CASE REPORT

Clinical Evaluation of Two Prosthetic Suspension Systems in a Bilateral Transtibial Amputee

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ABSTRACT

Gholizadeh H, Abu Osman NA, Kamyab M, Eshraghi A, Lúðviksdóttir ÁG, Wan Abas WAB: Clinical evaluation of two prosthetic suspension systems in a bilateral transtibial amputee. Am J Phys Med Rehabil 2012;91:00–00.

The effects of Seal-In X5 and Dermo liner (Össur) on suspension and patient's comfort in lower limb amputees are unclear. In this report, we consider the case of a 51-yr-old woman with bilateral transtibial amputation whose lower limbs were amputated because of peripheral vascular disease. The subject had bony and painful residual limbs, especially at the distal ends. Two prostheses that used Seal-In X5 liners and a pair of prostheses with Dermo liners were fabricated, and the subject wore each for a period of 2 wks. Once the 2 wks had passed, the pistoning within the socket was assessed and the patient was questioned as to her satisfaction with both liners. This study revealed that Seal-In X5 liner decreased the residual limb pain experienced by the patient and that 1–2 mm less pistoning occurred within the socket compared with the Dermo liner. However, the patient needed to put in extra effort for donning and doffing the prosthesis. Despite this, it is clear that the Seal-In X5 liner offers a viable alternative for individuals with transtibial amputations who do not have enough soft tissue around the bone, especially at the end of the residual limb.

Key Words: Rehabilitation, Amputation, Pain, Prostheses

Prosthetic suspension plays a significant role in ensuring the secure attachment of prosthesis to the residual limb. There is a strong correlation between the vertical movement within the socket, or pistoning, and the prosthetic suspension method. There is also evidence that patient satisfaction is associated with appropriate suspension.[1–3] Therefore, it is recognized that pistoning measurement is helpful for clinicians and researchers who wish to improve suspension systems and decrease the adverse effects of pistoning movement.[3–5]

Prosthetists rely on their experience and the technical information provided by manufacturer to choose appropriate liners for their patients.[6] There is a wide variety of suspension systems available for lower limb prostheses, of which, silicon liners are frequently used.[1] Silicon liners were first introduced in 1986. Their main advantage was claimed to be better suspension compared

with other soft sockets such as polyethylene foam (Pelite) liners because of enhanced bond with the residual limb.[7–10] When attempting to understand the effectiveness of a prosthetic suspension system, the amount of pistoning may be considered as an indicator.[9] One of the most recent prosthetic liner types, the Seal-In X5 liner, is a suction suspension liner that provides a hypobaric sealing membrane around the silicon liner without an external sleeve or shuttle lock (Fig. 1*A–D*). It was invented by Össur (Reykjavik, Iceland) to reduce the pistoning movement inside the socket through increased contact surface with the socket wall. It is also said to distribute pressure evenly in a manner that prevents discomfort at the end of the residual limb.

In the literature review, no comparative study was found regarding the effect of Seal-In X5 and locking liners on prosthetic suspension and satisfaction. Therefore, the purpose of this study was to clinically investigate the effects of two suspension systems on a subject with bilateral transtibial amputation.

CASE REPORT

This report describes the study that was conducted with the approval of University of the Malaya Ethics Committee. The research involved a 51-yr-old female volunteer whose lower limbs were amputated (bilateral transtibial) because of peripheral vascular disease. The patient had been classified with the mobility grade K2 (the ability to ambulate and cross environmental obstacles such as stairs, curbs, or uneven surfaces) according to the American Academy of Orthotists & Prosthetists grading system.[11] She had bony residual limbs with adventitious bursa[12] and no soft tissue or muscle at the distal end (Fig. 2*A*, *B*). She had been using two transtibial prostheses[13] that contained a silicone liner with pin, shuttle lock, and Multiflex feet for more than 10 yrs. She was referred to the Brace and Limb Laboratory, University of Malaya, because of pain at the end of the residual limbs, especially during the swing phase of gait.

