



The effect of Dermo and Seal-In X5 prosthetic liners on pressure distributions and reported satisfaction during ramp ambulation in persons with transtibial limb loss

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Background. Lower limb amputee's are greatly affected in dealing with the environmental barriers such as ramps and stairs and reported high interface pressure between the residual limb and socket/liner. Interface pressure between the residual limb and socket/liner can affect the satisfaction and use of the prosthesis. Until now, little attention has been paid to interface pressure between socket and stump during ramp negotiation and its effect on amputee's satisfaction.

Aim. The aim of this study was to evaluate the interface pressure produced by two different liners (Seal-In X5 and Dermo) between the residual limb and socket, and their effects on amputee's satisfaction during ramp negotiation.

Design. Observational study.

Setting. The study was performed in rehabilitation and biomedical departments of University Malaya Medical Centre.

Population. Total ten (7 male, 3 female) transtibial amputees with unilateral amputation were included.

Methods. Two prostheses were fabricated for each amputee. After four weeks of acclimation period, interface pressure between socket and residual limb was measured during walking on ramp and Prosthetic Evaluation Questionnaire (PEQ) was filled for each liner.

Results. Mean peak pressure was significantly ($P < 0.05$) lower with the Dermo liner compared with the Seal-In X5 liner in ramp walking. In addition, the participants were more satisfied with the Dermo liner (83.50 vs. 71.50) and mentioned fewer problems (87.00 vs. 69.00) compared with the Seal-In X5 liner during ramp negotiation.

Conclusion. It might be concluded that Dermo liner could be a good choice for the transtibial level of amputation due to relative decrease in interface pres-

sure, satisfaction and fewer problems.

Clinical Rehabilitation Impact. The advantages of the Dermo liner may improve clinical rehabilitation of transtibial amputee's, as it provides more satisfaction and experienced fewer problems during ramp negotiation. This provides an improved walking and better quality of life in long term.

KEY WORDS: Rehabilitation - Prosthesis - Pressure - Patient satisfaction.

Many factors can influence the use of prosthesis and the interface between prosthetic socket and skin, including shear force, moisture, distribution of weight and temperature.^{1, 2} The main concern for the rehabilitation of individuals with transtibial prosthesis is the failure to use and accept prosthesis, mainly because of discomfort within the prosthetic socket.³⁻⁵

The mechanical interaction of stump and socket can affect the comfort and use of the prosthesis. Extra care should be taken into account during the design and fitting of transtibial socket to avoid skin problems and discomfort while performing daily activities.⁶ Pressure should be distributed evenly over the stump to provide comfortable load transmission and good control for mobility, and to reduce skin damage by increasing the contact surface. It is clear that good socket design requires understanding of the bio-mechanics of socket and residual limb, including interface pressure, during ambulation.⁷

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The transtibial prosthetic (TTP) users experience different pathways such as level ground, ramps, stairs and other uneven surfaces during their daily activities. The ability to negotiate environmental obstacles, such as ramps and stairs is a significant factor for the functional freedom.⁸ Studies showed that lower limb amputee is greatly affected in dealing with the environmental barriers such as slopes and stairs because of the loss of foot and ankle mechanism and reported high interface pressure.^{9, 10} A number of skin issues might result from high interface pressure between the stump and inner socket wall during daily activities. These skin problems might disturb the everyday use of prosthesis and impede the independent life pattern.^{11, 12} Silicon liners are usually prescribed to prevent the formation of pressure sores.¹³ These liners are claimed to distribute the interface pressure between the stump and socket, and to provide a comfortable interface.

