Transtibial prosthetic socket pistoning: Static evaluation of Seal-In\textsuperscript{®} X5 and Dermo\textsuperscript{®} Liner using motion analysis system

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\textbf{A B S T R A C T}

Background: The method of attachment of prosthesis to the residual limb (suspension) and socket fitting is a critical issue in the process of providing an amputee with prosthesis. Different suspension methods try to minimize the pistoning movement inside the socket. The Seal-In\textsuperscript{®} X5 and Dermo\textsuperscript{®} Liner by Ossur are new suspension liners that intend to reduce pistoning between the socket and liner. Since the effects of these new liners on suspension are unclear, the objective of this study was to compare the pistoning effect of Seal-In\textsuperscript{®} X5 and Dermo\textsuperscript{®} Liner by using Vicon Motion System.

Methods: Six transtibial amputees, using both the Iceross Seal-In\textsuperscript{®} X5 and the Iceross Dermo\textsuperscript{®} Liner, participated in the study. The vertical displacement (pistoning) was measured between the liner and socket in single limb support on the prosthetic limb (full-weight bearing), double limb support (semi-weight bearing), and non-weight bearing on the prosthetic limb, and also under three static vertical loading conditions (30 N, 60 N, and 90 N).

Findings: The results demonstrated that the pistoning within the socket when Seal-In\textsuperscript{®} X5 was used, decreased by 71\% in comparison to the Iceross Dermo\textsuperscript{®} Liner. In addition, a significant difference between the two liners under different static conditions was found ($p<0.05$).

Interpretation: Participants needed to put in extra effort for donning and doffing the prosthesis with Seal-In\textsuperscript{®} X5; however, this type of liner provided less pistoning. The new approach that uses the motion analysis system in this study might be an alternative for measuring the pistoning effect in the prosthetic socket.

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1. Introduction

The lower limb prosthesis’s efficiency is mainly guaranteed by its optimal suspension method in order to secure the socket to the amputee’s stump. In fact, suspension and fitting play the main role in comfort and prosthetic function (Baars and Geertzen, 2005; Isozaki et al., 2006; Kristinsson, 1993; Tanner and Berke, 2001).

In addition, the most important factor mentioned by the amputees is the fit of their prosthesis and suspension (Datta et al., 1996; Fillauer et al., 1988; Legro et al., 1999). In some studies regarding lower limb prostheses, suspension with an Icelandic Roll-On Silicone Socket (ICEROSS) system was preferred by the amputees because of better suspension, fit, stump protection, and comfort when compared with the other suspension methods (Hachisuka et al., 1998; Heim et al., 1997). The function of the prosthesis was also improved with silicone liners when compared to the other suspension systems (Baars and Geertzen, 2005; Cluitmans et al., 1994; Legro et al., 1999; Trieb et al., 1999).

Prosthetic suspension and fit are said to be correlated to pistoning (Commean et al., 1997; Grevenst, 1978; Newton et al., 1988; Sanders et al., 2006). Thus, measuring the pistoning within the socket would be helpful in determining the optimal prosthetic fit (Commean et al., 1997). Liner technology has evolved significantly and many liners with different properties are available today (Sanders et al., 2004). Clinicians often try to choose appropriate liners (soft socket) for each subject based on their personal experience and producers’ technical information (Klute et al., 2010; McCurdie et al., 1997). Silicon liners were introduced in 1986 and their main advantage was claimed to be an enhanced bond with the stump and therefore, better suspension compared with the other soft sockets (Baars et al., 2008). Silicon liners are said to reduce pistoning of the stump and the bone compared with the polyethylene foam (Pelite) liners (Narita et al., 1997; Söderberg et al., 2003; Vigiter et al., 2002). It has been shown either clinically or by questionnaire. A clinical study by Tanner and Berke (2001) found only 2 mm of pistoning of the residual limb with silicone liner and shutle lock inside the TSB socket, while Sanders et al. (2006) stated the amount of pistoning of 41.7 mm with PTB socket. Questionnaire study by Cluitmans et al. (1994), Hachisuka et al. (1998) and Datta et al. (1996)
reported improved suspension in 96, 63 and 15% of their subjects with the silicon liners, respectively.

