INTRODUCTION

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. Individuals with limb amputation endure high ambulatory loading when wearing a 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.

The interface pressure is significantly influenced by ambulation tasks, among other factors, such as residual limb site, clinical condition, and socket alignment. 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.

The stress profile between the prosthetic socket and the interface of the residual limb is crucial to the socket design. Quantification methods use either the transducers that are embedded into the socket or the thin sensor pad between the skin and liner/socket. The pressure profiles of various suspension systems during level walking have been evaluated. 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. The pressures also vary depending on the walking styles and socket alignments.

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. 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. Only a few studies have investigated the pressure when negotiating inclines or stairs. Individuals with lower limb amputation are greatly affected by environmental barriers because of their loss of foot and ankle lever mechanism. 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.

Silicone soft liners increase comfort by decreasing friction. 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. 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. 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.
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 other two systems were created from a single negative cast. The characteristics of the MPSS have been described in other studies. 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 \( \times 3 \) (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 \( \alpha \) 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). The pressure was significantly lower with the pin/lock and MPSS systems compared with the Seal-In system at the anterior proximal ($P = 0.000$), posterior proximal ($P = 0.000$), and posterior distal ($P = 0.000$) 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 proximal ($P = 0.000$), posterior proximal ($P = 0.000$) and posterior distal ($P = 0.000$) regions. No statistically significant difference was found during the ramp ascent at the medial region among the three systems.

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 $P = 0.001$ and $P = 0.016$, respectively) and posterior regions ($P = 0.031$ and $P = 0.000$, respectively). 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 significantly 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
<table>
<thead>
<tr>
<th>Surface</th>
<th>Subregion</th>
<th>Pin/Lock</th>
<th>Seal-In</th>
<th>MPSS</th>
<th>Pin/Lock vs. Seal-In</th>
<th>Pin/Lock vs. MPSS</th>
<th>Seal-In vs. MPSS</th>
<th>Pin/Lock vs. MPSS</th>
<th>Seal-In vs. MPSS</th>
</tr>
</thead>
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<tr>
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<td>69.02 (18.43)</td>
<td>48.30 (19.21)</td>
<td>59.11 (18.10)</td>
<td>65.61 (23.14)</td>
<td>46.01 (20.51)</td>
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<td>0.001&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td></td>
<td>Dis</td>
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<td>64.04 (22.40)</td>
<td>50.15 (11.2)</td>
<td>54.11 (17.25)</td>
<td>67.05 (24.16)</td>
<td>41.70 (31.72)</td>
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<td>80.40 (48.20)</td>
<td>47.42 (20.30)</td>
<td>52.10 (15.52)</td>
<td>82.14 (38.31)</td>
<td>42.23 (15.50)</td>
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<td>0.011&lt;sup&gt;b&lt;/sup&gt;</td>
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<td>59.10 (17.51)</td>
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<td>58.16 (14.45)</td>
<td>68.56 (23.83)</td>
<td>49.06 (27.63)</td>
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<td>0.043&lt;sup&gt;b&lt;/sup&gt;</td>
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<td>61.13 (19.44)</td>
<td>42.78 (14.82)</td>
<td>60.42 (22.10)</td>
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<td>57.30 (12.20)</td>
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<tr>
<td>Med</td>
<td>Prox</td>
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<td>52.25 (35.04)</td>
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<td>45.05 (13.31)</td>
<td>54.20 (41.54)</td>
<td>41.70 (22.03)</td>
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<tr>
<td></td>
<td>Dis</td>
<td>43.03 (15.04)</td>
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<td>0.009&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.001&lt;sup&gt;b&lt;/sup&gt;</td>
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</table>

The values are expressed as mean (SD).

<sup>a</sup>Significant differences between the pair suspension systems are presented as pin lock vs. Seal-In, Seal-In vs. MPSS, and pin/lock vs. MPSS.

<sup>b</sup><i>P</i> < 0.05.

Ant, anterior; Dis, distal; Lat, lateral; Med, medial; Pos, posterior; Prox, proximal.
difference. Figure 2 presents the magnitudes of the interface pressure with the suspension systems during the ramp negotiation.