The following components were used to fabricate four transtibial prostheses (Fig. 1*A–D*): Dermo liner and shuttle lock (Icelock-clutch 4 H214 L

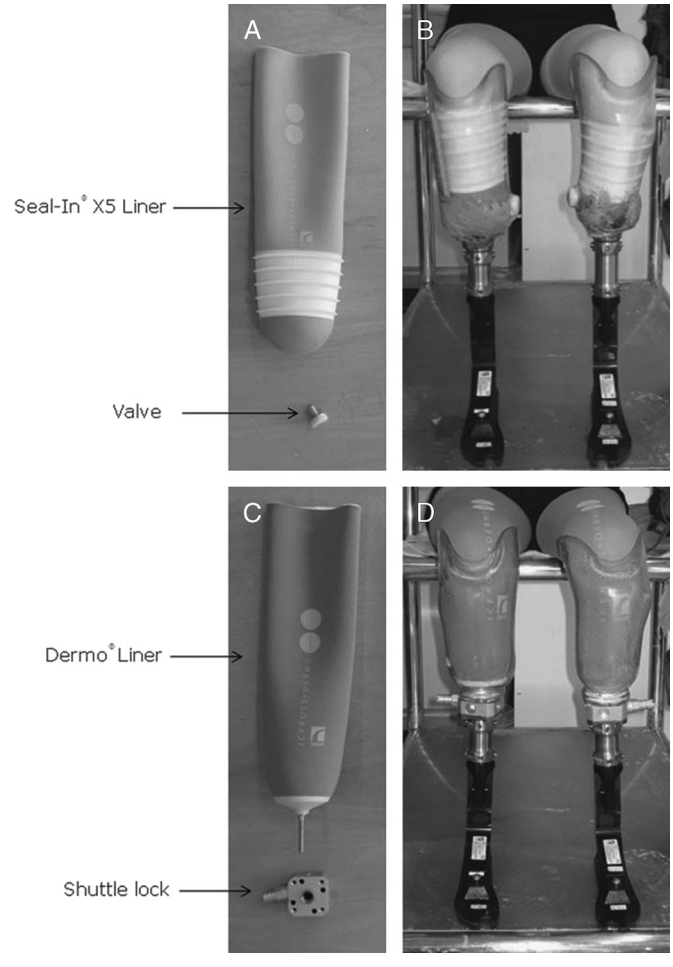

FIGURE 1 *The subject wearing the following: Seal-In X5 liner and valve (A and B); Dermo liner and shuttle lock (C and D).*

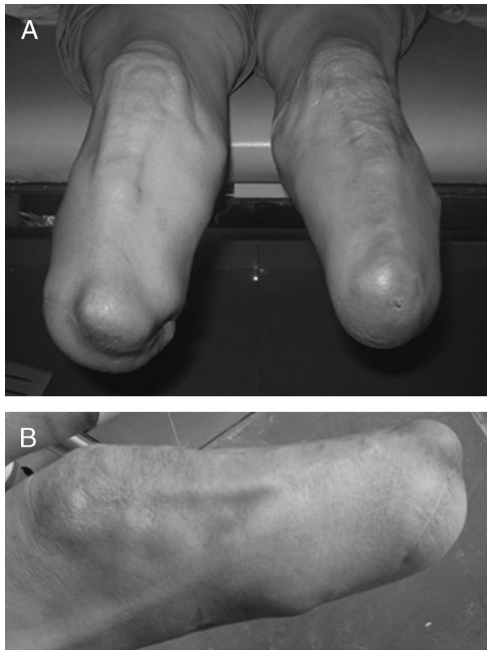

FIGURE 2 *The subject's residual limbs in anterior (A) and lateral views (B). Note the adventitious bursa over the distal-anterior ends of the residual limbs.*

214000), Seal-In X5 liner and valve (Icelock Expulsion Valve 551), double-ended adapters, and Flex-Foot Talux. The prostheses were designed and aligned by one registered prosthetist and orthotist to avoid the variability caused by fabrication, fitting, and alignment technique. The subject was fitted with transparent check sockets to ensure that the sockets were total surface bearing.[14]

Once the fitting was confirmed, the patient was asked to use each pair of the new prostheses for 2 wks to adapt to the new liners and prosthetic feet. After this period, the pistoning inside the socket of each prosthesis was determined by calculating the possible vertical movement between the socket and liner. To identify the pistoning movement inside the prosthetic socket, the following equipments[15] were used: (1) 30-, 60-, and 90-N loads; (2) a camera (Sony A, alpha, DSLR-A200K); (3) two reference rulers attached to the lateral side of the limb and the socket (Fig. 3*A–C*) to measure the real displacement on the photographs; and (4) markers (two on the socket and two on the liner).