Currently, clinicians and prosthetic practitioners use different liners in Malaysia, but commonly-used silicon liners are new Dermo liner with pin, and the Seal-In X5 suspension system. The Dermo liner provides suspension through pin and lock mechanism, while the Seal-In X5 liner provides suspension through suction mechanism. Few studies have evaluated the interface pressure with these systems during level walking;^{14, 15} however, the interface pressure between socket and stump during ramp negotiation is not clear. Researchers have investigated interface pressure between socket and stump in the past 46 years; however, most of the studies focused on the interface pressure during level walking.¹⁴⁻¹⁹ It is, therefore, important to collect the interface pressure data during ramp negotiation between the socket/stump, especially in young and active prosthetic users (K3 and K4) who take part in social activities and labor work. The purpose of this research was to compare the interface pressure between socket and stump with the Dermo and Seal-In X5 liners during ramp negotiation, and to survey their effects on users' satisfaction.

Materials and methods

Study population

All the subjects had a unilateral transtibial amputation since at least four years prior to the study.

Only those individuals who had not less than 12 cm stump length, no significant problem in the stump, no orthopedic or rheumatic, neurologic or cognitive impairment additional to the amputation were selected. Also, they were required not to take any medication that could influence balance, have severe heart problem, and could negotiate ramp without assistive devices. Only K2, K3 and K4 activity levels subjects were selected and these levels of activities were defined based on Medicare Functional Classification Level (MFCL). These activity levels are defined as: K2 means "limited community ambulatory", K3 means "community ambulatory" and K4 were "high level user". Exclusion criteria were stump problems within the last 3 months prior to the study and abnormalities of the sound limb. The ethics committee of University Malaya Medical Centre approved this research, and informed written consent was received from all the subjects.

Prosthesis intervention

A certified prosthetist fabricated and aligned two prostheses for each subject. Prosthesis with the Dermo liner included total surface bearing (TSB) socket, shuttle lock system, double adapter and carbon Talux foot. The prosthesis with the Seal-In X5 liner included TSB socket, prosthetic valve, socket adapter, aluminum pylon tube, male and female pyramid adapters and carbon Talux foot. Before the fabrication of final sockets, each subject was fitted with transparent check socket to ensure that the socket was total surface bearing. All the subjects participated in dynamic gait alignment sessions. They were also requested to use each prosthesis for at least four weeks, and to visit the Brace and Limb Laboratory once a week to monitor the stump health and fitting.

Sensors placement

In order to get better insight into the socket and stump interface, we used four F-socket sensors arrays (sensor type 9811E) with 8 inch length and 3 inch matrix width. Each sensor array is composed of 96 sensels. Each sensor array was affixed to the anterior, posterior, medial and lateral compartments of the stump and was trimmed according to the contours of the stump to allow 90% coverage (Figure 1). To ensure correct position of the sensor arrays,

