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Clinical investigation of the interface pressure in the trans-tibial socket with Dermo and Seal-In X5 liner during walking and their effect on patient satisfaction

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ABSTRACT

Background: The interface pressure between the residual limb and prosthetic socket has a significant effect on an amputee's satisfaction and comfort. Liners provide a comfortable interface by adding a soft cushion between the residual limb and the socket. The Dermo and the Seal-In X5 liner are two new interface systems and, due to their relative infancy, very little are known about their effect on patient satisfaction. The aim of this study was to compare the interface pressure with these two liners and their effect on patient satisfaction.
Methods: Nine unilateral transtibial amputees participated in the study. Two prostheses were fabricated for each amputee, one with the Seal-In liner and one with the Dermo liner. Interface pressure was measured at the anterior, posterior, medial and lateral regions during walking on the level ground. Each subject filled in a Prosthetic Evaluation Questionnaire (PEQ) regarding the satisfaction with the two liners.
Findings: The mean peak pressures with the Seal-In liner was 34.0% higher at the anterior, 24.0% higher at the posterior and 7.0% higher at the medial regions of the socket ($P=0.008$, $P=0.046$, $P=0.025$) than it was with the Dermo Liner. There were no significant differences in the mean peak pressures between the two liners at the lateral regions. In addition, significant difference was found between the two liners both for satisfaction and problems ($P<0.05$).
Interpretation: There was less interface pressure between the socket and the residual limb with the Dermo liner. The results indicated that the Dermo liner provides more comfort in the socket than the Seal-In liner.

1. Introduction

Transtibial amputation patients need prosthetic devices after amputation surgery in order to regain their functional mobility and appearance (Wolf et al., 2009). The socket design plays a significant role in determining the quality of the fit and provides an interface between the prosthesis and the residual limb (Jia et al., 2004). Appropriate socket fitting in prosthetic devices can have a significant effect on the patient's comfort, mobility and level of satisfaction with their prosthesis (Kristinsson, 1993; McCurdie et al., 1997).

Skin problems are common in prosthetic users and these can appear in the form of rashes, ulcers, irritation and allergies. Their presence is commonly attributed to one of several reasons: the inadaptability of the skin, due to the intolerance of pressure by the prosthetic socket on the residual limb; bacterial proliferation as a result of a snugly-fitted socket that causes entrapment of perspiration in a closed environment; skin irritation or allergic reaction due to the materials used in the prosthetic socket and liners (Dudek et al., 2005; Dudek et al., 2006). Lower limb amputees commonly experienced residual limb skin problems with the use of the prostheses (Laing et al., 2011). Amputees often need to stop using the prosthesis entirely for a period of time as a result of the pain and discomfort caused by such skin problems. This condition can badly effect the mental wellbeing of a patient and will ultimately impact their satisfaction with a device (Meulenbelt et al., 2006).

It is crucial that the risk of these skin complications is taken into consideration during the design of the prosthetic socket and that the design of the device is based on a good understanding of the pressure that can occur between the amputee's residual limb and the prosthetic socket (Jia et al., 2008). In order to reduce the possibility of these skin issues occurring, liners are fit inside the socket to provide the residual limb with a soft cushion. Liners have a direct contact with the residual limb inside the socket and play a significant role in transferring the load and distributing the interface pressure over the residual limb (Coleman et al., 2004; Lin et al., 2004).

Polyethylene foam liners with patellar tendon bearing (PTB) prosthetic socket have been in use since 1950; however, modern liners, which are generally made from silicone and other elastomers, offer better suspension and cushion (Dietzen et al., 1991; Haberman et al., 1992; Madigan and Fillauer, 1991). Silicon and gel liners were introduced worldwide in the mid 1990s and were designed to reduce shear forces and produce better interface bonds between the residual limb and the socket (Van de Weg

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and Van Der Windt, 2005). One of these silicone liners is known as the Seal-In X5 liner (Fig. 1). It was introduced by Ossur (Reykjavik, Iceland) and is composed of five seals that conform to the shape of the internal socket wall and the residual limb (Gholizadeh et al., in press). Through this, the Seal-In X5 liner provides suspension without the need for an external sleeve or lock and claim to be a good choice for high impact activities. The Dermo liner (Reykjavik, Iceland) is also made of silicone; however, unlike the Seal-In X5 liner, it cushions the limb and provides suspension through a shuttle lock system (Fig. 1).