In different static positions, photographs were taken from a fixed distance in such a way that the markers and the reference rulers could be clearly observed. We also made sure that they were not at an angle from the camera stand. The static positions consisted of (1) subject standing with full weight bearing on each prosthetic limb (unilateral stance); (2) subject standing without bearing weight on one prosthesis with the knee extended; and (3) applying the 30-, 60-, and 90-N loads,[16] consecutively, along the longitudinal axis of the prosthesis. The unilateral stance was considered the baseline position, with which all other positions were compared (Fig. 3*A–C*).

The loads were attached to the prosthetic feet via wire[16] to simulate the traction developed at the residual limb–socket interface during the swing phase of gait.

These conditions were repeated for each of the right and left legs. The subject performed the abovementioned positions three times, and the average values were used for the purpose of the statistical analysis. The accuracy of this measuring system had been previously evaluated by the authors.[15]

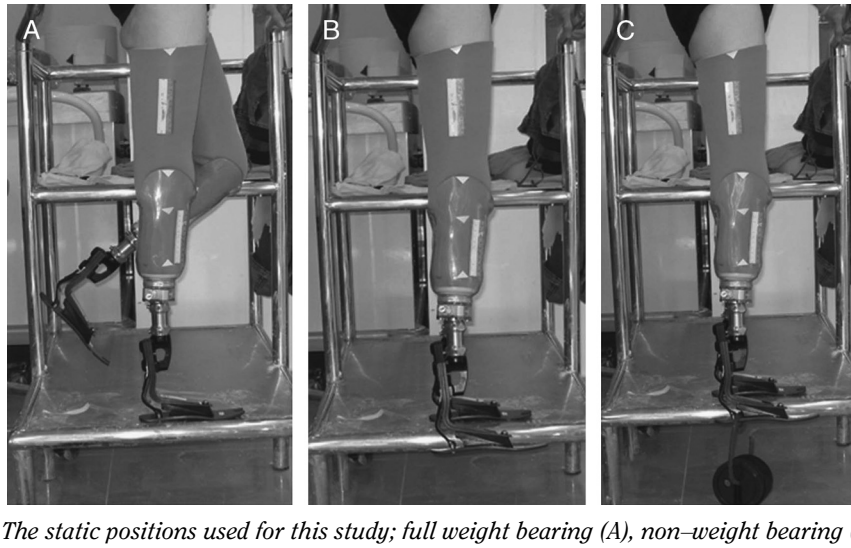

FIGURE 3 *The static positions used for this study; full weight bearing (A), non–weight bearing (B), and adding the loads (C).*

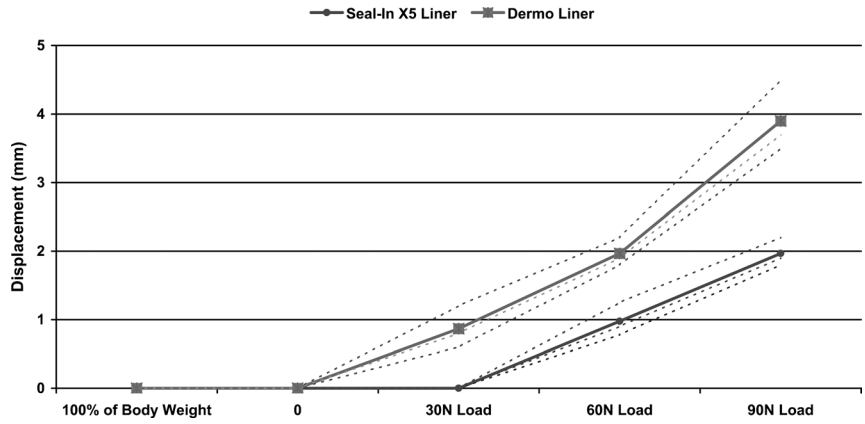

FIGURE 4 *The comparison of pistoning between Seal-In X5 liner and Dermo liner (n = 3) in full weight-bearing position (100% of body weight), non–weight-bearing position (0) and after adding 30-, 60-, and 90-N traction loads to the prosthesis.*

