score (SCS) assessed after each 4-week wear period

Left ends points are results from the smaller socket; right end points are results from the larger socket. Participant identifiers shown with numbers and letters. Solid lines are main study participants; dashed lines are case study participants.

FIGURE 6. Prosthesis Evaluation Questionnaire results

Left ends points are results from the smaller socket; right end points are results from the larger socket. Participant identifiers shown with numbers and letters. Solid lines are main study participants; dashed lines are case study participants.

TABLE 1

Prosthesis Evaluation Questionnaire (PEQ) questions included in the self-report survey.

Domain	Questions
Satisfaction	Over the past four weeks, rate...
Ambulation	how happy you have been with your current prosthesis. your ability to walk when using your prosthesis. your ability to walk in close spaces when using your prosthesis. your ability to walk up stairs when using your prosthesis. your ability to walk down stairs when using your prosthesis. your ability to walk up a steep hill when using your prosthesis. your ability to walk down a steep hill when using your prosthesis. your ability to walk on sidewalks and streets when using your prosthesis. your ability to walk on slippery surfaces (e.g. wet tile, snow, a rainy street, or a boat deck) when using your prosthesis.
Residual Limb Health	Over the past four weeks, rate... how much you sweat inside your prosthesis (in the sock, liner, socket). how smelly your prosthesis was at its worst. how much of the time your residual limb was swollen to the point of changing the fit of your prosthesis. any rash(es) that you got on your residual limb. any ingrown hairs (pimples) that were on your residual limb. any blisters or sores that you got on your residual limb.
Utility	Over the past four weeks, rate... the fit of your prosthesis. the weight of your prosthesis. your comfort while standing when using your prosthesis. your comfort while sitting when using your prosthesis. how often you felt off balance while using your prosthesis. how much energy it took to use your prosthesis for as long as you needed it. the feel (such as the temperature and texture) of the prosthesis (sock, liner, socket) on your residual limb (stump). the ease of putting on (donning) your prosthesis.
Well Being	Over the past four weeks... rate how satisfied you have been with how things have worked out since your amputation. how would you rate your quality of life?

TABLE 2a

Participant demographics.

Partic.	Gender	Since Last Socket Delivery (Years)	Age (years)	Height (cm)	Mass (kg)	BMI ¹	Since Amputation (years)	Residual Limb Length (cm) ²	Mid-limb Circumference (cm) ³	MFCL	Amputation Type	PAD (Y/N)	General Health Notes
1	M	3.0	52.0	165	80.6	29.6	6.5	16.5	27.5	K-3	Traumatic	N	High blood pressure, smokeless tobacco
2	M	3.1	49.3	183	100.0	29.9	22.7	10.0	42.6	K-3	Traumatic	N	Multiple pain medications
3	F	1.1	30.9	160	68.5	26.8	8.5	16.0	27.8	K-4	Traumatic	N	High blood pressure
4	M	5.5	47.2	180	85.2	26.3	20.3	17.0	30.9	K-4	Infection	N	No medications, smoker
5	M	5.1	72.2	180	83.9	25.9	35.7	18.1	27.5	K-4	Trauma/Infect	N	High cholesterol
6	M	1.4	68.1	186	88.2	25.6	40.5	12.3	34.6	K-3	Traumatic	N	High blood pressure
7	M	3.4	66.5	173	61.9	20.8	10.1	15.0	27.9	K-3	Traumatic	N	No medications
8	F	0.6	69.0	155	61.2	25.5	3.5	12.2	26.2	K-3	Congenital	N	High cholesterol, high blood pressure
9	M	1.7	31.6	170	96.1	33.3	29.1	25.8	24.7	K-4	Congenital	N	Diabetes
	AVERAGE	2.8	54.1	172	80.6	27.1	19.7	15.9	30.0				
	SD	1.7	15.9	11	14.0	3.5	13.4	4.6	5.5				
	MEDIAN	3.0	52.0	173	83.9	26.3	20.3	16.0	27.8				

