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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 4 weeks. 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 (measured 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 score, and self-reported utility. These variables may be viable metrics for early detection of deterioration in socket fit, and should be tested in a larger clinical study.

1. 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 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

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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.

2. Methods

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

2.1. 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 4 h/day, 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.

2.2. 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 101.2 kPa applied pressure). An as-prescribed socket normally worn with a sock thickness less than 3.0 mm was considered clinically safe to enlarge, while one with a sock thickness more than 3.0 mm was considered not safe to enlarge and instead was reduced. The basis for using a 3.0 mm threshold was the research practitioner's clinical judgment that 3.0 mm allowed a reasonable margin of safety when reducing a socket 1.8 mm (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 1–2 mm 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 0.10 mm mean radial error.

The CAD software was used to apply a uniform 1.80 mm 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.

2.2.1. 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."

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