DISCUSSION

Although able-bodied individuals can easily negotiate ramps and stairs, these tasks become challenging when the motor functions of a person are altered, as in the case of the elderly people or limb amputees. Plantar pressure and foot ulcer are suggested to be correlated with socket pressure and ulceration. Pressure mapping provides insights into the enhancement of prosthesis designs. The pressure profile among the pin/lock, Seal-In, and MPSS systems had been previously assessed during level walking. In this study, it was intended to evaluate pressure distribution inside the prosthetic socket with these systems during dynamic activities of slope and stairs negotiation.

Stair Negotiation

The peak pressure was significantly higher at the anterior, posterior, and medial regions with the Seal-In system compared with the pin/lock and MPSS systems both during the stair ascent and descent. These results are consistent with those in the authors’ previous study on level walking. The PP was lower with the pin/lock and MPSS systems compared with the Seal-In system at the distal and proximal subregions.

The anterior proximal socket area exhibited a significantly higher mean peak pressure during the stair ascent, which was consistent with the findings of Dou et al. However, Wolf et al. reported a high pressure at the anterior distal region during the stair ascent, which was contrary to the findings of this study. The pressure magnitude was higher at the posterior proximal area, which was contrary to the findings of Dou et al.
<table>
<thead>
<tr>
<th>Suspension System</th>
<th>Ant</th>
<th>Post</th>
<th>Lat</th>
<th>Med</th>
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<tr>
<td></td>
<td>Prox</td>
<td>Dis</td>
<td>Prox</td>
<td>Dis</td>
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<tr>
<td>Ramp up</td>
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</tr>
<tr>
<td>Seal-In</td>
<td>71.14 (9.35)</td>
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<td>81.66 (18.92)</td>
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<td>43.71 (14.20)</td>
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<td>p&lt;sup&gt;a&lt;/sup&gt;</td>
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<td></td>
<td></td>
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<td>pin/lock vs. Seal-In</td>
<td>0.001&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.130</td>
<td>0.000&lt;sup&gt;b&lt;/sup&gt;</td>
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<td>Seal-In vs. MPSS</td>
<td>0.000&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.042&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.000&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.003&lt;sup&gt;b&lt;/sup&gt;</td>
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<td>pin/lock vs. MPSS</td>
<td>0.031&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.074</td>
<td>0.025&lt;sup&gt;b&lt;/sup&gt;</td>
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<td>Ramp down</td>
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<tr>
<td>Seal-In</td>
<td>67.22 (25.38)</td>
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<td>MPSS</td>
<td>45.21 (11.24)</td>
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<td>55.04 (13.79)</td>
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<td>pin/lock vs. Seal-In</td>
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<td>0.024&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>Seal-In vs. MPSS</td>
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<td>0.000&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.000&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>pin/lock vs. MPSS</td>
<td>0.041&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.037&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.022&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.240</td>
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</tbody>
</table>

<sup>a</sup> Significant differences between the pair suspension systems are presented as pin/lock vs. Seal-In, Seal-In vs. MPSS, and pin/lock vs. MPSS.

<sup>b</sup> P < 0.05.
Wolf et al.\textsuperscript{23} found the most obvious changes in the distal area close to the end of the residual limb during the stair and ramp ascent, which opposed the findings of Dou et al.,\textsuperscript{18} who observed the most obvious changes in the anterior proximal regions. Such changes resulted from the increase in knee flexion and moments of knee flexing as compared with the level walking.\textsuperscript{28} The distal end of the tibia posteriorly shifted away from the anterior socket, which distally decreased the peak pressure in the anterior region.