Partic.	Gender	Since Last Socket Delivery (Years)	Age (years)	Height (cm)	Mass (kg)	BMI ¹	Since Amputation (years)	Residual Limb Length (cm) ²	Mid-limb Circumference (cm) ³	MFCL	Amputation Type	PAD (Y/N)	General Health Notes
A	M	7.9	27.1	183	110.0	32.8	7.7	18.0	33.2	K-3	Traumatic	N	No medications, smoker
B	F	1.5	56.8	160	80.0	31.3	2.1	11.3	32.8	K-2	Traumatic	N	High blood pressure, diabetes
C	M	1.1	39.4	175	71.6	23.4	0.8	12.5	31.6	K-3	Infection	N	High blood pressure, smoker
	AVERAGE	3.5	41.1	173	87.2	29.2	3.5	13.9	32.5				
	SD	3.8	14.9	12	20.2	5.1	3.7	3.6	0.8				
	MEDIAN	1.5	39.4	175	80.0	31.3	2.1	12.5	32.8				

¹Weight with prosthesis

²MPT to end of limb

³Average c1 and c3

TABLE 2b

Participant Prosthesis Information.

Partic.	Duplicate Socket (First)	Modified Socket (Second)	Sock Thickness (stance) (mm) (Larger)	Sock Thickness (stance) (mm) (Smaller)	Difference in Sock Thickness (mm) (Larger-Smaller)	Number of days between sessions	Foot	Suspension	Liner	Traditional Socket	Study Socket
1	Larger	Smaller	2.47	1.24	1.22	28	College Park Dynamic Response	Lock & Pin	OWW Alpha	Endo, LCF, PTB	Endo, LCF, PTB
2	Smaller	Larger	2.87	0.69	2.17	31	Freedom Innovations Renegade	Lock & Pin	OWW Alpha Silicone	Endo, LO, PTB	Endo, LCF, PTB
3	Smaller	Larger	1.21	0.40	0.81	28	Ossur Rotate	Lock & Pin	Freedom Innovations Inception	Endo, LCF, PTB	Endo, LCF, PTB
4	Smaller	Larger	1.54	0.00	1.54	28	Ossur Flex Foot	Lock & Pin	OWW Alpha	Endo, LCF, PTB	Endo, LCF, PTB
5	Smaller	Larger	3.09	0.64	2.45	28	Freedom Innovations Renegade	Lock & Pin	Ossur Iceross	Endo, LO, PTB	Endo, LCF, PTB
6	Smaller	Larger	2.36	0.00	2.36	27	Ossur Veri-Flex	Lock & Pin	OWW Alpha Silicone	Endo, LCF, PTB	Endo, LCF, PTB
7	Smaller	Larger	2.79	0.73	2.06	42	Otobock Trias	Lock & Pin	OWW Alpha	Endo, LCF, PTB	Endo, LCF, PTB
8	Larger	Smaller	3.30	0.82	2.47	26	College Park Tribute	Lock & Pin	OWW Alpha Hybrid	Endo, LO, PTB	Endo, LCF, PTB
9	Smaller	Larger	2.06	0.50	1.57	27	Freedom Innovations Renegade	Lock & Pin	Ossur Iceross	Endo, LCF, PTB	Endo, LCF, PTB
		MEAN	2.41	0.56	1.85	29					
		SD	0.70	0.39	0.59	5					
		MEDIAN	2.47	0.64	2.06	28					

Partic.	Duplicate Socket	Modified Socket	Old Socket Sock Thickness (mm) (stance)	New Socket Sock Thickness (mm) (stance)	Difference in Sock Thickness (mm) (Old-New)	Time Between Sessions (days)	Foot	Suspension	Liner	Old Socket	New Socket
A	N/A	N/A	2.13	1.18	0.96	128	Freedom Innovations Renegade	Lock & Pin	Ossur Iceross	Endo, LCF, PTB	Endo, LCF, PTB, Pads
B	N/A	N/A	1.30	3.03	-1.73	335	College Park Soleus	Lock & Pin	Ossur Iceross	Endo, LO, PTB	Pelite, Endo, LO, PTB
C	N/A	N/A	5.77	2.48	3.29	167	Freedom Innovations Renegade	Supracondylar, Sleeve	Pelite	Endo, LCF, PTB	Endo, LCF, PTB, Sleeve
		MEAN	2.41	1.25	1.23	103					
		SD	1.72	1.08	1.51	116					
		MEDIAN	2.13	0.64	1.57	29					