Finally, a questionnaire survey was conducted to obtain the subject's opinion concerning the liners. The patient was requested to complete two questionnaires for each liner type after 2 wks of continuous prosthetic use. The questionnaires included questions regarding the prosthetic fit, ability to don and doff the prosthesis, ability to walk with the prosthesis, presence of pain in the residual limb, skin traction at the end of the residual limb, and overall satisfaction with each liner. Some elements of the Prosthesis Evaluation Questionnaire (PEQ) questionnaire were used for the purpose of this assessment.[17]

The results revealed that the Seal-In X5 liner decreased pistoning inside the socket (Fig. 4) and skin traction and pain at the end of the residual limbs. The subject also found the prostheses to be more comfortable during walking because, according to her, the pressure was distributed uniformly at the distal end of the residual limbs.

DISCUSSION

The prescription and fitting of the appropriate liner for persons with lower limb amputation plays a significant role in the rehabilitation process. Every clinician (prosthetist) should be aware of different suspension methods and liners. This case study compared two suspension systems on a bilateral subject with transtibial amputation with regard to pistoning effect and satisfaction. The evaluation of piston motion has been performed with various prosthetic sockets and soft interfaces. The researchers used either a transtibial prostheses socket with Pelite liner and/or a total surface-bearing socket with silicone liner. The reported ranges of pistoning between the liner and socket with these two prosthetic designs show that less pistoning occurred with the total surface-bearing socket and silicone liner (2–5 mm)[9,18,19] compared with the transtibial prostheses socket and Pelite liner (6–41.7 mm).[3,5,9]

In this study, the mean values of the right and left limbs were used for the evaluation of the pistoning. When the subject was in the non–weight-bearing position (one of the prosthetic limbs suspended on a platform; Fig. 3*A–C*), pistoning occurred in none of the liners. When a 30-N load was added to the prosthesis, approximately 1-mm pistoning was found between the Dermo liner and socket. However, no pistoning was seen while using the Seal-In X5 liner. The 60-N load increased the pistoning in the Dermo liner by 1 mm, so that a 2-mm displacement happened between the liner and socket. These findings are similar to those identified in the study of Tanner and Berke.[19] Finally, adding 90-N load to the prosthesis caused a 4-mm pistoning between the Dermo liner and socket. These results closely resemble those previously found in a study by Board et al.[18] Pistoning was also developed in the Seal-In X5 (2 mm), but it was less than that of the Dermo liner (Fig. 4). It may be concluded that the high friction between the liner and the socket does contribute to pistoning reduction.[16] Nevertheless, the subject complained about the process of donning and doffing the Seal-In X5 liner and disclosed that she would be reluctant to wear the liner in the future. Because the literature survey revealed that the ease of donning and doffing had a considerable effect on prosthetic use,[7] this patient's statements are of significance.

Despite the difficulty of donning and doffing, the subject revealed that she was more comfortable and experienced significantly less pain with the Seal-In X5 liner during walking. It may be associated

with decreased traction at the end of the residual limbs.[16] Moreover, during the training sessions, the subject reported that she felt more secure with the Seal-In X5 liner than with the Dermo liner system. She also perceived the former prosthesis to be more like a natural part of her body. This is of importance because research indicates that low pistoning and improved fitting inside the socket can increase a prosthetic user's confidence and proprioception.[20] Also of interest is the fact that the patient felt more comfortable wearing the Seal-In X5 liner than the Dermo liner when loads were added. This was interpreted as elimination of the skin stretch at the end of the residual limbs.

More research with a larger sample size is required to generalize the results of this case study. The Seal-In X5 liner might be a suitable option for persons with lower limb amputation whose bone is immediately under the skin as a result of insufficient soft tissue. The satisfaction with donning and doffing requires more research because based on another study by the authors,[16] most subjects do complain about the donning and doffing process when using the Seal-In X5 liner.

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