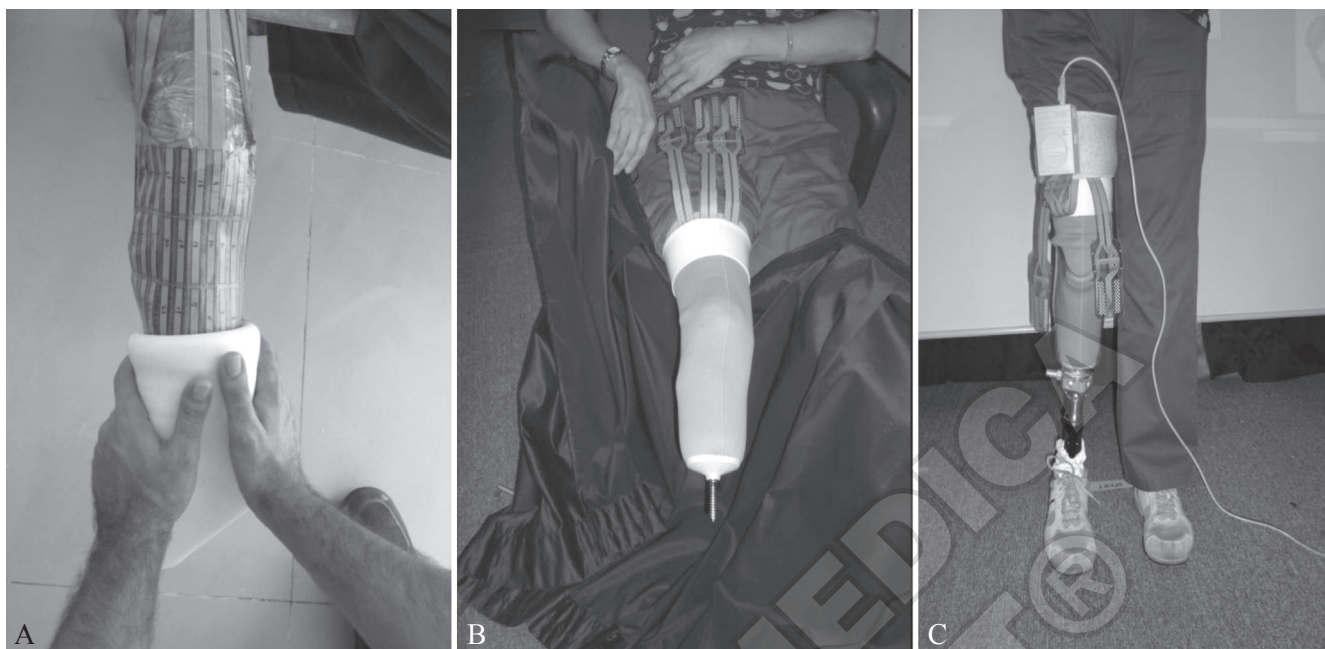


Figure 1.—A) Sensor attachments on stump; B) Dermo interface system on attached sensors (C) subject with study prosthesis.

stump was covered with wrapping plastic and the trimmed sensor arrays were attached to the plastic using adhesive spray. To ensure that placement of the sensors was the same between sessions, the mid patella was taken as the reference line for the placement of medial, lateral and anterior sensors, while the posterior sensor was positioned approximately 1 cm above the posterior trim line of the socket.

Data collection

Prior to the experiment, sensor arrays were equilibrated and calibrated using Tekscan pressure bladder to eliminate the variation among load cells. According to the manufacturer's instruction, each sensor array was individually placed inside the pressure bladder coupled with an air compressor applying 100 kPa steady pressure for equilibration. After equilibration, the calibration was accomplished according to body mass.

The participants were requested to walk on a 7.5 degree incline and 4-meter long custom-made ramp with a comfortable cadence. Before the experiments, all the participants walked up/down the ramp with the experimental prostheses several times to be-

come accustomed to the protocol, and to condition the sensors. The same procedure was followed for all the participants.

The data was recorded for 10 seconds at sample frequency rate of 50 Hz. The subjects completed five consecutive trials; in each trial the data was recorded for at least six to eight steps during ascent and descent the ramp. F-scan provides the essential data from separate transducers attached to stump and displays the Mean Peak Pressure (MPP) value obtained from every sensor for each time frame. The area within each array is further divided into two: a proximal region and a distal region. The middle step was chosen from each trial and MPP of two trials were employed for the purpose of statistical analyses. Pressure data was collected using the Tekscan software (version 6.51).

Questionnaires

We used few elements of Prosthetic Evaluation Questionnaire (PEQ). PEQ measure the quality of life of amputees with prosthetic-related issues. After the experiments, all the subjects were questioned to evaluate the effect of satisfaction as well as perceived problems with each liner during ramp nego-

tiation. We asked the following questions regarding satisfaction and perceived problems with each liner.

Satisfaction: Fitting, donning/doffing, ramp-down, ramp-up and overall satisfaction.

Problems: Pain, sounds, sweating, pistoning, rotation, smell and overall problems.

Statistical analysis

Paired sample *t*-test was employed to compare the MPP at the major and sub-regions at different areas of the stump for the two liners. We also used paired sample *t*-test to compare the satisfaction and problems with the two liners. Value $P < 0.05$ was set for the level of statistical significance. SPSS version 20.0 (SPSS, Chicago, IL, USA) was used for statistical analysis (Figure 1).