Manufacturers of prosthetic components have always attempted to come up with new innovative suspension systems to lessen pistoning (Trieb et al., 1999; Wirta et al., 1990). The recent development of the prosthetic liner Seal-In® X5 by Össur (Reykjavik, Iceland), a new suction suspension liner with hypobaric sealing membrane around the silicon liner without an external sleeve or shuttle lock which increases surface contact with the socket wall, motivated us to study the effects of this new liner on prosthetic suspension. Furthermore, the manufacturer has claimed that the Seal-In® X5 and Dermo® Liner can reduce the pistoning during ambulation (Össur, 2008). The objective of this study, therefore, was to compare the effects of the new Seal-In® X5 Liner and Dermo® Liner (both are considered silicone liners; Fig. 1) on transtibial prosthetic pistoning. The comparison was performed in full-weight bearing, semi-weight bearing, and non-weight bearing on the prosthetic limb, and also under three static vertical loading conditions (30 N, 60 N, and 90 N) using the Vicon Motion System.

In the literature review, as far as authors are aware, no study regarding the effects of Seal-In® X5 and Iceross Dermo® Liners on transtibial prosthetic suspension was found. Few studies that compared other suspension systems used techniques other than ours to monitor pistoning action within the transtibial or transfemoral socket. A number of methods, such as the ultrasonic method (Convery and Murray, 2000), roentgenological method (Erikson and Lemperg, 1969; Grevsten and Erikson, 1975; Söderberg et al., 2003), X-ray and cineradiography (Liija et al., 1993; Narita et al., 1997), or spiral computerized tomography (CT) (Madsen et al., 2000) have been used to measure either the bony structures’ positions within the stump relative to the socket or residual limb slippage within the socket. Photoelectric sensors and custom made transducers have been also used (Abu Osman et al., 2010a; Abu Osman et al., 2010b; Sanders et al., 2006). But, since these methods are costly and X-ray could be harmful to the subjects’ bodies, these studies have been mostly conducted as case studies in laboratories. Studying pistoning with the Vicon Motion System was employed for the first time in this study.

2. Methods

Six male unilateral transtibial amputees with a mean age of 43 (SD 16.5) and mobility grade K2–K3, based on the American Academy of Orthotists & Prosthetists, participated in this study on a voluntary basis. The mean time since amputation was 5 years. All subjects had undergone amputation at least 3 years before participating in the study. Ethical approval was granted from the University of Malaya Medical Centre (UMMC) Ethics Committee. All subjects were asked to provide a written informed consent. Characteristics per subject are listed in Table 1.

The inclusion criteria were unilateral transtibial amputees with at least 13 cm stump length (inferior edge of patella to distal end of the stump), stable limb volume, intact upper limbs (hand strength), no pain or wound in their stumps, and mobility without assistive devices, such as cane.

First, two transtibial prostheses with similar feet (Flex-Foot Talux®) and two different liners, Iceross Dermo® Liner with shuttle lock (Icelock-clutch 4 HZ14 L 214000) and Iceross Seal-In® X5 transtibial liner with valve (Icelock Expulsion Valve 551), were made for each subject by a Registered Prosthetist and Orthotist. All the prostheses were made by a single prosthetist to avoid variability due to manufacture, fit, and alignment. All the subjects were fitted with a transparent check socket to ensure that the socket was Total Surface Bearing (TSB) (Staats and Lundt, 1987), and the inside of the socket was visible. Then they were asked to walk with their two new prostheses in the Brace and Limb laboratory (Department of Biomedical Engineering, University of Malaya, Malaysia) to become familiar with and adapt to the new liners and Flex-Foot Talux® (Össur). The prosthetist checked the alignment and fit of the prosthetic socket; then all the subjects were given a trial period of at least 4 weeks to become accustomed to the new prostheses. Following this trial period, subjects attended the motion analysis laboratory for monitoring the pistoning within the socket by collecting data via a 7-camera Vicon 612 system (Oxford Metrics; Oxford, UK). Sixteen reflective markers according to the Helen Hayes marker set were attached to the subjects’ prosthesis and sound lower limbs. On the prosthetic side, the knee and tibia markers were located on lateral proximal socket wall (LPS) and lateral distal end of the socket (LDS), respectively (Fig. 2). In order to

