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Interface pressure in transtibial socket during ascent and descent on stairs and its effect on patient satisfaction

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ABSTRACT

Background: Transtibial amputees encounter stairs and steps during their daily activities. The excessive pressure between residual limb/socket may reduce the walking capability of transtibial prosthetic users during ascent and descent on stairs. The purposes of the research were to evaluate the interface pressure between Dermo (shuttle lock) and Seal-In X5 (prosthetic valve) interface systems during stair ascent and descent, and to determine their satisfaction effects on users.

Methods: Ten amputees with unilateral transtibial amputation participated in the study. Interface pressure was recorded with F-socket transducer (9811E) during stair ascent and descent at self-selected speed. Each participant filled in a questionnaire about satisfaction and problems encountered with the use of the two interface systems.

Findings: The resultant mean peak pressure (kPa) was significantly lower for the Dermo interface system compared to that of the Seal-In X5 interface system at the anterior, posterior and medial regions during stair ascent (63.14 vs. 80.14, 63.14 vs. 90.44, 49.21 vs. 66.04, respectively) and descent (67.11 vs. 80.41, 64.12 vs. 88.24, 47.33 vs. 65.11, respectively). Significant statistical difference existed between the two interface systems in terms of satisfaction and problems encountered ($P < 0.05$).

Interpretation: The Dermo interface system caused less pressure within the prosthetic socket compared to the Seal-In X5 interface system during stair negotiation. The qualitative survey also showed that the prosthesis users experienced fewer problems and increased satisfaction with the Dermo interface system.

1. Introduction

Studies have revealed that lower limb prosthetic users consider discomfort as one of the most significant problems they face when using prosthesis. It is common for prosthetic users to experience pain and discomfort in the stump while wearing their prostheses (Lee et al., 2005). Lower limb prosthesis should enable ambulation and improve the performance of daily routine activities. However, poor-fitted socket can lead to complications that have adverse effects on the activity level and gait of people with lower limb amputation (Gailey et al., 2008).

The distribution of interface pressure between the socket and stump is an important factor in socket design and fit. Lower limb prosthetic users experience pressure between the socket and stump during daily activities. The underlying soft tissues and skin of the stump are not accustomed to weight bearing; thus, there is the risk of degenerative tissue ulcer in the stump because of constant or repetitive peak pressure applied by the transtibial socket (Jia et al., 2004). The pressure also can lead to various skin problems such as follicular hyperkeratosis, allergic contact dermatitis, infection and veracious hyperplasia (Dudek et al., 2005, 2008; Lyon et al., 2000).

Despite significant advances in the field of prosthetics in the previous decades, still many transtibial amputees experience pressure ulcers with the use of prostheses. Sometimes, skin problems lead to chronic infection, which may necessitate re-amputation. This will prevent the long-term use of prosthesis, which significantly reduces the daily activities of prosthesis users and the quality of life (Ali et al., 2012).

Many studies have focused on interface pressure magnitude between the socket and stump during level walking (Convery and Buis, 1999; Goh et al., 2003; Silver-Thorn and Childress, 1996). However, a transtibial prosthesis user encounters stairs in his/her daily activities. The ability of a person to negotiate stairs and steps is a significant factor for functional freedom. This ability allows a person to become more active in the society, and to perform different daily activities (Gill et al., 1994; Jones et al., 2006). The ability of transtibial amputees to negotiate steps and stairs is severely affected by the loss of ankle joint and foot as

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well as reduced muscles' power, balance, mobility and stability, especially for young and strong amputees who perform manual labor and rigorous activities (Jones et al., 2006). It is important for transtibial prosthetic users to minimize the chances of pressure ulcers with underlying associated syndromes through information regarding the interface pressure between the socket and stump in dealing with stairs (Dou et al., 2006).