Many studies have been carried out to investigate the interface pressure and stresses (Jia et al., 2005; Sanders et al., 1998; Wolf et al., 2009). Some of them compared the socket pressure of polyethylene foam liners with silicone liners (Dumbleton et al., 2009). Some studies have investigated the effect of various casting techniques or socket design on the socket-residual limb interface pressure (Dumbleton et al., 2009; Jia et al., 2005; Lee and Zhang, 2007), while other studies have focused on the effect of alignment on interface pressure (Jia et al., 2008). However, none of these studies compared the effect of a Dermo liner that used a shuttle lock with a sealing system such as the Seal-In X5 liner. In the Seal-In X5 liner, the seals have the potential to impose extra pressure over the residual limb. This can cause excessive pressure, that in it can be a source of problems for diabetic patients or amputees with sensitive residual limbs. The aim of this clinical study was to measure and evaluate the interface pressure in the Dermo liner during normal walking and compare it with the Seal-In X5 liner. The study also aimed to assess the effect that the two liners had on patients' satisfaction.

2. Methodology

2.1. Subjects

A total of nine unilateral transtibial amputees (7 males, 2 females) participated in this study. All the subjects were selected from the Department of Rehabilitation of the University Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia. The ethics committee of UMMC approved this study, and informed written approval was attained from all the subjects. The inclusion criteria consisted of a minimum 15 cm residual limb length (from the mid patella to the distal end of residual limb), no wound and ulcers in the residual limb, no volume changes, and the ability to walk without the use of assistive devices. It was a requirement that the participants are experienced prosthetic users (more than 6 months). A sample of convenience is used for this study.

2.2. Prosthetic interventions

Two transtibial prostheses were made for each subject, one with the Dermo liner with shuttle lock (Icelock-200 series) and another with the Seal-In X5 liner with valve (Icelock Expulsion, Valve 551). All the prostheses were fabricated with Flex-Foot Talux (Ossur, Reykjavik, Iceland). One registered prosthetist fabricated all the prostheses to avoid alterations due to manufacturing, alignment and fitting. A total surface bearing (TSB) socket was fabricated for all the subjects (Staats and Lundt, 1987). In order to become familiar with their new prosthetic devices, the subjects practiced walking in the motion analysis laboratory (Biomedical Engineering Department, University of Malaya, Malaysia) and the prosthetist adjusted the fitting of the socket and alignment according to their needs. Subjects were required to use their prostheses for a minimum of four weeks. The subjects were asked to visit the brace and limb laboratory for follow up on a weekly basis to ensure that the fit of the prosthesis remained suitable.

2.3. Experimental setting and procedures

After four weeks of acclimation, the subjects attended the motion laboratory for pressure measurements. Four F-Socket sensors arrays 9811 (Tekscan Inc., South Boston, USA) were attached to the residual limb. The sensor arrays were positioned on the anterior, posterior, medial and lateral aspects of the residual limb (Fig. 1). The mid patella was taken as the reference line for the placement of medial, lateral and anterior sensors. The posterior sensor was positioned approximately 1 cm above the posterior trim line of the socket. Each sensor was trimmed to fit to the residual limb contours. To prevent sensor arrays displacement, the residual limb was covered with a cellophane cover. Following this, each sensor was attached to the cellophane covers by an adhesive spray (3 M Spray Mount Adhesive, 3 M corporate, St. Paul, USA). This sensor arrangement provided a pressure map that covered 90% of the residual limb during the gait. Tekscan software version 6.51 was used to record the interface pressure.

