

Transtibial prosthetic suspension: Less pistoning versus easy donning and doffing

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Abstract—Poor suspension increases slippage of the residual limb inside the socket during ambulation. The main purpose of this article is to evaluate the pistoning at the prosthetic liner-socket interface during gait and assess patients' satisfaction with two different liners. Two prostheses with seal-in and locking liners were fabricated for each of the 10 subjects with transtibial amputation. The Vicon motion system was used to measure the pistoning during gait. The subjects were also asked to complete a Prosthesis Evaluation Questionnaire. The results revealed higher pistoning inside the socket during gait with the locking liner than with the seal-in liner ($p < 0.05$). The overall satisfaction with the locking liner was higher ($p < 0.05$) because of the relative ease with which the patients could don and doff the device. As such, pistoning may not be the main factor that determines patients' overall satisfaction with the prosthesis and other factors may also contribute to comfort and satisfaction with prostheses. The article also verifies the feasibility of the Vicon motion system for measuring pistoning during gait.

Key words: amputation, gait, Iceross, lower-limb amputation, motion analysis, pistoning, satisfaction, suction, suspension, transtibial prosthesis.

INTRODUCTION

The main roles of the suspension systems incorporated into lower-limb prostheses are to hold the prosthesis on the residual limb and to decrease the motion that takes place at the bone-skin-liner-socket interface during

ambulation (pistoning, vertical movements within the socket) [1]. Effective suspension systems and prosthetic components can improve a person with amputation's gait and decrease his or her energy expenditure [2–3]. Prosthetic limbs should have an intimate fit with the residual limb in order to replace the lost body part with a device that offers high levels of comfort and satisfaction [3–6].

Individuals with amputation believe that both the suspension method and the fitting of a prosthetic device have significant effects on their overall satisfaction with the prosthesis [6–8]. Several questionnaires have been developed and a number of prosthetics surveys have been conducted to analyze patient satisfaction with prosthetic devices. The majority of researchers prefer the Prosthesis Evaluation Questionnaire (PEQ) as a means of evaluating differences in function, performance, and satisfaction between the different components or techniques of prosthetics fabrication and adjustment (**Appendix**, available online only) Good reliability and validity have been reported for the PEQ [9–11].

Evidence shows that silicone liners are preferred by many people with lower-limb amputation because they

Abbreviations: PEQ = Prosthesis Evaluation Questionnaire.

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offer enhanced suspension and fit within the socket as well as improved function [3,7–8,12]. Previous research on the silicone liners has found that patient comfort and satisfaction are particularly higher in contrast with other suspension systems, such as the belt for patellar tendon bearing socket [3,8,12]. Silicone liners are believed to be more effective in controlling the pistoning within the prosthetic socket than polyethylene foam (pelite) liners. Pistoning at the socket-liner interface is said to be lower with silicone liners (1–5 mm) than with pelite liners (6.0–41.7 mm) [13–21].

Based on the literature, the pistoning is correlated with the prosthetic suspension system and fit [15]. Thus, both clinicians and researchers should be able to determine the quality of suspension and prevent the negative effects of pistoning (such as gait deviation, skin breakdown, and discomfort) by pistoning measurement [13–22].

A number of methods exist to measure the pistoning of various interfaces within the socket (liner-socket) or the residual limb (bone-soft tissue). These include X-ray [12,20,23–25], spiral computerized tomography [26], and photoelectric sensors [22]. These measurement methods are mostly useful for measuring the bone movement inside the socket. Recently, two new methods were introduced for the liner-socket interface in transtibial prostheses: a photographic method and a motion analysis system [16–19]. The literature review revealed that the majority of researchers measured the pistoning during quiet standing (static) and only a few had evaluated the pistoning that occurred inside the socket during gait (dynamic) [15].

A previous study by Gholizadeh et al. revealed low levels of pistoning for the seal-in suspension (Seal-In X5 liner, Össur; Reykjavik, Iceland) than the locking system (Dermo liner, Össur) during standing [16]. The findings of that study motivated this current research and prompted investigation on the effects of these suspension systems during gait along with patient satisfaction. To our knowledge, no study has previously compared the quality of suspension systems during gait and the associated levels of patient satisfaction.