A high-quality interface system is required to prevent skin complications that will produce excellent interface union between the stump and transtibial socket (Sewell et al., 2000; Van de Weg and Van Der Windt, 2005). Silicone interface systems are believed to reduce the friction between the skin and improve comfort both in rest and during walking (Cluitmans et al., 1994). Manufacturers of prosthetic products seek to develop new interface systems. Dermo and Seal-In X5 interface systems are two new systems that increase the contact areas and distribute the pressure at the socket walls. These are commonly prescribed for transtibial amputees. There is minimal knowledge on their effect on patient's satisfaction. The manufacturer claims an easy donning and doffing with the Seal-In liner X5 but during the clinical practice, patients complained of discomfort with the Seal-In X5 liner, particularly during walking and donning/doffing. The Dermo silicon interface system provides suspension through pin/lock, while the Seal-In X5 silicon liner incorporates a series of five integrated seals that conform to the shape of the residual limb and the internal socket wall, providing an airtight seal. The Seal-In X5 interface system is claimed to provide a good response in high impact activities due to improved coupling between the socket and seals. Users reported discomfort with the Seal-In X5 liner due to localized pressure at the seals and high activity level compared to the Dermo interface system. This claim motivated us to determine the interface pressure generated by the two interface systems during stair ascent and descent. Only two studies have compared the interface pressure during stair negotiation with transtibial prosthesis (Dou et al., 2006; Wolf et al., 2009); however, no study has examined the effect of interface pressure on patient satisfaction and perceived problem during stair ascent and descent. Two studies have evaluated the interface pressure during level walking with these two systems (Ali et al., 2012; Eshraghi et al., 2012). Therefore, this study aimed to evaluate the interface pressure generated by these two interface systems, and to study the effect of interface pressure on patient satisfaction. It was our hypothesis that the subjects will experience less interface pressure and will be more satisfied with the Dermo interface system during stair negotiation compared to the Seal-In X5 interface system.

2. Methods

Ten amputees (seven males and three females) with transtibial amputation contributed to this study. All the participants had undergone unilateral amputation at least four years prior to the study. The inclusion criteria were: ability to negotiate stairs without any assistive devices, absence of stump problems and absence of pathological problems, which affected the mobility of the participants. The detailed particulars of the participants are shown in Table 1. The Ethics committee of the University Malaya Medical Centre (UMMC) approved this study. Written consent was obtained from all the participants.

Twenty Total Surface Bearing (TSB) prostheses were fabricated using the Dermo with shuttle lock (Össur, Reyjavik, Iceland) and the Seal-In X5 with prosthetic valve (Össur, Reyjavik, Iceland). Double adapters of different sizes (7 cm and 10 cm) were used to adjust the length according to the patient's height. Flex-Foot Talux was utilized for all the prostheses based on the foot size of the participants. The following procedures were applied for casting and modification.

The interface system was rolled on the subject's stump. Single layer of plastic was applied and it was insured that all the areas were covered. Pressure-sensitive areas were marked and all the required measurements (residual limb and sound side) were recorded on the measurement chart. The entire stump was wrapped with two rolls of 15 cm Plaster of Paris bandages and massaged properly until the cast dried. Trim lines were marked on the negative cast and they were filled with Plaster of Paris powder for modification. Negative cast was removed and it was ensured that all the marks were transferred to the positive model. All the unnecessary material was removed and the measurements were compared with the subject's measurements. Recommended reduction was done over the soft tissue areas and posterior of the stump. Minimal relief was applied to the bony areas and posterior trim lines were marked for hamstring relief. Model was smoothened after finalizing all the measurements.

To assure the accuracy during casting, modification, fabrication and alignment, all the prostheses were fabricated by a single certified prosthetist, and the laser liner was used for the alignment (Mathur and Gupta, 2005). Initial fitting was performed at the Department of Biomedical Engineering, University of Malaya (Brace and Limb laboratory). Prostheses were adjusted according to the participant's requirements. After achieving fitting and alignment satisfaction with each prosthesis, the participants were asked to use each prosthesis for at least one month. The participants were also requested to visit the Motion Analysis Lab after one month of trial period for interface pressure measurements.

Four F-socket transducers 9811E (Tekscan, Inc., South Boston, USA) were attached to the posterior, anterior, lateral and medial compartments of the stump to obtain better insights on the pressure between the stump and socket. Medial, lateral and anterior sensors were attached at the mid patella level. The posterior sensor was positioned approximately 1 cm above the posterior trim line of the socket. The residual limbs were covered with cellophane plastic wrap, and each transducer was attached to the cellophane plastic wrap with spray adhesive (Scotch Super Adhesive, 3M Corporate, St. Paul, USA) to ensure that the transducer was appropriately positioned on the stump. Each transducer was trimmed according to the contour of the stump. We enclosed 90% of the stump with these arrangements. Interface measurements were recorded using Tekscan software (version 6.51). Transducers were positioned for equilibration and calibration inside a bladder and pressure of 100 kPa was applied according to the instructions of the manufacturer. We were aware of the limitations of the pressure measurement system employed, including hysteresis and drift. Inaccuracies between individual cells have also been highlighted. However,

Table 1
Particulars of the participants.

