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Clinical investigation of the interface pressure in the trans-tibial socket with Dermo and Seal-In X5 liner during walking and their effect on patient satisfaction

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ABSTRACT

Background: The interface pressure between the residual limb and prosthetic socket has a significant effect on an amputee's satisfaction and comfort. Liners provide a comfortable interface by adding a soft cushion between the residual limb and the socket. The Dermo and the Seal-In X5 liner are two new interface systems and, due to their relative infancy, very little are known about their effect on patient satisfaction. The aim of this study was to compare the interface pressure with these two liners and their effect on patient satisfaction.
Methods: Nine unilateral transtibial amputees participated in the study. Two prostheses were fabricated for each amputee, one with the Seal-In liner and one with the Dermo liner. Interface pressure was measured at the anterior, posterior, medial and lateral regions during walking on the level ground. Each subject filled in a Prosthetic Evaluation Questionnaire (PEQ) regarding the satisfaction with the two liners.
Findings: The mean peak pressures with the Seal-In liner was 34.0% higher at the anterior, 24.0% higher at the posterior and 7.0% higher at the medial regions of the socket ($P=0.008$, $P=0.046$, $P=0.025$) than it was with the Dermo Liner. There were no significant differences in the mean peak pressures between the two liners at the lateral regions. In addition, significant difference was found between the two liners both for satisfaction and problems ($P<0.05$).
Interpretation: There was less interface pressure between the socket and the residual limb with the Dermo liner. The results indicated that the Dermo liner provides more comfort in the socket than the Seal-In liner.

1. Introduction

Transtibial amputation patients need prosthetic devices after amputation surgery in order to regain their functional mobility and appearance (Wolf et al., 2009). The socket design plays a significant role in determining the quality of the fit and provides an interface between the prosthesis and the residual limb (Jia et al., 2004). Appropriate socket fitting in prosthetic devices can have a significant effect on the patient's comfort, mobility and level of satisfaction with their prosthesis (Kristinsson, 1993; McCurdie et al., 1997).

Skin problems are common in prosthetic users and these can appear in the form of rashes, ulcers, irritation and allergies. Their presence is commonly attributed to one of several reasons: the inadaptability of the skin, due to the intolerance of pressure by the prosthetic socket on the residual limb; bacterial proliferation as a result of a snugly-fitted socket that causes entrapment of perspiration in a closed environment; skin irritation or allergic reaction due to the materials used in the prosthetic socket and liners (Dudek et al., 2005; Dudek et al., 2006). Lower limb amputees commonly experienced residual limb skin problems with the use of the prostheses (Laing et al., 2011). Amputees often need to stop using the prosthesis entirely for a period of time as a result of the pain and discomfort caused by such skin problems. This condition can badly effect the mental wellbeing of a patient and will ultimately impact their satisfaction with a device (Meulenbelt et al., 2006).

It is crucial that the risk of these skin complications is taken into consideration during the design of the prosthetic socket and that the design of the device is based on a good understanding of the pressure that can occur between the amputee's residual limb and the prosthetic socket (Jia et al., 2008). In order to reduce the possibility of these skin issues occurring, liners are fit inside the socket to provide the residual limb with a soft cushion. Liners have a direct contact with the residual limb inside the socket and play a significant role in transferring the load and distributing the interface pressure over the residual limb (Coleman et al., 2004; Lin et al., 2004).

Polyethylene foam liners with patellar tendon bearing (PTB) prosthetic socket have been in use since 1950; however, modern liners, which are generally made from silicone and other elastomers, offer better suspension and cushion (Dietzen et al., 1991; Haberman et al., 1992; Madigan and Fillauer, 1991). Silicon and gel liners were introduced worldwide in the mid 1990s and were designed to reduce shear forces and produce better interface bonds between the residual limb and the socket (Van de Weg

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and Van Der Windt, 2005). One of these silicone liners is known as the Seal-In X5 liner (Fig. 1). It was introduced by Ossur (Reykjavik, Iceland) and is composed of five seals that conform to the shape of the internal socket wall and the residual limb (Gholizadeh et al., in press). Through this, the Seal-In X5 liner provides suspension without the need for an external sleeve or lock and claim to be a good choice for high impact activities. The Dermo liner (Reykjavik, Iceland) is also made of silicone; however, unlike the Seal-In X5 liner, it cushions the limb and provides suspension through a shuttle lock system (Fig. 1).

Many studies have been carried out to investigate the interface pressure and stresses (Jia et al., 2005; Sanders et al., 1998; Wolf et al., 2009). Some of them compared the socket pressure of polyethylene foam liners with silicone liners (Dumbleton et al., 2009). Some studies have investigated the effect of various casting techniques or socket design on the socket-residual limb interface pressure (Dumbleton et al., 2009; Jia et al., 2005; Lee and Zhang, 2007), while other studies have focused on the effect of alignment on interface pressure (Jia et al., 2008). However, none of these studies compared the effect of a Dermo liner that used a shuttle lock with a sealing system such as the Seal-In X5 liner. In the Seal-In X5 liner, the seals have the potential to impose extra pressure over the residual limb. This can cause excessive pressure, that in it can be a source of problems for diabetic patients or amputees with sensitive residual limbs. The aim of this clinical study was to measure and evaluate the interface pressure in the Dermo liner during normal walking and compare it with the Seal-In X5 liner. The study also aimed to assess the effect that the two liners had on patients' satisfaction.

