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Interface pressure in transtibial socket during ascent and descent on stairs and its effect on patient satisfaction

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Introduction

Studies have revealed that lower limb prosthetic users consider discomfort as one of the most significant problems they face when using prosthesis. It is common for prosthetic users to experience pain and discomfort in the stump while wearing their prostheses (Lee et al., 2005). Lower limb prosthesis should enable ambulation and improve the performance of daily routine activities. However, poor-fitted socket can lead to complications that have adverse effects on the activity level and gait of people with lower limb amputation (Gailey et al., 2008).

The distribution of interface pressure between the socket and stump is an important factor in socket design and fit. Lower limb prosthetic users experience pressure between the socket and stump during daily activities. The underlying soft tissues and skin of the stump are not accustomed to weight bearing; thus, there is the risk of degenerative tissue ulcer in the stump because of constant or repetitive peak pressure applied by the transtibial socket (Jia et al., 2004). The pressure also can lead to various skin problems such as follicular hyperkeratosis, allergic contact dermatitis, infection and veracious hyperplasia (Dudek et al., 2005, 2008; Lyon et al., 2000).

Despite significant advances in the field of prosthetics in the previous decades, stillmany transtibial amputees experience pressure ulcers with the use of prostheses. Sometimes, skin problems lead to chronic infection, which may necessitate re-amputation. This will prevent the long-term use of prosthesis, which significantly reduces the daily activities of prosthesis users and the quality of life (Ali et al., 2012).

Many studies have focused on interface pressure magnitude between the socket and stump during level walking (Convery and Buis, 1999; Goh et al., 2003; Silver-Thorn and Childress, 1996). However, a transtibial prosthesis user encounters stairs in his/her daily activities. The ability of a person to negotiate stairs and steps is a significant factor for functional freedom. This ability allows a person to become more active in the society, and to perform different daily activities (Gill et al., 1994; Jones et al., 2006). The ability of transtibial amputees to negotiate

steps and stairs is severely affected by the loss of ankle joint and foot as well as reduced muscles' power, balance, mobility and stability, especially for young and strong amputees who perform manual labor and rigorous activities (Jones et al., 2006). It is important for transtibial prosthetic users tominimize the chances of pressure ulcerswith underlying associated syndromes through information regarding the interface pressure between the socket and stump in dealing with stairs (Dou et al., 2006).

A high-quality interface systemis required to prevent skin complications that will produce excellent interface union between the stump and transtibial socket (Sewell et al., 2000; Van de Weg and Van Der Windt, 2005). Silicone interface systems are believed to reduce the friction between the skin and improve comfort both in rest and during walking (Cluitmans et al., 1994). Manufacturers of prosthetic products seek to develop new interface systems. Dermo and Seal-In X5 interface systems are two new systems that increase the contact areas and distribute the pressure at the socketwalls. These are commonly prescribed for transtibial amputees. There is minimal knowledge on their effect on patient's satisfaction. The manufacturer claims an easy donning and doffingwith the Seal-In liner X5 but during the clinical practice, patients complained of discomfort with the Seal-In X5 liner, particularly during walking and donning/doffing. The Dermo silicon interface system provides suspension through pin/lock, while the Seal-In X5 silicon liner incorporates a series of five integrated seals that conform to the shape of the residual limb and the internal socketwall, providing an airtight seal. The Seal-In X5 interface systemis claimed to provide a good response in high impact activities due to improved coupling between the socket and seals. Users reported discomfort with the Seal-In X5 liner due to localized pressure at the seals and high activity level compared to the Dermo interface system. This claimmotivated us to determine the interface pressure generated by the two interface systems during stair ascent and descent. Only two studies have compared the interface pressure during stair negotiation with transtibial prosthesis (Dou et al., 2006; Wolf et al., 2009); however, no study has examined the effect of interface pressure on patient satisfaction and perceived problem during stair ascent and descent. Two studies have evaluated the interface pressure during level walking with these two systems (Ali et al., 2012; Eshraghi et al., 2012). Therefore, this study aimed to evaluate the interface pressure generated by these two interface systems, and to study the effect of interface pressure on patient satisfaction. Itwas our hypothesis that the subjects will experience less interface pressure and will be more satisfiedwith the Dermo interface systemduring stair negotiation compared to the Seal-In X5 interface system.