![Fig. 1. Transtibial suspension systems used in this study (A) Seal-In® X5 Liner; (B) transparent socket and valve; (C) Dermo® Liner; (D) transparent socket and shuttle lock.](image-url)
measure the liner vertical movement two extra markers were attached to a) lateral liner below the knee joint (LLin1) and b) 5 cm below the LLin1 (LLin2). A pilot study showed that the knee flexion and extension can bias the real amount of pistoning and should be eliminated. Therefore, in order to ensure the measurement accuracy the two extra markers (LLin1, 2) were attached over the liner below the knee level to avoid the knee motion. Static trials were carried out using dead weights. The trials were developed to ensure accurate application of loads in the vertical direction, held rigidly in a vertical attitude, and then loaded using weights hung from the prosthetic foot via wire. To simulate the centrifugal force during gait (Board et al., 2001; Commean et al., 1997; Narita et al., 1997), known loads (30, 60, and 90 N) were then applied to the prosthetic foot (Flex-Foot Talux®) and then unloaded (Fig. 3) while the signal outputs were recorded using the motion analysis system. The trials were repeated five times. Each subject was required to complete different static conditions such as single limb support on prosthetic limb (full-weight bearing), double limb support (semi-weight bearing), non-weight bearing (subjects suspended the prosthetic limb from the edge of a table), and adding and removing the loads on the prosthetic limb. Each subject went through three different vertical loading conditions.

Using a transparent socket enabled us to locate markers on the liner inside the hard socket (two fine, paper-thin 2D markers were attached on the liner inside the hard socket) so that the cameras would detect the marker and we would be able to see the pistoning movement inside the socket (Fig. 2). Moreover, by locating the markers all on one segment, that is, the tibia we could avoid knee flexion and thereby any fake displacement. During the pilot trials we noticed that a transparent socket resulted in reflections that were detected as markers by the cameras; hence we covered the transparent socket wall with paper tape, except the areas to which we added two new markers.

For calculating pistoning within the socket, we used the distance between two markers (one marker on the liner (LLin1) and another one on the socket (LPS)) during full-weight bearing on the prosthesis as a baseline. Then we compared the other conditions with the baseline to identify any pistoning movement. Additionally, an informal subjective subject survey and feedback was carried out to obtain qualitative information about the liners. Statistical data was analyzed with SPSS 17.0, and P-values of 0.05 or less were chosen to reflect statistical significance. Wilcoxon test was employed to compare the effect of two liners on the pistoning.

3. Results

The results obtained from static evaluation of Seal-In® X5 and Dermo® Liner showed that there was a significant difference between the two liners (P<0.05). Pistoning between Seal-In® X5 and the socket was not the same as that with Iceross Dermo® Liner and socket (71% less). The average displacement in the six subjects between the two liners and the socket under different static conditions (after adding loads and after removing loads) is listed in Table 2. The subjective feedback of the participants indicated less skin stretch, and more feeling of security (two amputees) with Seal-In®X5 Liner. However, diabetic subjects’ main complaint was about donning and doffing the Seal-In®X5; and when they were asked to choose one liner, they chose Dermo® Liner. When the loads were added to the prosthesis the subjects felt more comfortable at the end of residual limb with the Seal-In®X5.

3.1. Adding loads

The results showed that there was no pistoning movement between the socket and both liners while changing the position from full-weight bearing to semi-weight bearing. The mean of pistoning in the six subjects was 2 mm (SD 0.5) between the Dermo® Liner and socket while changing from semi-weight bearing to non-weight bearing position, but the average of pistoning in the six subjects was zero with Seal-In®X5 transtibial liner (100% less than Dermo® Liner). There was a significant difference (P<0.02) between the two liners after the subjects changed their positions to non-weight bearing. After adding 30 N to the prosthetic limb, there was 1 mm (SD 0.8) displacement between Seal-In® and socket (50% less), but the average displacement was 2 mm (SD 0.5) between Dermo® Liner and the socket, and the difference between the two liners was significant (P<0.04).

After adding 60 N to the prosthesis, the average displacement was 1 mm (SD 0.5) between Seal-In® X5 liner and the socket (75% less), and about 4 mm (SD 1.6) pistoning was seen between Iceross Dermo® Liner and the socket (P<0.04). The analysis of the data showed the maximum amount of pistoning within the socket after adding 90 N to the prosthetic limb. On average, 2 mm (SD 1) pistoning occurred with Seal-In®X5 (60% less) and 5 mm (SD 1.5) with Dermo® Liner (P<0.02), after adding 90 N load.

3.2. Removing loads

During the process of removing the loads, we first removed 30 N. The average displacement did not change with Seal-In®X5 (2 mm) when
compared to that when 90 N load was added to the prosthesis, but it remained at 4 mm (SD 1.4) with Dermo® Liner (P<0.03) after we removed 30 N load. After removing another 30 N, the amount of vertical movement was 2 mm (SD 1) and 4 mm (SD 1.5) with Seal-In® and Dermo® Liner, respectively (P<0.04). (The average displacement did not change.) However, there was no significant difference (P<0.06) between the two liners after we removed the entire load. When the subject again changed to semi-weight bearing position, 1 mm (SD 0.5) pistoning remained when Seal-In® Liner was used, while Dermo® Liner returned to the base position (full-weight bearing) (P<0.04). The pistoning between socket and two different liners in subjects 2 and 5 are illustrated in Fig. 4.