Subjects	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
Age (year)	37	50	24	41	71	63	62	51	49	32
Height (cm)	175	171	170	180	180	173	160	163	165	171
Sex	Male	Male	Male	Male	Male	Male	Female	Female	Female	Male
Body mass (kg)	90	65	60	101	80	76		49	50	62
Cause of amputation	Trauma	Trauma	Trauma	Diabetes	Diabetes	PVD	Diabetes	PVD	Diabetes	Trauma
Amputation side	Left	Right	Left	Right	Left	Right	Left	Left	Right	Right
Activity level	3–4	3–4	3–4	3–4	2–3	2–3	2–3	3–4	3–4	3–4
Years since amputation	4	4	4	4	9	6	3	8	8	5
Stump length (from mid patella to stump end)	16	15.5	15.5	17	16.5	15.5	15	16.5	16.5	15.8

by adopting a strict protocol to precondition, equilibrate, and calibrate the sensor array, we minimized the variation and inaccuracy of data recordings. We did the pre and post test to minimize the inaccuracies in the sensors (Fig. 1).

The participants were asked to ascend and descend a custom-made 82 cm wide staircase, consisting of 4 steps with step distance of 32 cm and step height of 14 cm. Data were recorded for two consecutive trials at the sample rate of 50 Hz for at least 6 cycles of ascent and descent. All the participants followed the same procedures to minimize variation in data collection and testing order of the interface systems was randomized. Each participant completed an orientation session before the experiment (Fig. 2).

The participants completed a questionnaire after the experiment to describe their one month experience with prostheses. We used a non-validated survey to determine the level of problems encountered and satisfaction with the prosthesis during ascent and descent on stairs. The following were asked from each participant regarding their satisfaction and problems with each prosthesis.

1. Satisfaction during stair ascent:
   Walking satisfaction during stair ascent; suspension satisfaction during stair ascent; balance satisfaction during stair ascent and overall satisfaction during stair ascent.
2. Satisfaction during stair descent:
   Walking satisfaction during stair descent; suspension satisfaction during stair descent; balance satisfaction during stair descent and overall satisfaction during stair descent.
3. Problem during stair ascent:
   Pain during stair ascent; pistoning during stair ascent and rotation of the socket during stair ascent.
4. Problem during stair descent:
   Pain during stair descent; pistoning during stair descent and rotation of the socket during stair descent.

Fig. 1. Placement of sensors on residual limb.

Numerical scores of 0–100 were utilized for the entire questions to indicate the level of satisfaction and problems encountered. Zero (0) indicated "extremely bothered or unsatisfied" and 100 indicated "no problem or complete satisfaction".

For each trial, the middle step was selected. The mean peak pressure (MPP) was calculated for all the trials. Non-parametric Wilcoxon signed-rank test was utilized to compare the pressure difference between the Seal-In X5 and Dermo interface systems at all the major regions (anterior, posterior, medial and lateral) and sub-regions (proximal and distal) of each major region of the residual limb. Paired-samples *t*-test was applied to obtain the overall score, and compared the satisfaction and problems between the two interface systems. Valve $P < 0.05$ was set for the level of statistical significance. Statistical analysis was performed by using SPSS version 20 (SPSS, Chicago, USA).

3. Results

3.1. Participants

Ten participants took part in this research, and their particulars are shown in Table 1.

3.2. Interface pressure during ascent

The MPP values of the 10 participants revealed a significant difference between three major regions ($P < 0.05$) and three sub-regions ($P < 0.05$) during ascent on stairs by performing Wilcoxon signed-rank test (see Fig. 3).