A Tekscan pressure bladder (PB100T, South Boston, USA) was used to equilibrate and calibrate the sensor arrays. Sensor arrays were placed inside the bladder and, according to the manufacturer's instructions, were subjected to a pressure of 100 kPa. Calibration was carried out based on each subject's body weight. That is, the applied pressure for calibration was the ratio of the subject's body weight to the respective sensor area (Buis, 1997).

2.4. Walkway and collection of the data

Subjects were asked to walk at a self-selected speed on a walkway that was 9-meter long and 5-meter wide. Prior to the data collection activity, the subjects were requested to walk on the walkway to familiarize with the procedure. Data acquisition was performed for 12 seconds with a sample rate of 50 Hz. The subjects completed four consecutive trials on the walkway and in each trial approximately eight to nine steps were taken. The middle step of each trial was chosen. The mean peak pressures (MPP) of four trials were employed for the purposes of statistical analyses.

2.5. Questionnaire

After the experiments were completed, each subject completed a questionnaire that asked for further information about their satisfaction with the two liners. Various parts of the Prosthetics Evaluation Questionnaire (PEQ) were adopted for this questionnaire. The questionnaire was composed of the following three sections:

1- Demographic variables (sex, age, weight, height, amputation side, cause of amputation, activity level and time since first prosthesis).
2- Satisfaction (fitting, donning and doffing, suspension, sitting, walking on level surfaces, ascending and descending stairs, walking on uneven ground, cosmesis and overall satisfaction).
3- Problems (Wound, skin irritation, sweating, pistoning, rotation, residual limb swelling, smell, sounds and residual limb pain).

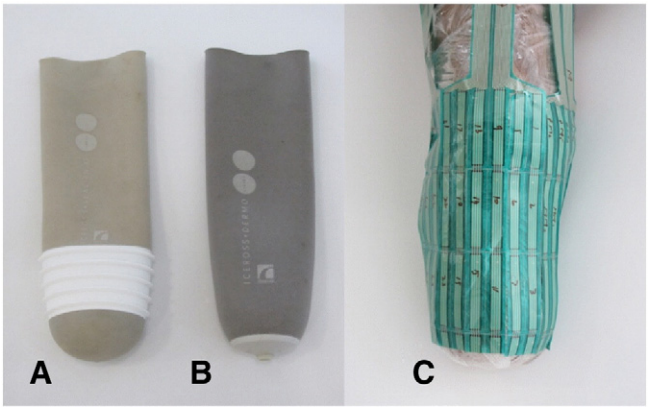

Fig. 1. (A) Seal-In Liner (B) Dermo Liner (C) Sensors attachments on residual limb.

A scale of 0–100 was used to score all the questions, where 100 indicated "complete satisfaction or no problems" and 0 indicated "unsatisfied or extremely bothered."

2.6. Analysis of data

Since the sample size of this study was small ($N=9$), non-parametric test were used to analyze the data. Therefore we used Wilcoxon signed ranks test to compare within-subject pressure measurements with the Dermo liner and Seal-In X5 liner for different regions in the socket. We also used Wilcoxon signed rank test to compare the satisfaction with the two liners. For the overall scores, which were distributed normally, paired-samples *t*-test was applied. Statistical analyses were carried out using Version 20 of SPSS, statistical software (SPSS, Chicago, IL).

3. Results

3.1. Subject's Profile

The mean age of the subjects was (mean = 49.3, SD = 15.0) and their activity level, based on the Medicare Functional Classification Level (MFCL) (Dudek et al., 2008), was K2–K3 and K3–K4. All the subjects had undergone amputation surgery at least three and half years prior to the study. The participants' demographic information is shown in Table 1.

3.2. Interface pressure

Pressure measurements were extracted in twelve regions of the residual limb. The mean of peak pressures are presented separately in Table 2. The pressures of the four major regions of the residual limb are presented in Fig. 2. In both the anterior and posterior regions, the mean pressures for the proximal, middle subregion areas were significantly higher ($P<0.05$) with the Seal-In X5 liner than they were with the Dermo liner. In both the lateral and medial regions, the pressure in the middle and distal subregion area was significantly higher ($P<0.05$).