4. Discussion

In this study, two different suspension systems, Iceross Dermo® Liner (Össur) with shuttle lock and Iceross Seal-In® X5 Transtibial Liner with valve, were compared. We used the simple and accurate Vicon motion system with accuracy level of less than ±0.1 mm (Jenkins, 2005) under different static positions to find the effects of these liners on prosthetic suspension, especially to check the pistoning occurring between the liner and socket in six transtibial amputees.

Pistoning is the most important indicator that shows the successful functioning of the prosthetic suspension system. Pistoning of less than 10 mm gives a feeling of added fit and security to the amputees (Newton et al., 1988). However, there is not enough evidence to support this pistoning threshold. In addition, in 2002, a research study was conducted on 20 transtibial amputees to compare Total Surface Bearing (TSB) and Patellar Tendon Bearing (PTB) sockets. Their study showed that there is a significant difference between the two types of sockets (P<0.05), and pistoning in TSB is less than that in the PTB prosthesis (Yigiter et al., 2002).

We faced some limitations during the study. There was no standard regarding the exact load application in prosthetic users possibly due to the variations in prosthetic components, mass, walking speed, etc. Moreover, this study only investigated axial, static loading effects of the liners on pistoning. Based on the findings, another study is ongoing by the authors to investigate dynamic pistoning during gait by Vicon motion system. Only two liners were evaluated in this experiment, which can be considered a limitation considering the varieties of commercial available liner types. Also, no direct comparison between the results and the methodology used in this study can be made with other studies that used different methodologies.

4.1. Evaluation of current methods

Based on our literature review, in order to check the pistoning inside the socket most of the researchers measured the displacement between the bone and the socket or the soft tissue by different techniques in static position (Madsen et al., 2000; Söderberg et al., 2003; Yigiter et al., 2002) or during the gait (Lilja et al., 1993; Sanders et al., 2006). Some researchers tried to mimic the gait by adding loads to the prosthesis in static positions; however, no sound reasoning was provided for the load selection (Board et al., 2001; Commean et al., 1997; Narita et al., 1997). In 2006, a noncontact sensor was used to monitor the pistoning between the stump and socket during the gait in supracondylar socket with Pelite liner, however, the authors could not measure the pistoning between the silicon liner and socket by this sensor (Sanders et al., 2006). In a recent study, a new method of three-dimensional (3D) socket–stump telescopic movement evaluation while performing tasks on the force

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<td>Average of displacement (SD) between two markers after adding load and after removing load in six subjects.</td>
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Fig. 4. Sample pistoning results of subject no.2 (top) and subject no.5 (bottom) with Dermo® and Seal-In® X5 Liners (Displacement ± SD).
plate was presented (Papaoannou et al., 2010). They measured the piston motion between the skin and socket by Roentgen stereogrammetric system through attachment of tantalum pigments on the bone, skin and socket.

Evaluation of piston motion has been performed with various prosthetic sockets and soft interfaces. The researchers have used either PTB socket with Pelite liner (Commee et al., 1997; Narita et al., 1997; Newton et al., 1988; Sanders et al., 2006; Wirta et al., 1990; Yigiter et al., 2002) and/or TSB socket with silicone liner (Board et al., 2001; Narita et al., 1997; Tanner and Berke, 2001; Yigiter et al., 2002). The reported ranges of pistoning between the liner and socket with these two prosthetic designs show that less pistoning occurs with TSB socket and silicone liner (2–5 mm) compared with PTB socket and Pelite liner (6–41.7 mm).

The aforementioned methods are complicated for measuring the pistoning between the liner and the socket but Vicon motion system brings the possibility of easy and fast determination of pistoning between the liner and socket. It can also be a safe method if exposing to X-ray is a concern (Sanders et al., 2006). Nevertheless, our method by the Vicon system cannot be employed to monitor the tibial movement within the soft tissue.