LCF = Laminated Carbon Fiber

LO = Laminated Other (Nylon)

TABLE 3

Gait analysis results

Bold text indicates the absolute value for the larger socket was greater than that for the smaller socket.

GAIT VARIABLE	SOCKET	PARTICIPANT NUMBER											
		1	2	3	4	5	6	7	8	9	A	B	C
# of Steps in Analysis	Smaller	66	56	53	50	60	52	59	67	59	69	118	67
	Larger	67	59	60	41	61	60	59	66	59	74	70	61
Speed (m/s)	Smaller	1.06	1.31	1.45	1.29	1.11	1.22	1.20	1.13	1.27	0.88	1.09	1.07
	Larger	0.99	1.16	1.37	1.46	1.16	1.16	1.22	1.13	1.32	0.89	0.98	1.07
Cadence (step/min)	Smaller	102.8	114.1	124.5	104.8	102.5	100.7	110.1	112.8	111.3	86.6	114.0	101.8
	Larger	99.1	106.9	123.1	108.7	105.5	97.7	112.7	110.2	113.3	93.0	109.4	105.7
P Step Length (cm)	Smaller	69.5	72.8	71.3	72.9	64.0	74.0	68.3	62.9	69.3	67.1	60.1	67.8
	Larger	65.8	67.9	67.2	80.6	65.4	72.3	67.8	63.3	71.3	59.1	54.3	64.0
NonP Step Length (cm)	Smaller	55.1	64.9	68.7	74.8	66.4	71.2	62.5	57.3	67.4	54.9	54.3	58.9
	Larger	55.3	62.7	65.8	80.4	66.0	70.0	61.7	59.5	69.0	55.8	52.7	57.8
Mean Step Length (cm)	Smaller	62.3	68.8	70.0	73.8	65.2	72.6	65.4	60.1	68.4	61.0	57.2	63.3
	Larger	60.5	65.3	66.5	80.5	65.7	71.1	64.7	61.4	70.1	57.5	53.5	60.9
Step Length Asym (cm/cm)	Smaller	-0.116	-0.058	-0.018	0.013	0.019	-0.019	-0.044	-0.047	-0.013	-0.100	-0.051	-0.070
	Larger	-0.087	-0.039	-0.010	-0.001	0.004	-0.016	-0.047	-0.031	-0.016	-0.029	-0.014	-0.051
P Step Width (cm)	Smaller	12.0	12.6	10.5	10.0	10.3	13.3	11.7	10.8	13.0	14.0	9.1	12.2
	Larger	10.4	14.3	8.7	8.7	7.9	12.5	12.1	11.2	14.2	12.1	13.7	10.6
NonP Step Width (cm)	Smaller	12.1	12.6	10.2	9.4	10.0	13.0	11.7	10.8	13.2	14.1	8.9	12.2
	Larger	10.4	14.2	8.8	8.5	8.0	12.4	12.5	11.2	13.8	12.1	13.7	10.5
Mean Step Width (cm)	Smaller	12.0	12.6	10.3	9.7	10.1	13.2	11.7	10.8	13.1	14.1	9.0	12.2
	Larger	10.4	14.3	8.7	8.6	8.0	12.5	12.3	11.2	14.0	12.1	13.7	10.5
Step Width Asym (cm/cm)	Smaller	0.002	0.000	-0.014	-0.031	-0.015	-0.009	-0.002	-0.002	0.006	0.004	-0.012	0.000
	Larger	0.000	-0.003	0.007	-0.009	0.005	-0.004	0.015	0.001	-0.014	-0.002	-0.003	-0.006
P Step Time (s)	Smaller	0.62	0.52	0.50	0.59	0.59	0.61	0.55	0.55	0.54	0.72	0.53	0.59
	Larger	0.64	0.56	0.49	0.56	0.57	0.63	0.54	0.56	0.53	0.67	0.55	0.54
NonP Step Time (s)	Smaller	0.55	0.53	0.47	0.55	0.59	0.58	0.54	0.52	0.54	0.66	0.52	0.59