METHODS

Subjects

Ten subjects with unilateral transtibial amputation participated in this study. We determined the participants' mobility grade based on the guidelines of the American Academy of Orthotists & Prosthetists [27]. **Table 1** lists subject characteristics.

In order to be eligible for the study, subjects with transtibial amputation were required to be unilateral, without pain or ulcer on the residual limb, and with a residual-limb length not less than 13 cm. Furthermore, they could not have volume fluctuation in the residual limb, could not depend on assistive devices such as a cane or crutches for ambulation, and had to have good upper-limb strength.

Table 1.
Subject characteristics.

Subject	Age (yr)	Height (cm)	Mass (kg)	Cause of Amputation	Amputated Side	Residual-Limb Length (cm)*	Mobility Grade†
1	45	168	75	Diabetic	Left	14	K2
2	35	173	90	Trauma	Left	15	K3
3	22	168	60	Trauma	Left	14	K3
4	71	181	75	Diabetic	Left	13.5	K2
5	49	167	64	Trauma	Right	13	K3
6	37	177	99	Diabetic	Right	17	K2
7	51	160	57	Diabetic	Right	14	K3
8	52	165	60	Diabetic	Left	15	K3
9	62	169	72	Trauma	Right	13	K2
10	34	172	86	Trauma	Left	16	K3

*Inferior edge of patella to distal end of residual limb.

†Based on American Academy of Orthotists & Prosthetists scale. K2 = Patient has ability or potential for ambulation with ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces—a typical community ambulator. K3 = Patient has ability or potential for ambulation with variable cadence—a typical community ambulator with ability to traverse most environmental barriers and may have vacation, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.

Procedures

Two transtibial prostheses (**Figure 1**) were manufactured for each subject. Two different suspension systems were used: Seal-In X5 liner with valve (Icelock Expulsion Valve 551, Össur) and Dermo liner with shuttle lock (Icelock Clutch 4H 214, Össur). All prosthetic feet were Flex-Foot Talux (Össur) [16,18].

One of the researchers (registered prosthetist) designed, fit, and aligned all the prosthetic limbs. Two separate total surface bearing sockets were fabricated individually for each of the two liners that were used in the study. Transparent thermoplastic material (NorthPlex 12 mm, North Sea Plastics Ltd; Glasgow, United Kingdom) enabled us to check the socket fit. The subjects attended a gait training session in the Brace and Limb Laboratory (Department of Biomedical Engineering, University of Malaya, Malaysia).

The prosthetist ensured that there was no gait abnormality and that the fit of the prosthetic sockets was satisfactory. We determined prosthetic alignment through bench, static (standing in an upright position), and

dynamic (during walking) alignment. All subjects had an acclimation period of 4 weeks for each prosthetic device. To ensure subject safety, one definite socket was also made for each liner type for the 4-week acclimation period. Check sockets were used only during the kinematic experiments.

Following the trial period, we performed pistoning evaluation in the motion analysis laboratory with the Vicon 612 system using seven MXF20 motion capture cameras (Vicon; Los Angeles, California), which is believed to have an accuracy level of less than ± 0.1 mm [28]. We adopted a sampling rate of 200 Hz for the data collection. The signals from the motion analysis system were filtered by a Butterworth filter (cutoff frequency of 10 Hz).

We fixed 16 reflective markers to the subjects' lower limbs in accordance with the Helen Hayes marker set. The knee and tibia markers for the prosthetic leg were located on the lateral proximal socket wall and the lateral distal end of the socket, respectively (**Figure 2**). We placed two additional markers on the liner under the knee joint level (LLin1) and 5 cm below that (LLin2) [16].

Because knee joint movement could affect the actual pistoning values, we positioned the additional markers (LLin1 and LLin2), aligned by laser liner, on the liner below the knee joint. With the transparent socket, the markers were visible through the hard socket and detectable by the cameras [16]. By fixing the markers to one segment (the shank), we avoided knee movements leading to unreal displacement.