Results

Subjects' demographics

Ten (30% female and 70% male) unilateral trans-tibial subjects participated in the study. Their mean age, height and body mass were 45.70 (16.48) years, 170.20 (6.89) cm and 75.90% (14.30) kg, respectively. The main causes of amputation were trauma (40%), diabetic (40%) and peripheral vascular disease (PVD) (20%), respectively. The numbers of right side amputees (60%) exceeded the numbers of left side (40%) amputees. Most of the participants (70%) reported activity level of K3-K4, while 30% reported activity level of K2-K3. Time since amputation was 4.40 (1.71) years. Demographics of ten subjects are shown in Table I.

Stump and socket interface pressure

Using the MPP of the selected step for all the subjects, significant differences ($P < 0.05$) were found

TABLE I.—*Demographic characteristics of subject.*

Variable	Results
Sex	Male (70%) Female (30%)
Age (years)	45.70 (16.48)
Body mass (kg)	75.90 (14.31)
Height (cm)	170.20 (6.89)
Activity level (%)	K2-K3 (30%) K3-K4 (70%)
Cause of amputation (%)	Trauma (40%) PVD (20%) Diabetic (40%)
Side of amputation	Right (60%) Left (40%)
Time since amputation (years)	4.40 (1.71)

between the two liners among the three major regions (anterior, posterior and lateral). During ramp ascent, the MPP (kPa) was significantly lower with the Dermo liner (60.57, 64.50 and 60.54, respectively) compared with the Seal-In X5 liner (83.48, 83.08 and 71.35, respectively). No significant difference was found between the medial regions with the two liners (Table II).

During ramp descent significant differences were observed at the anterior, posterior and medial regions with the two liners. The participants experienced significantly lower MPP with the Dermo liner at the anterior (66.43 *vs.* 85.21), posterior (61.64 *vs.* 90.03) and medial (48.16 *vs.* 64.36) major regions compared with the Seal-In X5 liner. No significant statistical differences were revealed during ramp ascent at the lateral region between the two liners (Table II).

There were also significant differences ($P < 0.05$) between the two liners at the sub-regions during ramp ascent. The interface pressure was significantly lower with the Dermo liner compared with the Seal-In X5 liner at proximal anterior (57.42 *vs.* 71.14), posterior proximal (59.64 *vs.* 81.66), and posterior distal (51.73 *vs.* 65.28) sub-regions. The same was

TABLE II.—*MPP (kPa) at the anterior, posterior, medial and lateral region during ramp ascent and descent.*

	Ramp ascent			Ramp descent		
	Seal-In X5 Mean (SD)	Dermo Mean (SD)	P-value	Seal-In X5 Mean (SD)	Dermo Mean (SD)	P-value
Anterior	83.48 (24.02)	60.57 (05.37)	0.00	85.21 (22.78)	66.43 (16.37)	0.00
Posterior	83.08 (14.54)	64.50 (11.62)	0.00	90.03 (18.46)	61.64 (15.62)	0.00
Lateral	71.35 (16.06)	60.54 (10.08)	0.00	70.18 (20.11)	67.07 (18.66)	0.25
Medial	53.58 (7.77)	53.47 (9.84)	0.94	64.36 (14.86)	48.16 (17.16)	0.01

SD: Standard deviation.

true with the lateral proximal, medial proximal and medial distal regions (Table III).

During ramp descent, the MPP was lower at the anterior proximal (52.22 *vs.* 67.22), anterior distal (60.81 *vs.* 74.20), posterior proximal (57.34 *vs.* 72.07) and posterior distal (53.80 *vs.* 83.00) sub-regions, respectively with the Dermo liner. No significant difference was seen at the lateral and medial proximal sub-regions between the two systems (Table III).

Satisfaction and problems

Significant differences were found in satisfaction. In four questions *i.e.* fitting, donning, doffing, ramp-down and overall satisfaction out of five, the participants were significantly satisfied with the Dermo liner compared with the Seal-In X5 liner (Table IV). Regarding the perceived problems, only two out of six questions showed significant differences (Table IV).