4.2. Adding loads

The result of this study on the six subjects showed significant difference between the two liners under different static conditions (p < 0.05). Across Seal-In® X5 Transstibial Liner helped in decreasing the pistoning through vacuum inside the socket and ensured firm attachment to the socket wall, so that in the non-weight bearing condition the average of pistoning was zero and even after adding 30 N and 60 N loads to the prosthesis there was only 1 mm pistoning between Seal-In® X5 Liner and the socket. However, the mean displacement in the six subjects with Dermo® Liner was about 2 mm during non-weight bearing which is similar to the work of Tanner and Berke (2001) with silicon liner and shuttle lock. After addition of 30 N to the prosthesis still 2 mm of pistoning was found (Table 2), however, there was about 4 mm displacement after adding 60 N load. The Seal-In® X5 Liner’s attachment to the socket wall possibly resulted in significant reduction in pistoning and rotation inside the socket.

After adding different loads, the Dermo® Liner’s contact with the socket decreased possibly due to liner stretch and the rotation would have also increased, while in Seal-In® X5 Liner the attachment was not lost even after adding 90 N load and rotation was not allowed. The mean pistoning for six subjects after adding 90 N was about 2 mm with Seal-In® X5 Liner, while mean pistoning with Dermo® Liner was about 5 mm which resembles the results of Board et al. (2001). Furthermore, amputees stated improved security with Seal-In® X5 Liner during the addition of different loads.

Moreover, during the training sessions in the clinic to adapt to the new liner and prosthetic foot, two subjects reported that they felt more secure with the Seal-In® X5 Liner compared to the Dermo® Liner system and conceived the prosthesis as a part of their body. Also, after adding loads with Seal-In® X5 Liner, the subjects felt more comfortable at the end of the stump, possibly due to elimination of the skin stretch at the end of the stump.

4.3. Removing loads

After removing the loads, we noticed that the liners, especially Seal-In® X5 Liner, did not return to the first position (Table 2, Fig. 4) until the subject put all the weight on the prosthetic limb (full-weight bearing). As shown in Table 2, after removing 30 N from 90 N load, no displacement was found in Seal-In® X5 Liner, that is, the displacement remained at 2 mm for Seal-In® X5 liner, which is equal to that observed after adding 90 N, while the pistoning decreased 1 mm in the case of Dermo® Liner (mean, 4 mm). But when the load decreased to 30 N, the two liners showed the same behavior so that the displacement with Dermo® Liner and Seal-In® X5 remained the same as in the previous step. Even after removing all the loads, no displacement was seen in Seal-In® X5 liner and it did not show the same displacement when compared with the first non-weight bearing condition. While in Dermo® Liner, there was a decrease in displacement by 1 mm (average in the six subjects), 1 mm more displacement was found compared with the first non-weight bearing condition.

In the case of Dermo® Liner, during the second semi-weight bearing position all pistoning due to the addition of load disappeared (zero) but in Seal-In® X5 liner, possibly due to high friction between the liner and socket, 1 mm pistoning was observed, and then became zero under full-weight bearing condition on the prosthetic limb.

5. Conclusion

In conclusion, amputee’s rehabilitation is a challenging procedure which requires expertise especially in the selection of prosthetic components based on amputee’s needs. This study showed that Seal-In® X5 liner decreased the pistoning significantly, which can be attributed to high friction between each liner and socket. In addition, a significant difference was found between Seal-In® X5 and Dermo® Liner (p < 0.05) under different static conditions.

The ease of donning and doffing has a significant effect on prosthetic use (Baars et al., 2008; Gauthier-Gagnon et al., 1999). Although the Seal-In® X5 users found it hard to don or doff the liner, the pistoning showed to be statistically less than Dermo Liner. Nevertheless, two of our active subjects (K3) preferred to use Seal-In® X5 Liner despite the difficulty in donning and doffing (see Table 1). It might be concluded that the difference in pistoning may not be clinically significant and that other factors may play a greater role in subject comfort and confidence once a reasonable level of pistoning is reached. Vacuum suspension is said to enhance proprioception in prosthetic users (Street, 2006); it might be the reason why they favored Seal-In® X5 Liner. However, it was not the purpose of our study to evaluate the proprioception effect of liners and we only asked the patients to express their subjective feelings. A further study to investigate the proprioception objectively, therefore, is needed.

All the subjects claimed that skin stretch was less with Seal-In® X5 Liner. However, donning and doffing was the main complaints with the Seal-In® X5 and subjects preferred Dermo® Liner. Furthermore, the use of the Vicon system brings with it the possibility of easy and quick determination of static pistoning between the liner and socket; at the same time, it is not harmful for the subject’s body when compared with X-ray; however, future studies comparing these different methodologies are also needed to assist with interpretations across studies or to identify a “gold standard” to which other methodologies can be compared and more research with a larger sample size is needed to prove this preliminary result.

Conflict of interest statement

The authors have no conflict of interest.

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