The transparent socket could create some reflections that could be mistakenly considered as markers, therefore we used paper tape (except for the areas where additional markers were located) to mask the socket wall [16]. Prior to the test, we asked subjects to walk in the motion analysis laboratory in order to accustom themselves to the environment. Afterward, the subjects walked at a self-selected speed on an 8 m walkway. We recorded five successful trials per subject with each type of liner. We considered a trial to be successful if the cameras could capture all the markers. We could measure the pistoning by analyzing the markers' positions; however, in order to detect one gait cycle in each trial, we also used two Kistler force plates. There was a 1 min rest interval between the trials. We used the distance between the markers on the liner and on the socket to identify the piston motion.

The reproducibility of measurements was evaluated by intraobserver intrasession, intraobserver intersession, and interobserver intersession variabilities. Two observers



Figure 1. Transtibial suspension systems: (a) Seal-In X5 liner (Össur; Reykjavik, Iceland) with transparent socket and valve and (b) Dermo liner (Össur) with transparent socket and shuttle lock.

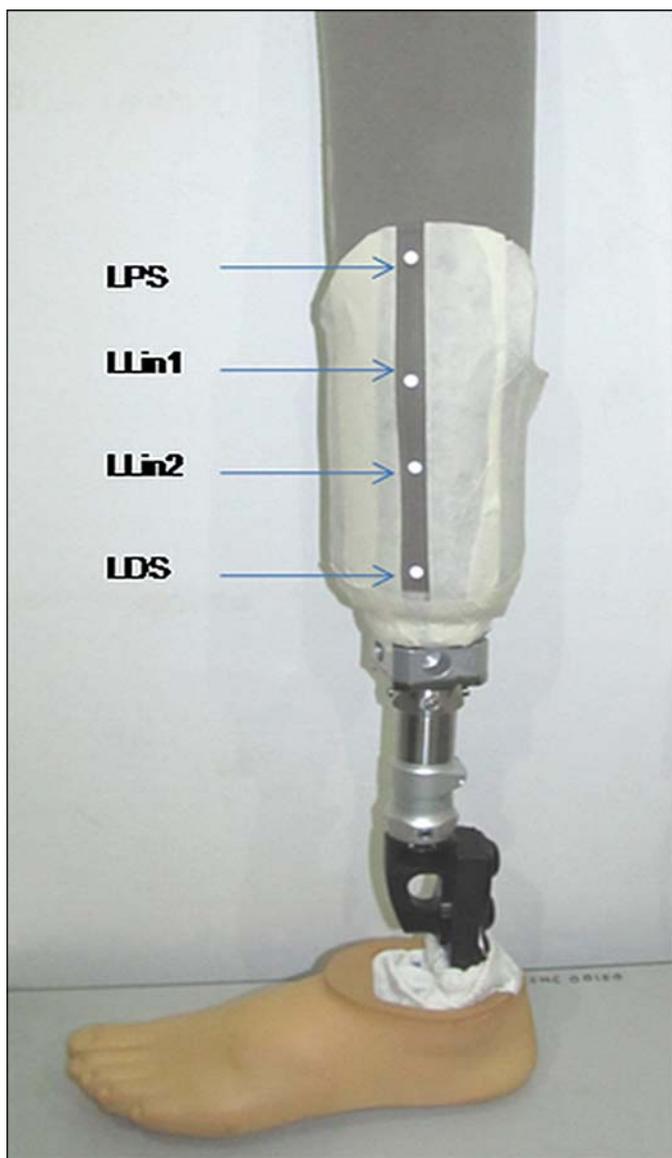


Figure 2. Marker positions on socket (lateral proximal socket wall [LPS] and lateral distal end of socket [LDS]) and liner (LLin1 and LLin2).

performed the experiments over two sessions with a 1 week interval.

Prosthesis Evaluation Questionnaire

Following the experiments, we asked the subjects to complete one PEQ for each studied liner. We used some parts of the PEQ to quantitatively assess patient satisfac-

tion [10]. The PEQ consisted of the following three sections:

- Demographic data (sex, age, weight, height, time since amputation, and cause of amputation).
- Satisfaction (fit, donning and doffing, sitting, walking on level surface, walking on unlevel ground, ascending and descending stairs, cosmesis, and overall satisfaction).
- Problems (sweat, wound, skin irritation, pistoning, pain, swelling [edema], smell, and unwanted sounds).