Discussion

Distribution of Interface pressure between the socket and stump is an important indication of socket design and fit. Amputees can feel pressure between the stump and socket during daily activities.^{20, 21} Although significant technical advances have been made in prosthetics technologies in fabrication of transtibial prostheses in the last few years, still some amputees experience high interface pressure between the socket/stump during walking, especially on stairs, ramp and uneven ground. This study compared the interface pressure between socket/stump with the Seal-In X5 and Dermo liners during ramp negotiation and their effects on users' satisfaction.

All the participants showed higher pressure with the Seal-In X5 liner and significant differences ($P < 0.05$) were shown for the anterior, posterior and

TABLE III.—MPP (kPa) at the anterior, posterior, lateral and medial subregions during ramp ascent and descent.

	Ramp ascent			Ramp descent		
	Seal-In X5 Mean (SD)	Dermo Mean (SD)	P-value	Seal-In X5 Mean (SD)	Dermo Mean (SD)	P-value
Anterior proximal	71.14 (9.35)	57.42 (7.12)	0.00	67.22 (25.38)	52.22 (10.99)	0.03
Anterior distal	63.67 (32.12)	50.15 (15.31)	0.13	74.20 (28.30)	60.81 (20.02)	0.02
Posterior proximal	81.66 (18.92)	59.64 (18.29)	0.00	72.07 (13.24)	57.34 (13.56)	0.00
Posterior distal	65.28 (12.88)	51.73 (20.01)	0.02	83.00 (20.23)	53.80 (18.55)	0.00
Lateral proximal	66.89 (17.27)	56.86 (20.29)	0.00	55.67 (20.75)	49.32 (11.09)	0.15
Lateral distal	69.56 (10.74)	62.99 (19.34)	0.21	61.19 (19.62)	56.34 (12.74)	0.29
Medial proximal	63.95 (13.79)	44.16 (11.12)	0.00	49.63 (14.19)	44.26 (18.11)	0.43
Medial distal	60.83 (17.36)	39.14 (18.32)	0.00	54.11 (18.18)	39.82 (19.02)	0.01

SD: standard deviation.

TABLE IV.—Satisfaction and problems with Dermo and Seal-In X5 liners.

Satisfaction	Dermo (SD)	Seal-In X5 (SD)	P-value
Fitting satisfaction	83.10 (8.130)	76.20 (7.81)	0.00
Donning/Doffing satisfaction	86.00 (8.75)	65.50 (7.61)	0.00
Ramp-down satisfaction	83.50 (5.79)	77.00 (5.37)	0.00
Ramp-up satisfaction	79.00 (9.36)	77.50 (10.60)	0.39
Overall satisfaction	83.50 (8.54)	71.50 (7.47)	0.00
Problems	Dermo (SD)	Seal-In X5 (SD)	P-value
Sounds problem	72.50 (10.06)	74.00 (8.43)	0.34
Pain problem	84.00 (5.16)	72.00 (6.32)	0.00
Sweating problem	78.00 (7.52)	68.80 (10.85)	0.00
Pistoning problem	75.00 (5.50)	75.00 (7.81)	0.84
Rotation problem	80.00 (8.16)	82.00 (6.32)	0.26
Smell problem	77.50 (7.16)	78.00 (7.52)	0.59
Overall problems	87.00 (6.32)	69.00 (5.67)	0.00

Satisfaction: 100 indicated "completely satisfied" and 0 represented "unsatisfied".

Problem: 100 represented "not bothered at all" and 0 indicated "extremely bothered".

lateral regions ($P=0.00$, $P=0.00$ and $P=0.00$, respectively) during the ramp ascent. During ramp descent, the statistics showed significant differences at the anterior, posterior and medial regions ($P=0.00$, $P=0.00$ and $P=0.001$, respectively). In addition, the participants were more satisfied and experienced fewer problems with the Dermo liner.