GAIT VARIABLE	SOCKET	PARTICIPANT NUMBER											
		1	2	3	4	5	6	7	8	9	A	B	C
Mean Step Time (s)	Larger	0.58	0.56	0.48	0.54	0.57	0.60	0.53	0.53	0.53	0.62	0.54	0.59
	Smaller	0.59	0.53	0.48	0.57	0.59	0.60	0.55	0.53	0.54	0.69	0.53	0.59
	Larger	0.61	0.56	0.49	0.55	0.57	0.61	0.53	0.54	0.53	0.64	0.55	0.57
Step Time Asym (s/s)	Smaller	-0.055	0.010	-0.033	-0.032	0.000	-0.025	-0.009	-0.025	-0.004	-0.043	-0.013	0.005
	Larger	-0.049	-0.003	-0.013	-0.017	0.005	-0.023	-0.014	-0.019	-0.001	-0.044	-0.008	0.048

TABLE 4
Means, 95% confidence intervals, and effect sizes for differences (larger — smaller socket) in measures of Gait, Fluid Volume Change, Survey, and Activity — sorted from largest to lowest absolute effect size within each category (N=9)

Gait measures are in same units as in TABLE 3.

Measures	Mean Difference (Larger-Smaller)	95% Confidence Interval		Effect Size (Mean/SD)
		Lower Bound	Upper Bound	
Gait Measures				
Step Time Asymmetry	0.005	-0.002	0.012	0.591
Step Width Asymmetry	0.009	-0.003	0.021	0.562
Prosthetic Step Width	-0.467	-1.575	0.642	-0.324
Mean Step Width	-0.409	-1.441	0.623	-0.305
Non-Prosthetic Step Width	-0.349	-1.315	0.617	-0.278
Non-Prosthetic Step Time	0.005	-0.009	0.019	0.273
Step Length Asymmetry	0.003	-0.010	0.016	0.188
Cadence	-0.711	-3.609	2.186	-0.189
Non-Prosthetic Step Length	0.229	-1.769	2.226	0.088
Prosthetic Step Length	-0.367	-3.382	2.648	-0.094
Speed	-0.007	-0.079	0.065	-0.077
Mean Step Time	0.001	-0.012	0.015	0.072
Prosthetic Step Time	0.001	-0.016	0.018	0.044
Mean Step Length	-0.070	-2.504	2.364	-0.022
AM-PM Fluid Vol Change (%/h)				
Anterior	-0.770	-1.768	0.228	-0.593
Anterior Distal *	-2.171	-5.636	1.293	-0.580
Posterior Distal *	0.264	-0.919	1.447	0.206
Posterior	0.100	-0.729	0.929	0.093
Self-Report Measures				
Socket Comfort Score (0 to 10)	-1.556	-3.593	0.482	-0.587
PEQ Utility (0 to 100)	-10.286	-25.306	4.734	-0.526
PEQ Satisfaction (0 to 100)	-14.222	-36.822	8.378	-0.484
PEQ Res. Limb Health (0 to 100)	-3.919	-10.568	2.731	-0.453
PEQ Well-Being (0 to 100)	-5.611	-15.182	3.960	-0.451
PEQ Ambulation (0 to 100)	-10.100	-30.042	9.842	-0.389
Activity Duration(h/d)	0.0066	-0.3017	0.3149	0.016

SD = Standard deviation

* N=7 (2 missing values because 2 participant limbs too short to attach mid-limb electrodes)