The MPP for the four major regions of the residual limb was also obtained. The MPP values for the whole anterior region of the residual limb was significantly higher for the Seal-In X5 liner compared to the Dermo liner ($P=0.008$, $Z=-2.66$; mean = 84.90 kPa, SD = 30.46; mean = 60.2 kPa, SD = 13.00, respectively). Moreover, at the posterior region, MPP was significantly higher with the Seal-In X5 liner compared to the Dermo liner ($P=0.046$, $Z=-1.99$; mean = 74.51 kPa, SD = 12.04; mean = 54.10 kPa, SD = 11.21, respectively). There was a statistically significant difference between the pressure values for the two liners in the medial region of the residual limb, ($P=0.025$, $Z=-2.24$; Dermo: mean = 50.00 kPa, SD = 12.34; Seal-In X5: mean = 53.80 kPa, SD = 9.45). There was no statistically significant difference between the pressure values for the two liners in the lateral regions of the residual limb ($P=0.601$, $Z=-0.42$; Dermo: mean = 50.00 kPa, SD = 11.21; Seal-In X5: mean = 51.50 kPa, SD = 7.70) (Fig. 3).

Table 1
Demographic variables of the subjects.

Weight (SD)		72.44 (16.30) Kg
Height (SD)		169.11 (7.78) Cm
	Female	3 (33.30%)
Gender (%)		
	Male	6 (66.70%)
Body mass index (SD)		25.22 (4.83)
Age of the patient (SD)		49.33 (15.05)
	K2-K3	8 (88.90%)
Activity level (%)		
	K3-K4	1 (11.10%)
	Right	4 (44.44%)
Amputation side (%)		
	Left	5 (55.55%)
	Trauma	3 (33.30%)
Cause of amputation (%)	Peripheral Vascular Disease (PVD)	2 (22.20%)
	Diabetic	4 (44.50%)

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

Liner type	Anterior			Posterior		
	Proximal	Middle	Distal	Proximal	Middle	Distal
Dermo Liner	60.9 (19.1)	62.7 (11.5)	57.0 (14.4)	56.6 (12.7)	62.8 (23.2)	59.7 (25.6)
Seal-In X5 Liner	85.3 (31.3)	86.5 (29.6)	82.8 (35.4)	67.4 (11.9)	82.7 (22.7)	78.8 (26.2)
P-value	0.038*	0.021*	0.011*	0.046*	0.028*	0.260
Z	−2.07	−2.31	−2.54	−1.99	−2.19	−1.125

Liner type	Medial			Lateral		
	Proximal	Middle	Distal	Proximal	Middle	Distal
Dermo Liner	47.6 (13.9)	49.9 (12.8)	49.5 (19.0)	53.0 (26.3)	56.1 (14.5)	48.2 (9.4)
Seal-In X5 Liner	47.7 (10.2)	63.0 (17.3)	57.6 (17.5)	51.0 (28.7)	56.1 (5.8)	60.8 (17.2)
P-value	0.674	0.008*	0.028*	0.767	0.889	0.093
Z	−0.42	−2.66	−2.19	−0.29	−0.14	−1.68

* Significant differences between the Dermo and Seal-InX5 liner.

3.3. Questionnaire

In five out of the nine questions on the satisfaction scale of the questionnaire, the Wilcoxon Signed Rank Test revealed statistically significant higher scores for the Dermo liner than those for the Seal-In X5 liner. However, the Seal-In X5 liner scored better on the question about the suspension of the prosthesis (Table 3).

In the element of the questionnaire that was aimed at assessing problems with a device, the Wilcoxon Signed Rank test showed significantly higher scores across five items for the Dermo liner and two items (including pistoning within the socket and unwanted sounds) for the Seal-In X5 liner (Table 3).