2. Methodology

2.1. Subjects

A total of nine unilateral transtibial amputees (7 males, 2 females) participated in this study. All the subjects were selected from the Department of Rehabilitation of the University Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia. The ethics committee of UMMC approved this study, and informed written approval was attained from all the subjects. The inclusion criteria consisted of a minimum 15 cm residual limb length (from the mid patella to the distal end of residual limb), no wound and ulcers in the residual limb, no volume changes, and the ability to walk without the use of assistive devices. It was a requirement that the participants are experienced prosthetic users (more than 6 months). A sample of convenience is used for this study.

2.2. Prosthetic interventions

Two transtibial prostheses were made for each subject, one with the Dermo liner with shuttle lock (Icelock-200 series) and another with the Seal-In X5 liner with valve (Icelock Expulsion, Valve 551). All the prostheses were fabricated with Flex-Foot Talux (Ossur, Reykjavik, Iceland). One registered prosthetist fabricated all the prostheses to avoid alterations due to manufacturing, alignment and fitting. A total surface bearing (TSB) socket was fabricated for all the subjects (Staats and Lundt, 1987). In order to become familiar with their new prosthetic devices, the subjects practiced walking in the motion analysis laboratory (Biomedical Engineering Department, University of Malaya, Malaysia) and the prosthetist adjusted the fitting of the socket and alignment according to their needs. Subjects were required to use their prostheses for a minimum of four weeks. The subjects were asked to visit the brace and limb laboratory for follow up on a weekly basis to ensure that the fit of the prosthesis remained suitable.

2.3. Experimental setting and procedures

After four weeks of acclimation, the subjects attended the motion laboratory for pressure measurements. Four F-Socket sensors arrays 9811 (Tekscan Inc., South Boston, USA) were attached to the residual limb. The sensor arrays were positioned on the anterior, posterior, medial and lateral aspects of the residual limb (Fig. 1). The mid patella was taken as the reference line for the placement of medial, lateral and anterior sensors. The posterior sensor was positioned approximately 1 cm above the posterior trim line of the socket. Each sensor was trimmed to fit to the residual limb contours. To prevent sensor arrays displacement, the residual limb was covered with a cellophane cover. Following this, each sensor was attached to the cellophane covers by an adhesive spray (3 M Spray Mount Adhesive, 3 M corporate, St. Paul, USA). This sensor arrangement provided a pressure map that covered 90% of the residual limb during the gait. Tekscan software version 6.51 was used to record the interface pressure.

A Tekscan pressure bladder (PB100T, South Boston, USA) was used to equilibrate and calibrate the sensor arrays. Sensor arrays were placed inside the bladder and, according to the manufacturer's instructions, were subjected to a pressure of 100 kPa. Calibration was carried out based on each subject's body weight. That is, the applied pressure for calibration was the ratio of the subject's body weight to the respective sensor area (Buis, 1997).

2.4. Walkway and collection of the data

Subjects were asked to walk at a self-selected speed on a walkway that was 9-meter long and 5-meter wide. Prior to the data collection activity, the subjects were requested to walk on the walkway to familiarize with the procedure. Data acquisition was performed for 12 seconds with a sample rate of 50 Hz. The subjects completed four consecutive trials on the walkway and in each trial approximately eight to nine steps were taken. The middle step of each trial was chosen. The mean peak pressures (MPP) of four trials were employed for the purposes of statistical analyses.

2.5. Questionnaire

After the experiments were completed, each subject completed a questionnaire that asked for further information about their satisfaction with the two liners. Various parts of the Prosthetics Evaluation Questionnaire (PEQ) were adopted for this questionnaire. The questionnaire was composed of the following three sections:

1- Demographic variables (sex, age, weight, height, amputation side, cause of amputation, activity level and time since first prosthesis).
2- Satisfaction (fitting, donning and doffing, suspension, sitting, walking on level surfaces, ascending and descending stairs, walking on uneven ground, cosmesis and overall satisfaction).
3- Problems (Wound, skin irritation, sweating, pistoning, rotation, residual limb swelling, smell, sounds and residual limb pain).

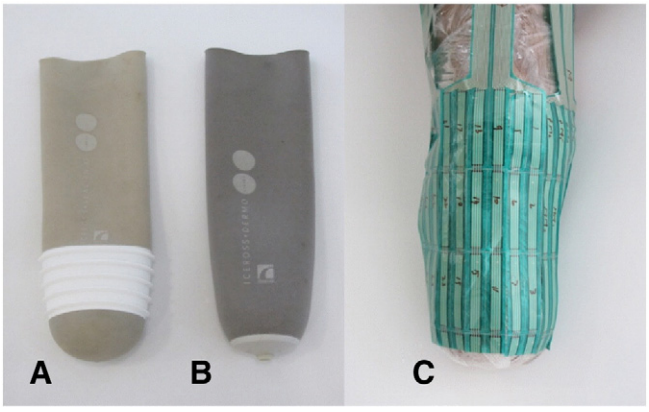

Fig. 1. (A) Seal-In Liner (B) Dermo Liner (C) Sensors attachments on residual limb.