The magnitude of the MPP at the whole posterior region was significantly higher ($P = 0.03$, $Z = -2.09$) with the Seal-In X5 interface system (mean = 90.44 kPa, SD = 46.34) compared to the Dermo interface system (mean = 63.13, SD = 9.21). Furthermore, the MPP at the anterior region was significantly higher ($P = 0.00$, $Z = -2.80$) with the Seal-In X5 interface system (mean = 80.14 kPa, SD = 18.01) compared to the Dermo interface system (mean = 63.14 kPa, SD = 13.40). Significant difference ($P = 0.03$, $Z = -2.09$) was also observed with the Seal-In X5 interface system (mean = 66.04 kPa, SD = 30.22) compared to the Dermo interface system (mean = 49.21 kPa, SD = 8.03) at the medial region. A significant difference was recorded at the anterior and posterior proximal sub-regions of the Seal-In X5 and Dermo interface system. No statistical difference was recorded at the lateral regions of the two interface system. However, a significant difference was observed at the medial distal sub-region of the stump (see Table 2).

3.3. Interface pressure during walking descent

MPP was significantly higher ($P < 0.05$) with the Seal-In X5 interface system than with the Dermo interface system in the entire anterior ($P = 0.03$, $Z = -2.09$; mean = 80.41 kPa, SD = 22.11; mean = 67.11 kPa, SD = 17.40, respectively), posterior ($P = 0.01$, $Z = -2.39$; mean = 88.24 kPa, SD = 39.21; mean = 64.12 kPa, SD = 12.35, respectively), and medial ($P = 0.03$, $Z = -2.09$; mean = 65.11 kPa, SD = 30.04; mean = 47.33 kPa, SD = 16.31, respectively) regions. No significant difference was recorded at the lateral region between the Seal-In X5 and Dermo interface systems ($P = 0.64$, $Z = -2.09$; mean = 65.23 kPa, SD = 21.01; mean = 64.23 kPa, SD = 15.01, respectively) (see Fig. 4). A significant increase in MPP was observed at the anterior distal, posterior proximal and medial distal region of the Seal-In X5 interface system unlike the Dermo interface system (see Table 3).

With regard to satisfaction, participants gave significantly ($P < 0.05$) higher scores to the Dermo interface system compared to the Seal-In X5 interface system for three out of the four questions. However, the Seal-In X5 interface system obtained higher score for the suspension of the prosthesis with the stump during stair negotiation. Overall satisfaction

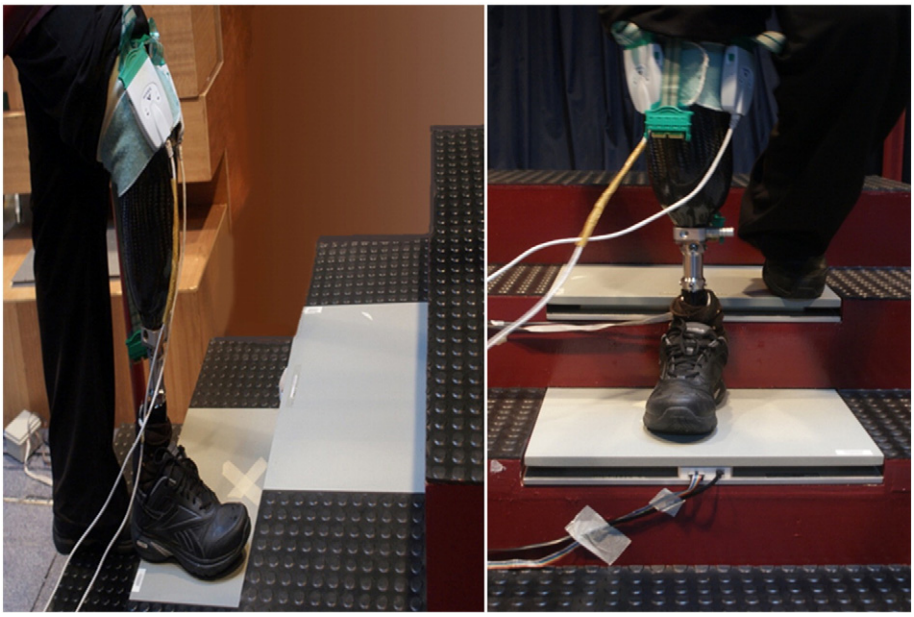

Fig. 2. (Left) Stair ascent; (right) stair descent.

was significantly higher ($P < 0.05$) for the Dermo interface system compared to the Seal-In X5 interface system (see Table 3).