The overall scores (average) of the two scales of the questionnaire were also calculated and compared for the two liners. A paired-samples *t*-test was performed to compare the scores of satisfaction and problems scales for the Dermo and Seal-In liners. In both scales, the subjects assigned significantly higher scores to the Dermo liner ($P<0.05$) than they did to the Seal-In liner.

4. Discussion

Biomechanical understanding of the interface pressure between the socket and residual limb is one of the primary objectives in prosthetic

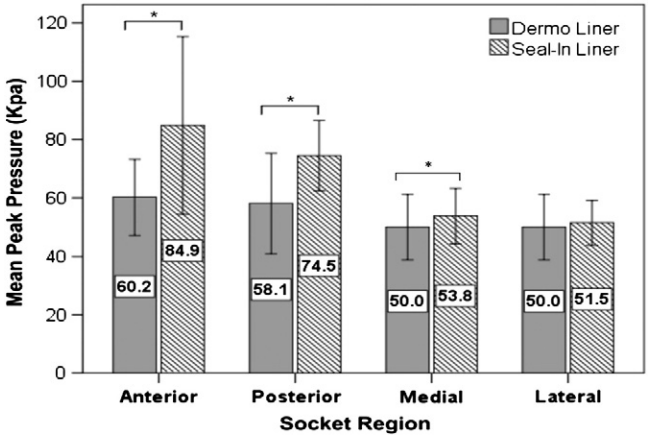

Fig. 2. Mean peak pressure for the four major regions of the stump. The asterisks (*) indicate significant differences between the Dermo and Seal-In X5 liner.

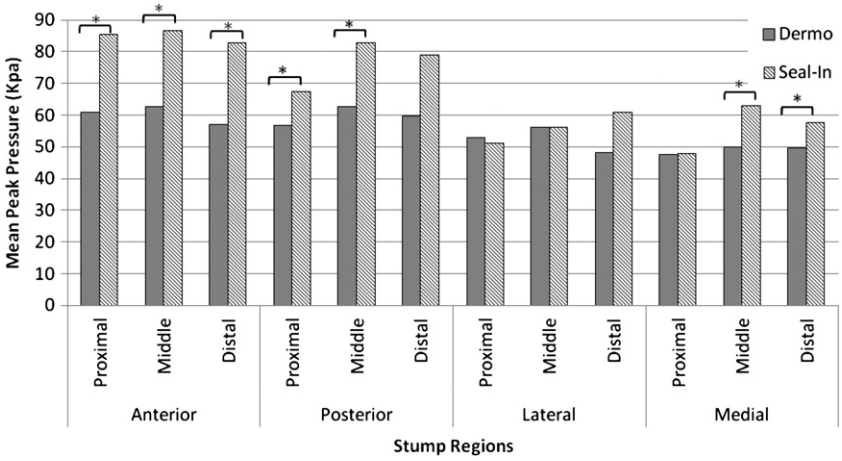

Fig. 3. Mean peak pressure in all subsections of the stump. The asterisks (*) indicate significant differences between the Dermo® and Seal-In® liner.

rehabilitation (Mak et al., 2001). The level of patient satisfaction with a prosthesis is said to be greatly dependent on the proper allocation of interface pressures at pressure-relief and pressure-tolerant areas of the residual limb (Haberman et al., 1992). Residual limb and socket interface pressure is considered to be of high significance when assessing the biomechanics of the dissimilar socket designs. Measuring the degree of these pressures is a direct technique that can be used to evaluate the comfort and fit of the socket (Laing et al., 2011). Two different interface liners for transtibial prosthesis were examined in this study: the Seal-In X5 liner and the Dermo liner with shuttle lock system.

