Socket Fit May Influence Residual Femur Motion in Individuals with Transfemoral Amputations

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INTRODUCTION: Approximately 220,000 people in the United States live with a transfemoral amputation[1]. Many individuals with transfemoral amputations experience pain and physical limitation due to poor fit between the residual limb and prosthesis[2]. The movement of the residual femur while using a prosthesis can irritate the surrounding soft tissue and cause localized pain, edema, and other debilitating conditions[3,4,5]. These patients often experience additional pathologies associated with the use of their prosthesis such as lower back pain, osteoarthritis, osteoporosis and other musculoskeletal issues[6]. Although residual femur range of motion (ROM) within the prosthetic socket during gait has been reported in individuals with transfemoral amputations[7,8], little research has been done to determine how socket design affects residual femur motion, and if residual femur motion is associated with patient-reported comfort and function. The aims of this ongoing study are to investigate how prosthetic socket design affects residual femur motion, intra-socket pressure, residual limb skin strain, and patient-reported comfort and function. This interim analysis focuses on how prosthetic socket design affects residual femur ROM during gait, and if residual femur ROM is associated with patient-reported comfort and function.

METHODS: Individuals with unilateral transfemoral amputations provided written informed consent to participate in this ongoing IRB-approved study. All participants had been walking with their prosthesis for more than a year and had no other major health conditions. A licensed prosthetist casted and fitted participants for custom check sockets that varied in fit based on geometry, brim height, stiffness, and volume. Participants then walked on a treadmill at a self-selected pace for three trials per socket lasting one to three minutes each. Participants were blinded to each socket modification. Synchronized biplanar radiographs of the residual femur were collected at 100 images per second during gait. Ground reaction forces (GRF) were recorded at 1000 Hz using a Bertec dual-belt instrumented treadmill. A 12-camera Vicon motion capture system and markers were used to track the motion of the socket and prosthetic knee. After completing each socket trial, participants rated the socket's function and comfort compared to their personal (definitive) device on a scale of -7 to 7 using the Global Rate of Change (GROC) scale[9]. CT scans of the residual femur were also collected (average 0.55 x 0.55 mm in-plane resolution, 0.625 mm slice thickness). A combination of manual and automated bone segmentation was performed on the CT images of the residual femur to create three-dimensional subject-specific bone models using Mimics 22 software. Digitally reconstructed radiographs, created from subject specific bone models, were matched to the biplane radiographs using a previously validated volumetric model-based tracking method[10] to measure residual femur motion. Foot strike and push off events were identified using a 50 N threshold in the vertical component of the GRF. Relative motion between the residual femur and the socket over the stance phase of gait was calculated using custom MATLAB code, interpolated to percent stance phase, and averaged across the three trials of each socket. ROM was calculated as the maximum minus the minimum translation and rotation of the distal end of the residual femur. Correlations between residual femur ROM and patient reported socket comfort and function were calculated using Spearman correlation coefficients in Matlab ($p<0.05$).

RESULTS: Five individuals with traumatic unilateral transfemoral amputations were included in this analysis (1F, age: 25-64 years, height: 169-186 cm, weight with prosthesis: 59.4-95.7 kg). 35 walking trials were included in the analysis. The average gait speed was 0.8 ± 0.2 m/s. All three components of femur translation ROM were greatest while wearing the less stiff socket (Figure 1A). Medial-lateral residual femur ROM (11.4 ± 7.3 mm) was less than anterior-posterior (24.6 ± 7.3 mm) and proximal-distal (pistoning) (18.0 ± 6.1 mm) ROM for all sockets. Similarly, anterior tilt and varus-valgus ROM were greatest while wearing the less stiff socket (Figure 1B). Residual femur internal-external rotation ROM ($9.5 \pm 3.8°$) was less than varus-valgus ROM ($12.0 \pm 8.0°$) and anterior tilt ROM ($15.8 \pm 11.0°$) for all sockets (Figure 1B). Vertical ground reaction forces were consistent across all sockets (0.9 ± 0.1 xBW). Greater residual femur pistoning ROM was correlated with higher patient reported function scores ($\rho=0.483$, $p=0.017$), however, no other discernable trends related to residual femur motion and patient reported function or comfort were observed (all $p>0.131$).

DISCUSSION: This interim analysis suggests that the effect of prosthetic socket design on residual femur motion during gait is small but detectable using biplanar radiography. Socket stiffness appears to have a greater influence on residual femur motion than other socket characteristics. The inability to detect strong associations between residual femur motion and patient-reported comfort and function may be due to the short time each socket was worn or that other factors, such as skin strain or pressure, are the primary determinants of comfort and function.

SIGNIFICANCE: Clinicians may be able to influence residual femur motion by modifying the socket material, potentially leading to improved comfort and function.

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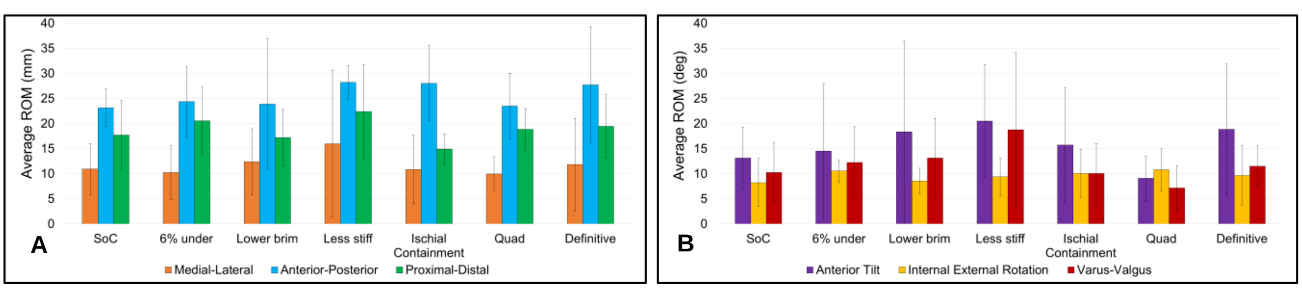

Figure 1. *Average residual femur translation (A) and rotation (B) ROM during the stance phase of gait across five modified sockets, a standard of care (SoC) check socket, and their definitive socket.*