

# Perceived Socket Comfort and Function Does Not Correlate With Residual Limb Skin Shear Strain During Gait In Patients With Transfemoral Amputation

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**INTRODUCTION:** There are approximately 29,000 cases of above knee amputations recorded in the United States every year<sup>1</sup>. Artificial limbs are generally connected to the residual limb with a socket prosthesis that facilitates weight bearing, suspension, and force coupling. Surface contact pressure and friction between the socket and the residual limb induce skin problems such as ulcers, calluses, or blisters<sup>2</sup>. Although a previous study that measured skin movement within the socket prosthesis demonstrated that increased skin strain was associated with decreased prosthetic use<sup>3</sup>, it is not known how well individuals with transfemoral amputation can perceive changes in skin shear strain during gait. This is important because socket fitting is an iterative process wherein the prosthetist relies on patient feedback to inform socket design. This ongoing study aims to determine if skin shear strain within the socket correlates to the prosthetic user's perception of socket comfort and function. It was hypothesized that increased skin shear strain during gait would correlate with a decrease in patient-reported socket comfort and function.

**METHODS:** Following institutional review board approval and informed consent, 7 people with transfemoral amputations were enrolled in the study. A key inclusion criterion was the ability to ambulate without the use of assistive devices. Participants were casted and fitted for 4 custom check sockets by a licensed prosthetist. The sockets varied in fit and one check socket was modified to create two additional fits (standard of care, 6% decreased volume, lowered brim, ischial containment, quad, and pliable material). Approximately 40-60 stainless steel beads (1.6-2.0mm diameter) were glued to the participants' residual limb, then usual donning of the liner and socket was performed. The beads were imaged using a biplane radiography system (100 images/sec, 80kV, 125mA maximum, 1ms pulse width, 2s trial duration) while participants walked at a self-selected gait speed ( $7.7 \pm 0.20$  m/s) on a treadmill. Images were collected for three steps per socket, including the 6 check sockets and the participant's definitive socket. The participants were blinded to the socket modification, and asked at the end of each socket testing to rate the comfort and function of the socket using the 15-point Global Rate of Change (GROC) scale, where -7 is considered greatly worse and +7 is considered greatly better and 0 is no change compared to their definitive socket. Additionally, the limb and beads were imaged as the participant stood within the system without wearing the socket or liner. For each socket tested, one trial worth of bead locations were semi-autonomously tracked in each pair of synchronized radiographs with an accuracy of 0.02mm using radiostereometric analysis (RSA)<sup>4</sup>. The bead locations in the no-liner condition were used to create a skin mesh model, and the change in position of the beads during walking was used to drive the deformation of the skin mesh. The skin mesh model deformation was fed into FEBio<sup>5</sup> to calculate the skin shear strain. The shear strains were averaged across anatomical quadrants (anterior, posterior, medial, and lateral aspects of the residual limb). Correlation between the GROC comfort and function scores and the maximum regional skin shear strains were tested using Spearman's correlation.

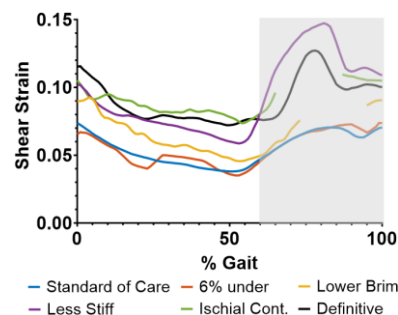
**RESULTS:** Data from 27 sockets across 5 subjects were included in this interim analysis (32 static trials and 27 walking trials). The typical pattern for the strain waveform during gait consisted of a peak strain during late swing phase and a decrease in strain after foot strike (Figure 1). Regions with the greatest amount of strain differed between participants and socket types. No correlation was found between GROC scores (range -7 to +2) and maximum skin shear strain per region (range 0.007 to 0.20) (Figure 2).

**DISCUSSION:** This interim analysis suggests that patient-reported comfort and function of the socket may not be related to maximum skin shear strain during gait. Explanations for these results include: the quadrants used to average the shear strains may have been too large to capture focal strains associated with comfort and function; other factors, such as the residual bone motion and localized pressure or pain sensitivity, may be the primary factors driving socket comfort and function; the duration of wear may have been insufficient to elicit discomfort associated with changes in skin strain. Further analysis considering anatomical differences such as residual limb length and known pressure tolerant/intolerant sites may also elucidate new results.

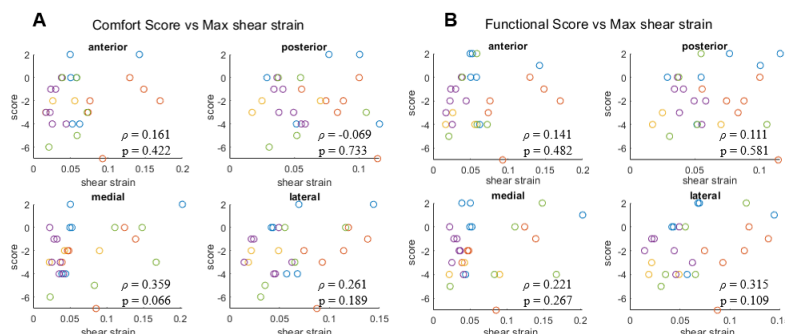
**SIGNIFICANCE:** Prosthetists should be aware that patient-reported comfort and function may not reflect residual limb skin strain during gait. Quantitative measures of skin strain, rather than patient feedback, may be needed to inform socket design to minimize skin problems for transfemoral amputees.

**REFERENCES:** [1] U.S. Department of Health & Human Services, 2021. [2] Dudek et al., Arch. Of Phys. Med. And Rehab., 2005. [3] Gale et al., J. of Biomech., 2021. [4] Anderst et al., J of Biomech Eng., 2003. [5] Mass et al., J. of Biomech. Eng., 2012.

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**Figure 1:** Example shear strain over the gait cycle. Data is from the anterior region of the residual limb from one participant wearing 6 different sockets. The non-shaded area represents stance phase and grey-shaded area represents swing phase.



**Figure 2:** Regional maximum shear strain vs (A) Comfort score and (B) Functional score. Each color represents a single participant, with each circle representing a different socket.  $\rho$  = Spearman correlation coefficient.