High MPP has been reported at the proximal anterior (PT bar) and posterior proximal (PP) regions during the stance phase of the gait with the patellar tendon bearing (PTB) socket. This is consistent with the study of Dou *et al.* which demonstrated higher pressure at the PT bar and popliteal depression (PD) while ascending ramp.¹⁰ Our study also revealed higher pressure at these areas (Table III). On the other hand, lower pressure was recorded at the distal sub-region (kick point), which is compatible with the findings of Dou *et al.*¹⁰ but contradicts the study of Wolf *et al.*²²

During ramp descent, the knee flexion moment is larger in contrast to the level walking.²³ However, to guarantee stability with transtibial prosthesis, the amputees position their prosthesis onto the lower step with extra extended knee, which decreases the magnitude of pressure at the anterior proximal and increases at the anterior distal area.⁹ This study obtained similar results with the above biomechanical changes of the knee during ramp ascent; the MPP was higher at the anterior distal sub-region compared with the anterior proximal sub-region. This is also consistent with the study by Dou *et al.*¹⁰

Different studies showed less pistoning with the suction sockets such as the Seal-In X5 liner.²⁴⁻²⁶ In this study, pressure magnitude was significantly higher with the Seal-In X5 liner in all the regions of the stump that may result in less pistoning. These findings clarify the abovementioned study results. Board *et al.*²⁵ stated that suction mechanism leads to elevated magnitude of pressure and socket fit. However, in turn, the increase in net pressure causes blood flow disturbance and stump muscle loss.²⁵ The Seal-In X5 liner in our study also showed higher pressure magnitude, and the participants reported that tight fit during walking created discomfort and/or pain. Apparent significant differences were measured between the two interface systems during the stance phase of the gait, while identical body mass was applied over the same surface in the two sockets. This is in contrast with the study of Beil *et al.*, where the research team reported more pressure in stance phase.²⁷

The results of the questionnaire revealed a preference for the Dermo over the Seal-In X5 liner. The participants rated that their stump was healthier when wearing the Dermo liner and they were more satisfied compared with the Seal-In X5 suspension system. The participants stated that their abilities to ambulate were significantly higher while wearing the Dermo liner. These results are consistent with the findings of Klute *et al.*, where the participants reported high performance with locking liners.²⁴ Comfort of the socket is disturbed by the increased pressure between the socket/stump;^{10, 28} this might be the reason that the participants were less satisfied with the Seal-In X5 liner.

Silicon liners are rolled on over the stump to achieve prosthesis fit. Easy doning and doffing play significant role in the satisfaction of users. Doning and doffing was significantly easier with the Dermo liner ($P=0.00$). Ninety percent (90%) of the subjects reported difficult doning and doffing with the Seal-In X5 liner and revealed that the doning and doffing was very irritating. These difficulties in doning and doffing might be due to the five seals located around the liner, which produce friction and do not slide easily, unless using lubricating spray. Despite all others problems, few participants reported more stable ramp negotiation with the Seal-In X5 liner because of the firm contact with the stump. This is consistent with the results of Gholizadeh *et al.* where participants were more stable during walking with the suction liner.²⁶

In summary, the MPP was significantly lower with the Dermo liner during ramp ascent and descent. All the participants reported that they were more active and mobile with the Dermo liner as compared with the Seal-In X5 liner; they could walk for longer time with the Dermo liner. The results clarify that the participants were more satisfied and experienced less problems with the Dermo liner. The results of this study may provide useful and valuable information to the clinicians and prosthetic practitioners. It may also help in producing an interface liner that can provide a comfortable interface pressure between the socket/stump. However, the sample size in this study was smaller and it was a challenge to compare the results with other studies due to the use of different sensors and activity level. Participants' selection and retaining was also challenging. Further study is needed with larger sample size and longer acclimation period to measure the effect of different liners on participants' satisfaction.

Conclusions

The study findings revealed that high magnitude of pressure were recorded with the Seal-In X5 liner during ramp negotiation. Transtibial amputees feel more satisfied with minimum prosthetic issues using the Dermo liner. The Dermo liner might be a good choice for transtibial prosthetic users.

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