We rated the responses on a scale from 0 to 100, where 0 indicated “dissatisfaction or extreme problems” with the system and 100 indicated “complete satisfaction or no problems.”

We used SPSS 18.0 (IBM Corporation; Armonk, New York) for the data analyses, with p -values set at 0.05. A paired-samples t -test compared the effects of the two different liners on pistoning during each gait cycle. We divided the gait cycle (stance and swing) into eight phases. We divided the stance phase by initial contact, loading response, midstance, terminal stance, and pre-swing. Initial swing, midswing, and terminal swing formed the swing phase of gait. In order to analyze the data, we first calculated the peak pistoning that occurred during each phase of one gait cycle for one gait trial of each subject. Following that, we computed the average peak pistoning that occurred across five successful gait trials. Finally, we found the overall average of peak pistoning across the different phases of gait for all 10 subjects for the comparison between the liners.

RESULTS

Pistoning Evaluation

The mean time since amputation was 7 years and all subjects had undergone amputation at least 3 years prior to study participation. The reproducibility of the measurements across the different trials of one session and between two sessions by two observers was shown to be high. The intraclass correlation coefficients of intraobserver intrasession, intraobserver intersession, and interobserver intersession were 0.92, 0.87, and 0.79, respectively.

The results of the motion analysis revealed that the amount of pistoning that occurred when the Seal-In X5 liner was used was significantly less than the pistoning with the Dermo liner throughout the gait cycle ($p < 0.05$), with the exception of loading response (0.5 mm), midstance

(0.0 mm) and terminal stance (0.0 mm). Both liners exhibited no pistoning during preswing (**Table 2, Figures 3–4**).

During initial contact, the Dermo liner was displaced 5.1 ± 0.7 mm (mean \pm standard deviation) within the socket. However, this value decreased rapidly to 0.0 mm at the end of loading response and remained the same until the initial swing. Only 1.9 ± 0.4 mm of pistoning was found with the Seal-In X5 liner during initial contact. Maximum displacements in 10 subjects were 5.4 ± 0.6 mm for the Dermo and 2.5 ± 0.4 mm for the Seal-In X5 liners during the initial swing.

Satisfaction

The PEQ revealed that the subjects were overall more satisfied ($p < 0.05$) with the Dermo liner than the Seal-In X5 liner. Nevertheless, many of them mentioned increased levels of pain and pistoning when using the Dermo liner. Donning and doffing the Seal-In X5 liner was more difficult, but the satisfaction with the socket fit was higher (**Table 3**). The participants also stated that the prosthesis with the Seal-In X5 liner acted like a natural part of their body and that they did not experience any traction at the end of the liner.

Table 2.
Average of displacement in different phases of gait cycle ($n = 10$).

Phase	Suspension	Displacement,	
		Mean \pm SD (mm)	<i>p</i> -Value
Initial Contact	Dermo*	5.1 ± 0.7	$<0.001^\dagger$
	Seal-In X5*	1.9 ± 0.4	
Loading Response	Dermo	0.5 ± 0.1	$<0.001^\dagger$
	Seal-In X5	1.6 ± 0.4	
Midstance	Dermo	0	$<0.001^\dagger$
	Seal-In X5	0.8 ± 0.2	
Terminal Stance	Dermo	0	0.02^\dagger
	Seal-In X5	0.3 ± 0.1	
Preswing	Dermo	0	—
	Seal-In X5	0	
Initial Swing	Dermo	5.4 ± 0.6	$<0.001^\dagger$
	Seal-In X5	2.5 ± 0.4	
Midswing	Dermo	4.2 ± 1.1	$<0.001^\dagger$
	Seal-In X5	1.7 ± 0.5	
Terminal Swing	Dermo	5.1 ± 0.7	$<0.001^\dagger$
	Seal-In X5	1.9 ± 0.4	

*Ossur; Reykjavik, Iceland.

† Statistically significant.

SD = standard deviation.

