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ORIGINAL RESEARCH ARTICLE

Interface Stress in Socket/Residual Limb with Transtibial Prosthetic Suspension Systems During Locomotion on Slopes and Stairs

ABSTRACT

Eshraghi A, Abu Osman NA, Gholizadeh H, Ali S, Abas WABW: Interface stress in socket/residual limb with transtibial prosthetic suspension systems during locomotion on slopes and stairs. Am J Phys Med Rehabil 2015;94:1–10.

Objective: This study aimed to compare the effects of different suspension methods on the interface stress inside the prosthetic sockets of transtibial amputees when negotiating ramps and stairs.

Design: Three transtibial prostheses, with a pin/lock system, a Seal-In system, and a magnetic suspension system, were created for the participants in a prospective study. Interface stress was measured as the peak pressure by using the F-socket transducers during stairs and ramp negotiation.

Results: Twelve individuals with transtibial amputation managed to complete the experiments. During the stair ascent and descent, the greatest peak pressure was observed in the prosthesis with the Seal-In system. The magnetic prosthetic suspension system caused significantly different peak pressure at the anterior proximal region compared with the pin/lock ($P = 0.022$) and Seal-In ($P = 0.001$) during the stair ascent. It was also observed during the stair descent and ramp negotiation.

Conclusions: The prostheses exhibited varying pressure profiles during the stair and ramp ascent. The prostheses with the pin/lock and magnetic suspension systems exhibited lower peak pressures compared with the Seal-In system. The intrasystem pressure distribution at the anterior and posterior regions of the residual limb was fairly homogenous during the stair and ramp ascent and descent. Nevertheless, the intrasystem pressure mapping revealed a significant difference among the suspension types, particularly at the anterior and posterior sensor sites.

Key Words: Rehabilitation, Prostheses, Gait, Motion Analysis

The increased incidence of diabetes mellitus worldwide has led to higher rates of lower-limb amputations.[1,2] Individuals with limb amputation endure high ambulatory loading when wearing prosthesis during their daily activities. This loading is mostly applied by the prosthesis to the skeletal structure through the socket walls, with the interface located between the soft tissues of the residual limb and the prosthetic socket as part of the suspension means. The soft tissue of the residual limb is not adapted to high shear loading and epidermal pressure during locomotion. A large number of lower-limb amputees experience pressure sores because of their use of prostheses. Therefore, many persons with amputation avoid using prostheses, which considerably decreases their daily activities. Individuals with amputation also develop skin problems, such as cysts, blisters, dermatitis, and edema because of their use of prostheses.[3–5]

The interface pressure is significantly influenced by ambulation tasks, among other factors, such as residual limb site, clinical condition, and socket alignment.[6] Socket walls, soft insert (liner), and coupling devices such as pins and seals comprise the suspension system of lower-limb prostheses. These constituents can alter the pressure profile of the residual limb within the prosthetic socket. Various suspension systems are found to affect the interface pressure during level walking.[7,8]

The stress profile between the prosthetic socket and the interface of the residual limb is crucial to the socket design.[9] Quantification methods use either the transducers that are embedded into the socket or the thin sensor pad between the skin and liner/socket.[10–13] The pressure profiles of various suspension systems during level walking have been evaluated.[12,14,15] The pressures at the socket/skin interfaces vary considerably among individuals, sites, and clinical conditions. The highest peak pressure for the patellar-tendon-bearing socket has reportedly surpassed 300 kPa, which can be attributed to different prostheses and fitting methods as well as the divergence of soft-tissue thickness, site, and residual-limb geometry.[11,16–18] The pressures also vary depending on the walking styles and socket alignments.[18–20]

Individuals with amputation are required to negotiate ramps and stairs when performing most of their daily activities. Therefore, the biomechanics of the residual limb when a person performs these tasks should be investigated. The ability to negotiate various surfaces enables an individual to conduct more strenuous activities.[21,22] The absence of foot and ankle joints, in addition to altered balance, stability, and decreased muscle power during rigorous activities, negatively affects the activity level of prosthesis users.[21] Only a few studies have investigated the pressure when negotiating inclines or stairs.[18,23] Individuals with lower limb amputation are greatly affected by environmental barriers because of their loss of foot and ankle lever mechanism.[21] They have reported a high interface pressure when negotiating ramps and stairs. For instance, compared with the level walking, the conventional patellar-tendon-bearing socket increases the pressure by 30% when negotiating stairs.[18]

Silicone soft liners increase comfort by decreasing friction.[24] Some soft liners use a coupling system, such as pin and seal. Few studies have evaluated the interface pressure with suspension systems that incorporate silicone liners during level walking.[7,25] However, the interface pressure between the residual limb and the socket during ramp negotiation is unclear. A suspension system with a silicone liner has been introduced.[26] The interface pressure with the magnetic prosthetic suspension system (MPSS) is shown to be different from other systems during level walking. Therefore, this study aimed to investigate the pressure profile with the MPSS and to compare it with those of the pin/lock and Seal-In suspension systems during ramp and stairs negotiation. These two suspension systems were selected because they are commonly used systems that are widely available. The study hypothesized a significant difference among the pressure magnitudes of the three systems.