Concerning the problems encountered, significant differences ($P < 0.05$) were recorded in terms of pain among others. The participants reported less pain with the Dermo interface system unlike the Seal-In X5 interface system (see Table 4).

4. Discussion

Selection of suitable interface system for lower limb amputees plays a major role in the process of prosthetic rehabilitation. Fitting between the socket and stump is a key determinant for successful ambulation. A high-quality fit prosthesis offers a functional and comfortable limb, allowing pursuit of more vocational and recreational activities. Determination of the quality of fit remains a subjective process in the clinical setting and no compromise on appropriate fitting and assessment procedure (Dumbleton et al., 2009; Mak et al., 2001). Pressure measurements have the potential to provide information for the improvement of the prosthesis design.

Only two studies have compared the interface pressure during stair negotiation with transtibial prosthesis (Dou et al., 2006; Wolf et al., 2009); however, no study has examined the effect of interface pressure on patient satisfaction and perceived problem during stair ascent and descent.

The findings of this present study revealed that the MPP was significantly higher at posterior, anterior and medial regions with the Seal-In X5 interface system compared to the Dermo interface system both during stair ascent and descent (24.72%, 35.56% and 29.20%, respectively). MPP was lower both at the proximal and distal sub-regions with the Dermo interface system compared to the Seal-In X5 interface system.

This study showed that pressure was significantly higher at the proximal socket area, including patellar tendon, during ascent on stairs. These particular results are parallel to the findings of a research carried out by Dou et al. (2006), which showed highest pressures at the patellar tendon area during stair ascent. However, Wolf et al. (2009) observed high pressure at the anterior distal area during ascent, which is contrary to our findings (Wolf et al., 2009). In our study, pressure magnitude was higher at the posterior proximal area. This finding contradicts the findings of Dou et al. (2006).

The neutral position of the ankle limits knee movements and keeps knee flexion small; thus, pressure increases in the proximal anterior region. However, with the dorsiflexed ankle, the knee flexion increases, and the ground reaction moves far behind; thus, the pressure load increases distally (McIntosh et al., 2006). In the present study, the participants experienced higher pressure at the anterior distal area with the Seal-In X5 interface system compared to the Dermo interface system during stair descent. This particular result is consistent with the findings of Wolf et al. (2009).

Previous studies indicated that less pistoning occurs with the Seal-In X5 interface system compared to the Dermo interface system (Gholizadeh et al., 2011). In the present study, significant difference was observed in the amount of pressure generated by the two interface systems. A relation possibly exists between low pistoning and higher MPP with the Seal-In X5 interface system. As the socket fit improves,

Table 2
Mean peak pressure (kPa) at the anterior, posterior, medial and lateral sub-regions.

Major regions	Sub-regions	Stairs ascent			Stairs descent		
		Dermo	Seal-In X5	*P*-value	Dermo	Seal-In X5	*P*-value
Anterior	Proximal	56.10 (10.54)	69.02 (18.43)	0.03[a]	59.11 (18.10)	65.61 (23.14)	0.28
	Distal	58.03 (11.10)	64.04 (22.40)	0.37	54.11 (17.25)	67.05 (24.16)	0.02[a]
Posterior	Proximal	57.10 (10.26)	80.40 (48.20)	0.05[a]	52.10 (15.52)	82.14 (38.31)	0.00[a]
	Distal	54.01 (12.60)	59.10 (17.51)	0.57	58.16 (14.45)	68.56 (23.83)	0.28
Lateral	Proximal	58.31 (20)	61.13 (19.44)	0.44	60.42 (22.10)	55.45 (19.03)	0.38
	Distal	63.13 (16.36)	60.01 (11.21)	0.20	55.15 (29.17)	57.30 (12.20)	0.64
Medial	Proximal	45.56 (10.54)	52.25 (35.04)	0.95	45.05 (13.31)	54.20 (41.54)	0.95
	Distal	43.03 (15.04)	52.20 (12.24)	.00[a]	43.35 (17.33)	50.24 (13.03)	0.04[a]

[a] Significant differences in the interface pressure between the Dermo and Seal-In X5 interface systems.