DISCUSSION

Selecting a suitable suspension system for individuals who have undergone transtibial amputation is a critical issue in rehabilitation [7,16,18]. In this study, we evaluated two different prosthetic suspension systems in 10 subjects with transtibial amputation to compare pistoning movement and patient satisfaction with the device during ambulation. The Vicon motion system was introduced for the purpose of evaluating pistoning during gait.

The literature review revealed that the majority of existing research was based on pistoning measurement in the static position of quiet standing as opposed to walking [15]. The complications of taking such measurements during gait and concerns over subject safety by exposure to X-ray hampered such practice [22]. A few studies attempted to use videofluoroscopy [29], photoelectric sensors [22], or axial movement detectors [30] to measure the pistoning that occurred during ambulation. However, they were only able to measure vertical movement between the pelite liner and socket [22,30]. Among them, only Sanders et al. provided the value of the pistoning that occurred across different phases of gait [22].

In this study, the Vicon motion system was shown to be an efficient method of measuring the pistoning at the liner-socket interface during the gait. It also offered a harmless method of pistoning measurement [22]. However, it is unable to detect bone displacement within the soft tissue.

Pistoning

This study showed that the Seal-In X5 liner helps to decrease pistoning by developing suction against the socket wall. The resultant suction ensures firm attachment between the liner and the socket wall. The purpose of silicone liners is to provide enhanced suspension by causing less pistoning within the prosthetic socket [3,8,12,15]. The findings of this study support this statement because the pistoning values with both Seal-In X5 and Dermo liners were lower than those found with the polyethylene foam liners [22,29–30].

With the exception of the preswing phase, we found significant differences between the two liners during the gait cycle ($p < 0.05$) (**Figures 3–4, Table 2**). These significant differences can be attributed to the different elongation properties of the liners used [16,18]. The pistoning that occurred during the initial swing might have been high as a result of peak flexion in the knee joint.

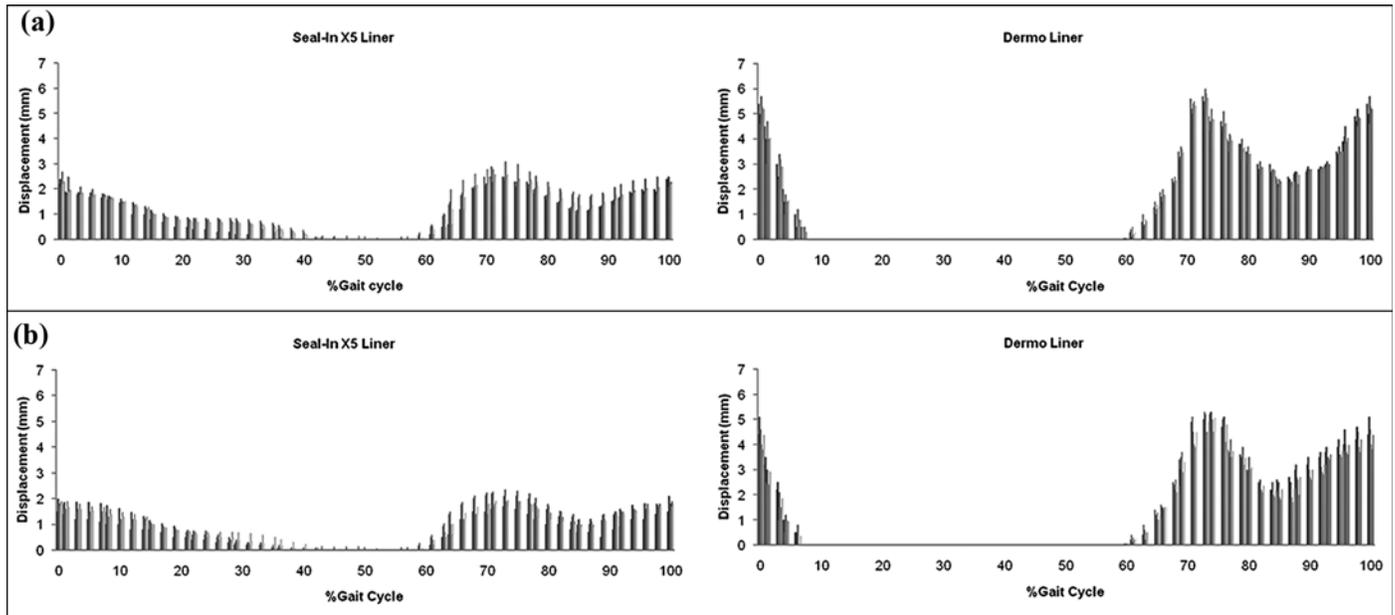


Figure 3. Sample pistoning patterns with Seal-In X5 liner (Össur; Reykjavik, Iceland) and Dermo liner (Össur) during one gait cycle for subjects (a) 2 and (b) 5.

