

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

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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., 1989; 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; Grevsten, 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 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; Yigiter et al., 2002). It has been showed 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 shuttle 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 newsuction 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 newliner 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](#)),



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.

roentgenological method (Erikson and Lemperg, 1969; Grevsten and Erikson, 1975; Söderberg et al., 2003), X-ray and cineradiography (Lilja 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 slippagewithin the socket. Photoelectric sensors and custommade 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.

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 H214 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 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 deadweights. 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), nonweight

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.

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.

Full text is available at :

http://ac.els-cdn.com/S0268003311001859/1-s2.0-S0268003311001859-main.pdf?_tid=82dd2720-a019-11e3-952c-00000aab0f01&acdnat=1393551905_7c6f57e23f3b01c0a079afa004aac1b0

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