The results of the study revealed that the MPP value in the Seal-In X5 liner was significantly higher for the whole anterior and posterior region of the residual limb than it was with the Dermo liner with shuttle lock. The average MPP difference was 34.04% at the anterior and 24.04% at the posterior region. In the study, the anterior proximal subregion pressure was lower than the anterior middle subregion for both liners. This finding is similar to the results of a study conducted by Dumbleton et al., which found that the interface pressure was the lowest at the proximal region of the residual limb (Dumbleton et al., 2009). This present study showed that the interface pressure in the Seal-In X5 was higher at the middle sub-region of the residual limb than it was with the distal and proximal subregions, both in the anterior/posterior and the medial/lateral aspects. This higher pressure might be associated with the five seals around the liner, which provide an airtight fit inside the socket. In the current study, the MPP at posterior-proximal region were recorded as 56.6 kPa, and 67.4 kPa for the Dermo liner and Seal-In X5 liner respectively. Beil and Street compared the interface pressure between the urethane liners using suction socket and pin and lock socket. Their study revealed average pressures of 68.6 kPa and 66.4 kPa at the posterior proximal region for the suction and TSB socket respectively (Beil and Street, 2004). This is consistent with the current study's findings with regard to the Dermo liner. Overall, in the current study, the pressure was higher at all the subregions of anterior and posterior regions with the Seal-In X5 liner.

In the present study, there was a statistically significant difference between the two liners on the whole medial region and no statistically significant differences between the two liners on the whole lateral region of the residual limb were recorded. MPP values were significantly higher ($P<0.05$) for the Seal-In X5 liner at the middle and distal subregions. This is also consistent with a study by Dumbleton et al., which identified higher pressure at the lateral distal end (Dumbleton et al., 2009). Three of the subjects in the current study refused to continue

Table 3
Satisfaction and problems with Dermo and the Seal-In liner.

	Dermo liner mean (SD)	Seal-In liner mean (SD)	*P*-value	Z	Effect size
Satisfaction					
Fit of prosthesis	78.1(5.6) ↑	73.3(5.6)	0.01[a]	−2.46	0.58
Ability to don and doff the prosthesis	86.7(7.9) ↑	50.0(7.1)	0.01[a]	−2.68	0.63
Ability to sit with the prosthesis	77.2(7.1)	75.6(5.3)	0.47	NS[b]	-
Ability to walk with the prosthesis	84.2(5.3) ↑	76.1(5.5)	0.01[a]	−2.72	0.64
Ability to walk on uneven terrain	75.8(6.4) ↑	72.8(5.7)	0.03[a]	−2.12	0.50
Ability to walk up and down on stairs	75.0(9.4)	77.8(6.2)	0.25	NS	-
Suspension	82.2(3.6)	85.6(5.8) ↑	0.03[a]	−2.12	0.50
Appearance of the prosthesis	81.4(5.1)	83.9(4.2)	0.13	NS	-
Overall satisfaction with the prosthesis	84.7(5.7) ↑	70.6(4.6)	0.01[a]	−2.09	0.49
Overall score	80.6(5.1) ↑	73.9(4.0)	0.00[a]	t = 9.02	0.91
Problems/complaints					
Sweating	76.7(6.6)	73.9(9.6)	0.49	NS	-
Wounds/ingrown hairs/blisters	87.8(7.9) ↑	82.2(7.9)	0.04[a]	−2.06	0.49
Skin irritations	84.4(8.8) ↑	77.2(9.7)	0.04[a]	−2.03	0.48
Pistoning within the socket	78.9(6.0)	86.7(5.6) ↑	0.01[a]	−2.14	0.50
Rotation within the socket	84.6(8.1)	82.8(9.1)	0.46	NS	-
Swelling of the stump	87.8(6.2) ↑	78.6(8.4)	0.01[a]	−2.54	0.60
Unpleasant smell of prosthesis or stump	82.8(7.5) ↑	74.4(4.6)	0.02[a]	−2.39	0.56
Unwanted sounds	77.8(3.6)	83.9(4.9) ↑	0.01[a]	−2.42	0.57
Pain in stump	86.7(4.3) ↑	73.0(8.0)	0.01[a]	−2.71	0.64
Overall Score	83.0(4.6) ↑	79.2(5.9)	0.01[a]	t = 3.20	0.57

[a] Significant differences between the Dermo and Seal-In liner.
[b] Non significant.

using the prosthesis with the Seal-In X5 liner on a long-term basis as they felt tightness and excessive pressure on the residual limb, particularly in the areas where the seals were located.