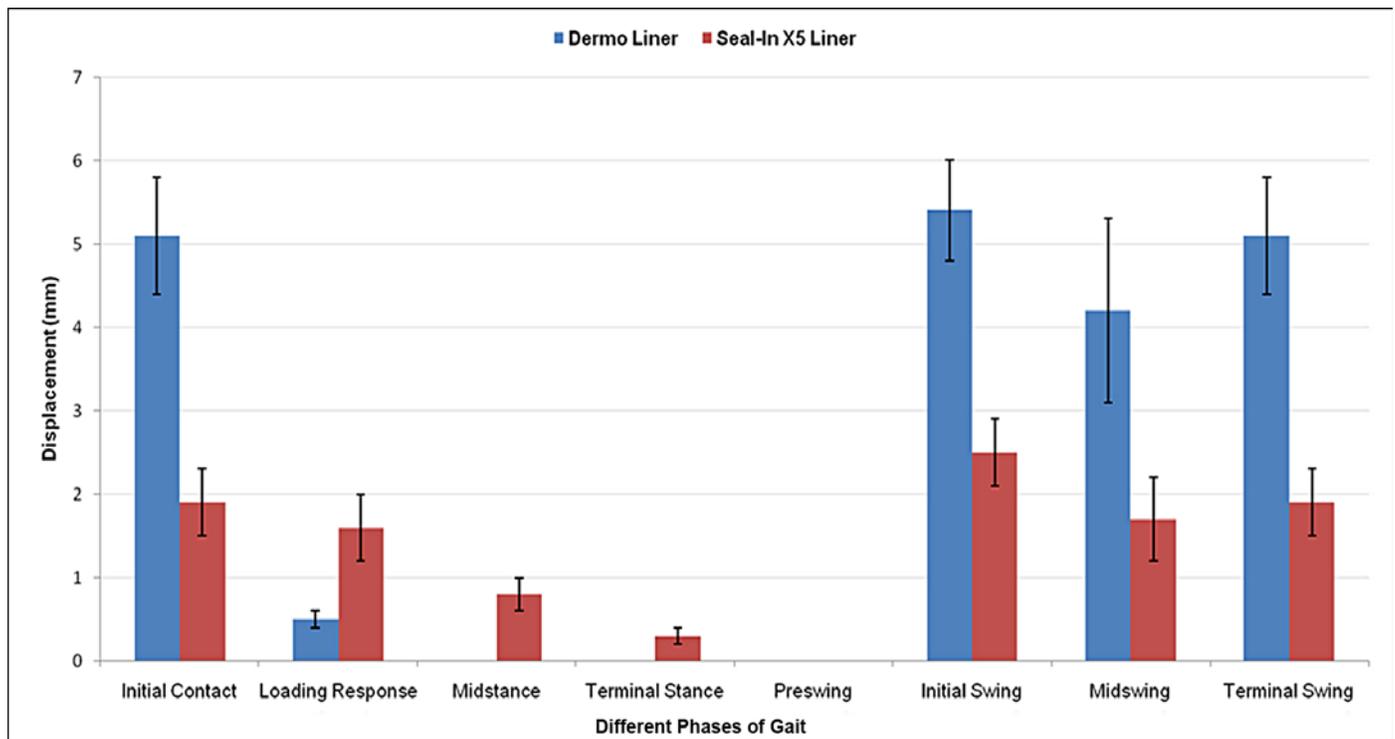


Figure 4. Comparison of mean displacement in different phases of gait cycle ($n = 10$).

Table 3.