The alignment of the ankle in a neutral position during the stair ascent limits the external knee flexion moments. Therefore, the dominant pressure is located at the anterior proximal socket. However, the knee would become more flexed with a dorsiflexed ankle and the ground reaction force would move further behind the knee joint. Therefore, the pressure load would distally increase as the external flexion moments grew larger.\textsuperscript{23} In the current study, a higher pressure was observed at the anterior distal area during the stair descent with the Seal-In system than with the pin/lock and MPSS systems, which was consistent with the findings of Wolf et al.\textsuperscript{23} In addition, to ensure their stability, the individuals with transtibial amputation position their prostheses onto the lower step with a longer knee extension during the stair descent\textsuperscript{21} to decrease and increase the pressure proximally and distally, respectively.\textsuperscript{23}

The Seal-In system was reported to have less pistoning compared with the pin/lock and MPSS systems.\textsuperscript{29} Possibly, there is a relation between higher PP and low pistoning with the Seal-In interface system. The extent of pistoning decreased as the socket fit was improved. A higher pressure could also be detrimental to the residual limb because it might interrupt blood circulation and promote skin problems.\textsuperscript{8}

**Ramp Ascent/Descent**

All the participants exhibited a higher pressure with the Seal-In system, and significant differences were observed at the anterior, posterior, and lateral regions during the ramp ascent. Significant statistical

\begin{figure}
\centering
\includegraphics[width=\textwidth]{figure2.png}
\caption{The peak pressure values at the four major residual limb surfaces when walking on the slope.}
\end{figure}
differences were also observed at the anterior, posterior, and medial regions. Dou et al. observed increased pressure at the anterior proximal and posterior proximal (popliteal area) sockets during the ramp ascent, which was consistent with the observations in this study (Table 2). A lower pressure at the anterior distal subregion (kick point) was also found, which opposed the findings of Wolf et al.

Contrary to the level walking, the knee flexion moment was larger during the ramp descent. To guarantee stability, the individual with transtibial amputation position their prostheses down the ramp with a longer extended knee, which decreases the magnitude of the pressure at the anterior proximal region and increased the pressure at the anterior distal area. The results of this study were consistent with the aforementioned biomechanical changes of the knee during the ramp descent. In all of the systems, the mean peak pressure was higher at the anterior distal subregion compared with the anterior proximal subregion, which was also consistent with the findings of Dou et al. The pressure magnitude during ramp negotiation was observed to be lower with the MPSS system compared with the pin/lock system, except for the anterior distal during the ramp ascent and the posterior distal during the ramp descent, as well as for the medial and lateral regions.

The development of pressure at the anterior, proximal, and distal areas were comparable during the stair and ramp ascent. The differences among the pressures at these sites were even more significant during the ramp negotiation, which reflected that a 7.5-degree ramp ascent was more challenging than a regular stair ascent. The pressure distribution within the socket varied the most during the ramp descent than during the level walking. Flexion and extension were the main movements at the knee joints during the stair and ramp negotiation, which was reflected in the pressure profile of all the systems because there was almost no significant difference in the medial and lateral socket pressures. Most of the participants stated that they felt more pressure on their residual limb when they used the Seal-In system.

Finally, the study might have clinical implications for the selection of one suspension system over others in active users of prostheses who frequently negotiate ramps/stairs. For instance, clinicians should be more cautious to choose the Seal-In suspension because of higher in-socket pressure typically found with this system in this study. Between the MPSS and pin/lock, some significantly lower pressure values were found with the MPSS in this study. The satisfaction survey had formerly shown that the participants were more satisfied with the MPSS than with the pin/lock during stair negotiation ($P = 0.000$). The overall satisfaction was also significantly higher with the MPSS. Thus, it can be taken into account when prescribing the suspension system for lower limb prosthesis.

**Study Limitations**

The comparisons among the findings of various studies could be affected by the type of prosthetic foot used in a particular study. Two studies used dynamic carbon feet, whereas Dou et al. used a prosthesis that incorporated a solid-ankle-cushion-heel foot. The properties of each prosthetic foot could influence the pressure distribution within the socket. The few available studies did not clearly explain the strategies of amputees when negotiating stairs, which might also affect the comparison of findings.

**CONCLUSIONS**

Intrasystem pressure distribution at the anterior and posterior surfaces of the residual limb was fairly homogenous during the stair and ramp ascent or descent. Nevertheless, intrasystem pressure mapping revealed significant differences among the suspension types, particularly at the anterior and posterior sensor sites.

**REFERENCES**