Significant differences were found between the two liners with respect to the levels of patient satisfaction and the problems they experienced. Subjects were more satisfied with the Dermo liner ($P<0.05$) than they were with the Seal-In X5 liner. The overall score was (mean = 80.59, SD = 5.14) for the Dermo liner with shuttle lock compared to (mean = 73.95, SD = 4.03) for the Seal-In X5 liner. The average difference across the 9 questions on the satisfaction scale of the questionnaire was 8.67% higher for the Dermo liner and the mean difference for the problem and complaints scale of the questionnaire was 4.69% higher for the Dermo liner than the Seal-In X5 liner. These differences were both statistically significant.

The results of this study revealed that the subjects preferred the Dermo liner with shuttle lock and, as such, it supports the findings of McCurdie et al., which clearly reported the preference to locking liners. Moreover, it is consistent with a recent study by Gohlezadeh et al., which revealed higher patient satisfaction with the Dermo liner and shuttle lock when compared with the Seal-In X5 liner. However, Linde et al. stated that experts in the field of rehabilitation were more satisfied with the locking liners (Linde et al., 2004).

A study by Astrom and Stenstrom revealed that locking liners provided more comfort and a better fit within the socket (Åström and Stenström, 2004) and their findings are consistent with those of the current study, where the subjects were more satisfied with the fit of the Dermo liner with shuttle lock. Another study by Klute et al. established that the participants were more satisfied with the locking system (Klute et al., 2011). The results of the present study revealed that a subject's ability to walk with the prosthesis was higher and they walked more comfortably with the Dermo liner than they did the Seal-In X5 liner. Similar findings were established in a study by Hatfield and Morrison (Hatfield and Morrison, 2001).

The socket fit and suspension in prostheses have significant impact on the user's mobility, comfort and satisfaction (Baars and Geertzen, 2005). Within the questionnaire, the subjects rated the Seal-In X5 liner higher than the Dermo liner. Gholizadeh et al. also mentioned improved suspension with the Seal-In X5 liner (Gholizadeh et al., 2011). However, the findings of the current study contradict the study of Cluitmans et al., where enhanced suspension was measured with the locking liners (Cluitmans et al., 1994).

The ease with which a subject can don and doff a prosthetic device plays a significant role in prosthetic use and their satisfaction with that device (Baars et al., 2008; Gauthier-Gagnon et al., 1999). This study revealed that the subjects found doffing and donning the Seal-In X5 liner much more difficult than they did the Dermo liner with shuttle lock. Similar findings were revealed by Gholizadeh et al. The subjects involved in this study, all of whom were over 50 years old, were not ready to accept the Seal-In X5 liner because of difficulties in donning and doffing the device and the excessive tightness of the socket. Furthermore, the satisfaction score was higher for the Dermo liner with shuttle lock than it was for the Seal-In X5 liner, with the exception of suspension. Moreover, statistical analysis showed significantly fewer problems with the Dermo liner with the shuttle lock.

It is acknowledged that the findings of the current study are limited to only nine subjects and to normal walking on level ground. Further clinical studies are required to evaluate the interface between the liner and socket and satisfaction during walking on uneven ground, stairs and slopes.

5. Conclusion

The selection of good prosthetic components is considered to present a challenging task in amputee rehabilitation. The result of the interface pressure analyses showed less pressure within the socket wearing the Dermo liner. Moreover, the subjects had less problems and complaints with the Dermo liner. Hence, it can be concluded that the Dermo liner provides more comfortable socket-residual limb interface than the Seal-In X5 liner. However, despite this, the Seal-In X5 liner offers better suspension. All these issues should be taken into account when choosing prosthetic components for amputees.

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