METHODS

Participants and Prostheses

Thirteen individuals with transtibial amputation were selected as samples in a clinical trial study. To enter the study, a registered prosthetist checked the subject's medical record and performed physical examination, especially on the residual limb. A person was deemed eligible for the study if he/she was a unilateral transtibial, could ambulate independently, had a residual limb that was free from ulcer and pain, had undergone amputation at least 1 yr before the study, and had upper limbs that were healthy enough to independently don and doff the prosthesis. Those who had moderate residual limb length; had no significant problems with their residual limb; had no heart problem; could independently negotiate stairs and ramps; and had no orthopedic, rheumatic, neurologic, or cognitive impairments were selected to participate in the study. The participants were also asked to report taking any medication that could influence their balance. Persons with amputation who experienced residual limb problems within 3 mos before the study, had abnormalities in their limbs, or took medication affecting the balance were excluded from the sample. The study secured the approval of the University of Malaya Medical Centre ethics committee, and informed written consents were obtained from all study participants.

The differences in the prosthetic fabrication techniques, alignment, and fitting could significantly influence the results of the study. Therefore, one of the authors, a registered prosthetist, created three prostheses for each participant. These prostheses used three different suspension systems: (*a*) pin/lock suspension system (Dermo liner with shuttle lock), (*b*) new magnetic lock MPSS, and (*c*) Seal-In system (Seal-In X5 liner). The third system required a separate negative cast, and the two other systems were created from a single negative cast. The characteristics of the MPSS have been described in other studies.[26] Before the fabrication of final sockets, each participant was fitted with a transparent check socket to ensure its total surface bearing. The prosthetic foot of all prostheses was a carbon fiber flex-foot Talux (Össur). The participants were asked to use each prosthesis for at least 4 wks and were requested to visit the brace and limb laboratory once a week to monitor the health of the stump and the fitting changes.

Equipment and Protocol

To better understand the socket and residual limb interface, four 8-in-long, 3-in-wide F-socket transducers 9811E (Tekscan Inc, South Boston, MA) of 0.2-mm thickness were used in this study. Every sensor array is composed of printed circuits divided into load-sensing regions. The smallest sensing element of sensor consists of two thin, flexible mats holding the pressure-sensitive ink applied in columns and rows between them. The juncture of column and row forms the smallest element of area sensing known as the sensel. Each 9811E sensor has 96 sensels. The pressure profiles were recorded using Tekscan software version 6.51. Each sensor array was affixed to the anterior, posterior, medial, and lateral compartments of the stump. The sensors were first trimmed according to the contours of the residual limb to allow for 90% coverage. To ensure that the sensor arrays were accurately positioned, the residual limb was covered with wrapping plastic and the trimmed sensor arrays were attached to the plastic using an adhesive spray.

Before the experiment, the sensor arrays were equilibrated and calibrated using the Tekscan pressure bladder to eliminate the variation among the load cells. Following the instructions of the manufacturer, each sensor array was placed individually inside the pressure bladder and coupled it to an air compressor that provided a 100-kPa steady pressure for equilibration. After the equilibration, the calibration was accomplished according to the body mass.

Two separate experiments were conducted for the stair and ramp negotiations. The order of the experiments was randomized for each participant. The participants were required to ascend to and descend from, with a comfortable cadence, a 4-m custom-made ramp with a 7.5-degree inclination. They were also asked to ascend to and descend from a custom-made 82-cm-wide staircase with four steps that were 14-cm high and 32-cm apart from each other. Transtibial amputees usually observe two patterns when negotiating stairs, namely, the step-to gait and the step-over-step patterns. The participants in this study adopted the step-to-gait pattern to ensure consistency.

Data were recorded for the two consecutive trials at a 50-Hz sample rate for at least six cycles of ascending and descending the ramp and stairs. Before the experiments, each participant practiced the protocol to accustom himself/herself to the experimental protocol and the sensors. All the participants underwent the same procedure to reduce the variations in the recorded data. The participants completed five consecutive trials. The area within each array of sensors was further subdivided into a proximal region and a distal region. The middle step of each trial and the average peak pressure of the trials were used in the statistical analyses.

Data Analysis

The assumption of normality was verified for most of the variables. A repeated-measure analysis of variance with Bonferroni adjustment was adopted for the analysis. The peak pressures (PPs) were varied within the four transducer sites (anterior, posterior, medial, and lateral) and the suspension systems using a 4×3 (sensor $\times$ suspension systems) repeated-measure analysis of variance. The non–parametric statistical analysis and the Friedman test were applied in few cases. The Wilcoxon's signed-rank (Bonferroni adjusted α value) test was applied if a significant difference was observed among the three systems. Statistical analyses were conducted using Statistical Package for the Social Sciences 20.0 (SPSS, Chicago, IL). The level of significance was set at 0.05.