Comparison of satisfaction and perceived problems with Dermo (Össur; Reykjavik, Iceland) and Seal-In X5 (Össur) liners.

Satisfaction	Suspension Type	Mean*	p-Value	Problem	Suspension Type	Mean†	p-Value
Fit	Dermo	75.59	0.003‡	Sweat	Dermo	70.53	0.082
	Seal-In X5	87.09			Seal-In X5	72.50	
Donning and Doffing	Dermo	87.50	<0.001‡	Wound	Dermo	100.00	—
	Seal-In X5	35.44			Seal-In X5	100.00	
Sitting	Dermo	76.30	—	Irritation	Dermo	100.00	—
	Seal-In X5	77.80			Seal-In X5	100.00	
Walking	Dermo	78.25	0.001‡	Pistoning Within Socket	Dermo	72.50	<0.001‡
	Seal-In X5	85.80			Seal-In X5	95.75	
Uneven Walking	Dermo	75.20	0.04‡	Pain	Dermo	70.83	<0.001‡
	Seal-In X5	80.30			Seal-In X5	83.52	
Stair	Dermo	76.50	0.09	Swelling (edema)	Dermo	100.00	—
	Seal-In X5	78.75			Seal-In X5	100.00	
Overall	Dermo	85.77	0.004‡	Smell	Dermo	95.80	0.15
	Seal-In X5	75.20			Seal-In X5	94.00	
Cosmetic	Dermo	82.50	0.46	Sound	Dermo	74.85	<0.001‡
	Seal-In X5	80.75			Seal-In X5	95.50	

*Greater mean indicates higher satisfaction.

†Greater mean indicates less complaints/problems.

‡Statistically significant.

Finally, as a result of centrifugal forces, the pistoning increased between the liners and socket during the terminal swing. We noted significant difference in pistoning between the studied liners during this phase of the gait ($p < 0.05$), which can be associated with the firm attachment between the Seal-In X5 liner and the socket.

Satisfaction

Prosthetic satisfaction is an issue influenced by several factors. Prosthetic users require more time and energy to don and doff the Seal-In X5 liner [16,18]. They also need lubricant sprays to facilitate donning. Moreover, hand dexterity is more critical for donning and doffing a Seal-In X5 liner than for the Dermo liner. All locking liners usually have an umbrella-shaped feature at the distal part that is connected distally to a pin. Weight bearing during ambulation over this rigid and small pin may result in pain at the distal end of the residual limb [31].

The Seal-In X5 liner seems to resolve the so-called problem of “milking” (distal tissue stretch caused by the pin and lock) [32]. This milking phenomenon can also result in pain, particularly at the end of the tibia and along the tibial crest. The subjects in the current study had more pain with the pin and lock suspension (Dermo liner) than the Seal-In X5 liner.

Little is known about the effects of different prosthetic components and systems on patient satisfaction with prostheses. Effortless donning and doffing does appear to have a positive effect on satisfaction with a prosthesis [6]. The participants of this study were mainly dissatisfied with the Seal-In X5 in terms of donning and doffing and many of them specified that donning and doffing was significantly easier with the Dermo liner than with the Seal-In X5 liner. As such, the subjects stated a preference for this suspension system over the Seal-In X5 liner for long-term use.

One limitation of this study was the small sample size, particularly for the satisfaction survey. In addition to this, further research is needed to compare more suspension alternatives in order to provide a better guideline for suspension system selection. Future research should also investigate and compare the effects of these suspension systems on proprioception.

CONCLUSIONS

In conclusion, amputation rehabilitation is influenced by appropriate choice of prosthetic components in accordance with the real needs of the individual. We can infer from the results of this study that the Seal-In X5 liner

decreased the pistoning within the prosthetic socket significantly, possibly as a result of the strong suction seal between the liner and the socket. Nevertheless, the subjects had difficulty with donning and doffing. We can therefore conclude that pistoning may not be the main factor that determines subjects' overall satisfaction with the prosthesis.

The study introduced a new method for evaluating the pistoning at the liner-socket interface in transtibial prostheses during gait. The Vicon system has the potential to detect the pistoning during gait while also offering a safer alternative to X-ray. Further studies are needed to come to a "gold standard" for pistoning.

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