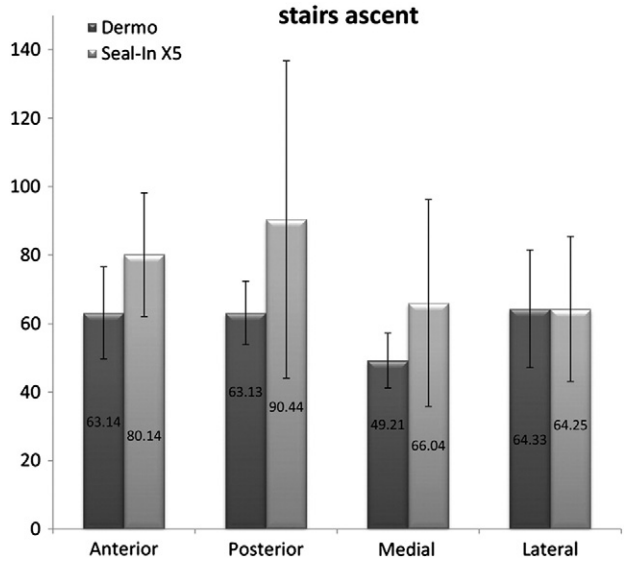

Fig. 3. MPP for the four major regions of the stump during stair ascent.

the amount of pistoning will decrease. Thus, tight fit of Seal-In socket might be associated with lower pistoning. On the other hand, this tight fit has caused higher pressure at the interface that might be harmful for residual limb. Although low pistoning and enhanced socket fit are good qualities, increased interface pressure might disturb the blood flow and cause skin problems (Beil and Street, 2004; Bennett et al., 1979; Board et al., 2001).

Many researchers have utilized single-spot transducers to monitor the interface pressure among the socket and stump (Beil and Street, 2004; Beil et al., 2002; Wolf et al., 2009). The transducers employed in the current research were very thin that facilitated the placement between the stump and interface system, and covered more than 90% of the stump for a full pressure map. This particular quality of the transducer provides better sketch of the stump pressure compared to the single-spot transducers, and can offer additional important information for the clinical evaluation of pressure-related problems. We were aware of the limitations of the pressure measurement system employed, including hysteresis and drift. Inaccuracies between individual cells have also been highlighted. However, by adopting a strict protocol to precondition, equilibrate, and calibrate the sensor array, we minimize the variation and inaccuracy of data recordings. We did the pre and post test to minimize the inaccuracies in the sensors.

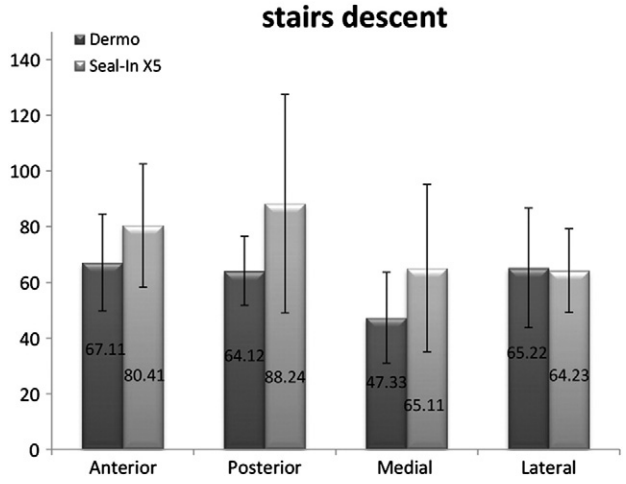

Fig. 4. MPP for the four major regions of the stump during stair descent.

Table 3
Satisfaction with Dermo and Seal-In X5 interface systems during stair ascent and descent.