RESULTS

Demographics

Twelve participants completed the study. Their mean (SD) age, body weight, and height were 46.8 (12.3) yrs, 73.6 (11.5) kg, and 170.4 (4.9) cm, respectively. The mean residual limb length was 14.9 (1.2) cm. Trauma and diabetes were identified as the main causes of amputation.

Stair Negotiation

A significant difference in the PPs among the four major regions in every suspension system was revealed through the statistical analysis ($P < 0.05$). The proximal and distal regions among the three systems also had significantly different pressures during the stair ascent and descent. Considering the four sensor sites, the main differences among the systems were evident at the anterior and posterior regions. The average pressure values at the medial and lateral sites of the residual limb were less than those at the anterior and posterior sites (Table 1).

During the stair ascent, a significantly higher magnitude of PP was found in the Seal-In system compared with the pin/lock and MPSS systems both at the posterior (90.44 kPa *vs.* 63.13 kPa and 57.79 kPa; both $P = 0.000$) and anterior regions (80.14 kPa *vs.* 63.14 kPa and 51.03 kPa; $P = 0.001$ and $P = 0.000$, respectively). A significant difference was also observed at the medial region in the pin/lock and MPSS systems compared with the Seal-In system (49.21 kPa and 44.81 kPa *vs.* 66.04 kPa; $P = 0.013$ and $P = 0.000$, respectively). These systems had significantly different PPs at the anterior and posterior proximal subregions. The anterior proximal region showed the highest pressure among all the systems during the stair ascent. No statistical difference was found in the lateral regions of these systems. However, the PP at the medial distal subregion of the residual limb exhibited a significant difference (Table 1).

During the stair descent, the PP was significantly higher with the Seal-In system than with the pin/lock and MPSS systems in the entire anterior (80.41 kPa *vs.* 67.11 kPa and 58.41 kPa; $P = 0.021$ and $P = 0.000$, respectively), posterior (88.24 kPa *vs.* 64.12 kPa and 50.04 kPa; both $P = 0.000$), and medial (65.11 kPa *vs.* 47.33 kPa and 42.32 kPa; $P = 0.011$ and $P = 0.023$, respectively) regions. No significant difference was observed at the lateral region among the three systems ($P = 0.713$). Figure 1 shows the differences among the PPs of the three suspension systems during the stair ascent and descent.

Ramp Ascent/Descent

Significant differences were found in the PPs of the three interface systems at the three aspects of the residual limb (anterior, posterior, and lateral) during the ramp negotiation ($P < 0.05$). The maximum and minimum peak pressures were 90.03 kPa and 45.93 kPa with the Seal-In and MPSS systems, respectively. The PP was significantly lower with the pin/lock system (60.57 kPa, 64.50 kPa, and 60.54 kPa, respectively) and MPSS (56.60 kPa, 54.04 kPa, and 58.13 kPa, respectively) compared with the Seal-In system (83.48 kPa, 83.08 kPa, and 71.35 kPa, respectively) during the ramp ascent. No significant difference was found in the medial regions with the three suspension systems (Table 2).

Significant differences were found among the three systems at the residual limb subregions (distal and proximal) during the ramp ascent. The pressure was significantly lower with the pin/lock and MPSS systems compared with the Seal-In system at the proximal anterior (57.42 kPa and 48.21 kPa *vs.* 71.14 kPa; $P = 0.031$ and $P = 0.000$, respectively), posterior proximal (59.64 kPa and 49.54 kPa *vs.* 81.66 kPa; both $P = 0.000$), and posterior distal (51.73 kPa and 43.71 kPa *vs.* 65.28 kPa; $P = 0.041$ and $P = 0.016$, respectively) regions. The same finding was observed at the lateral proximal, medial proximal, and medial distal regions.

Significant differences were observed at the anterior, posterior, and medial regions with the three systems during the ramp ascent. The participants experienced a significantly lower PP with the pin/lock and MPSS systems compared with the Seal-In system at the anterior (both $P = 0.000$), posterior ($P = 0.001$ and 0.000), and lateral regions (both $P = 0.000$). No statistically significant difference was found during the ramp ascent at the medial region among the three systems.

During the ramp descent, the PP was lower with the pin/lock and MPSS systems compared with the Seal-In system at the anterior proximal (22.31% and 32.74%, respectively), anterior distal (18.04% and 27.89%, respectively), posterior proximal (20.43% and 32.26%, respectively), and posterior distal (35.18% and 33.68%, respectively) subregions. The lateral and medial proximal subregions among the systems showed no significant

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