Satisfaction type/interface type	Mean	*P*-value	Z
Stair ascent			
Walking satisfaction during stair ascent		0.00[a]	−0.86
Dermo	84.50		
Seal-In X5	72.90		
Suspension satisfaction during stair ascent		0.01[a]	−2.37
Dermo	72.50		
Seal-In X5	82.13		
Balance satisfaction during stair ascent		1.00	0.00
Dermo	78.00		
Seal-In X5	78.00		
Overall satisfaction during stair ascent		0.02[a]	−2.32
Dermo	78.30		
Seal-In X5	72.50		
Stair descent			
Walking satisfaction during stair descent		0.00[a]	−1.03
Dermo	85.00		
Seal-In X5	70.50		
Suspension satisfaction during stair descent		0.00[a]	−2.69
Dermo	75.20		
Seal-In X5	85.21		
Balance satisfaction during stair descent		0.31	−1.00
Dermo	75.20		
Seal-In X5	76.33		
Overall satisfaction during stair descent		0.01[a]	−2.53
Dermo	84.20		
Seal-In X5	76.20		

[a] Significant differences between the Dermo and Seal-In X5 interface systems.

Previous studies indicate that the Dermo interface system with the pin/lock suspension provides a secure close contact. However, the pressure during swing phase can cause distal end stump problems (Klute et al., 2011). Such occurrences were not observed in the current study after the acclimation period.

As predicted, the results of this research revealed a significant difference with respect to the level of satisfaction and problems identified by participants who utilized the two different prosthetic interface systems. The participants experienced fewer problems with the Dermo interface system compared to the Seal-In X5 interface system. Overall satisfaction was significantly higher for the Dermo interface system (8.01%) and participants had fewer problems with the Dermo interface system (9.97%).

Table 4
Comparison between Dermo and Seal-In X5 interface systems during stair ascent and descent with regards to problem.

Problem type/interface type	Mean	*P*-value	Z
Stair ascent			
Pain during stair ascent		0.00[a]	−2.67
Dermo	87.00		
Seal-In X5	64.10		
Pistoning during stair ascent		0.14	−1.47
Dermo	72.00		
Seal-In X5	76.50		
Rotation of the socket during stair ascent		0.48	−0.70
Dermo	85.50		
Seal-In X5	86.50		
Stair descent			
Pain during stair descent		0.01[a]	−2.55
Dermo	78.00		
Seal-In X5	70.00		
Pistoning during stair descent		0.17	−1.36
Dermo	74.50		
Seal-In X5	79.00		
Rotation of the socket during stair descent		0.48	−0.70
Dermo	85.50		
Seal-In X5	86.50		

[a] Significant differences between the Dermo and Seal-In X5 interface systems.

4.1. Anecdotal evidence

The participants reported that they could walk for longer time while using prosthesis with the Dermo interface system compared to the Seal-In X5 interface system during stair negotiation. This findings is consistent with the results of Dou et al. (2006), which indicated a high activity level when walking with pin/lock system on all types of surfaces (Klute et al., 2011). Pressure among the socket and stump is supposed to be a strong factor of the amputee's comfort (Dou et al., 2006; Sanders et al., 2006; Sewell et al., 2000). All the participants in the current study criticized the "comfort" with the Seal-In X5 interface system, which could have been the result of firm socket fit. Easy donning and doffing have positive effect on a user's experience with a prosthetic device (Gholizadeh et al., 2013). In the present study, the participants stated that they were less frustrated with the Dermo interface system than with the Seal-In X5 interface system. The results also support this statement. Appropriate socket suspension increases prosthetic user's confidence and have important outcomes on user's comfort and satisfaction (Ali et al., 2012). Fifty percent of the participants stated that they felt more secure during stair ascent and descent with the Seal-In X5 interface system than with the Dermo interface system. Two of the participants perceived that the prosthesis with the Seal-In X5 interface system was more like a natural part of their body. However, Cluitmans et al. (1994) reported improved suspension with the pin/lock interface system, which contradicts to our results (Cluitmans et al., 1994).

Findings of the current study offer clinicians further insight into the mechanics of stump and socket pressure in transtibial amputees, and may provide helpful information for the socket design. However, lager sample size is required to evaluate the effect of interface pressure on patient satisfaction. A four-week acclimation period was provided to the subjects for the study prostheses, but some subjects might require a longer time. Subject's selection and retaining was also challenging.

5. Conclusion

The current study revealed that high interface pressure exists between the stump and socket with the Seal-In X5 interface systems. The Dermo interface system caused minimal pressure, and the participants were more comfortable while using it during stair negotiation. The participants were more confident and comfortable with the use of the Dermo interface system during stairs negotiation.

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