Methods

Ten amputees (seven males and three females) with transtibial amputation contributed to this study. All the participants had undergone unilateralamputation at least four years prior to the study. The inclusion

criteria were: ability to negotiate stairs without any assistive devices, absence of stump problems and absence of pathological problems, which affected the mobility of the participants. The detailed particulars of the participants are shown in Table 1. The Ethics committee of the University Malaya Medical Centre (UMMC) approved this study. Written consent was obtained from all the participants.

Twenty Total Surface Bearing (TSB) prostheses were fabricated using the Dermo with shuttle lock (Össur, Reyjavik, Iceland) and the Seal-In X5 with prosthetic valve (Össur, Reyjavik, Iceland). Double adapters of different sizes (7 cm and 10 cm) were used to adjust the length according to the patient's height. Flex-Foot Talux was utilized for all the prostheses based on the foot size of the participants. The following procedures were applied for casting and modification.

The interface system was rolled on the subject's stump. Single layer of plasticwas applied and itwas insured that all the areaswere covered. Pressure-sensitive areas were marked and all the required measurements (residual limb and sound side) were recorded on the measurement chart. The entire stump was wrapped with two rolls of 15 cm Plaster of Paris bandages and massaged properly until the cast dried. Trim lines were marked on the negative cast and they were filled with Plaster of Paris powder for modification. Negative cast was removed and it was ensured that all the marks were transferred to the positive model. All the unnecessary material was removed and the measurements were compared with the subject's measurements. Recommended reduction was done over the soft tissue areas and posterior of the stump. Minimal relief was applied to the bony areas and posterior trim lines were marked for hamstring relief. Model was smoothened after finalizing all the measurements.

To assure the accuracy during casting, modification, fabrication and alignment, all the prostheses were fabricated by a single certified prosthetist, and the laser liner was used for the alignment (Mathur and Gupta, 2005). Initial fitting was performed at the Department of Biomedical Engineering, University ofMalaya (Brace and Limb laboratory). Prostheses were adjusted according to the participant's requirements. After achieving fitting and alignment satisfaction with each prosthesis, the participants were asked to use each prosthesis for at least one month. The participants were also requested to visit the Motion Analysis Lab after one month of trial period for interface pressure measurements.

Four F-socket transducers 9811E (Tekscan, Inc., South Boston, USA) were attached to the posterior, anterior, lateral and medial compartments of the stump to obtain better insights on the pressure between the stump and socket. Medial, lateral and anterior sensors were attached at themid patella level. The posterior sensor was positioned approximately 1 cm above the posterior trim line of the socket. The residual limbs were covered with cellophane plastic wrap, and each transducer was attached to the cellophane plastic wrap with spray adhesive

(Scotch Super Adhesive, 3M Corporate, St. Paul, USA) to ensure that the transducer was appropriately positioned on the stump. Each transducer was trimmed according to the contour of the stump. We enclosed 90% of the stumpwith these arrangements. Interface measurements were recorded using Tekscan software (version 6.51). Transducers were positioned for equilibration and calibration inside a bladder and pressure of 100 kPa was applied according to the instructions of the manufacturer. We were aware of the limitations of the pressure measurement system employed, including hysteresis and drift. Inaccuracies between individual cells have also been highlighted. However, by adopting a strict protocol to precondition, equilibrate, and calibrate the sensor array, weminimized the variation and inaccuracy of data recordings. We did the pre and post test to minimize the inaccuracies in the sensors (Fig. 1).

The participants were asked to ascend and descend a custom-made 82 cm wide staircase, consisting of 4 steps with step distance of 32 cm and step height of 14 cm. Data were recorded for two consecutive trials at the sample rate of 50 Hz for at least 6 cycles of ascent and descent. All the participants followed the same procedures to minimize variation in data collection and testing order of the interface systems was randomized. Each participant completed an orientation session before the experiment (Fig. 2).

The participants completed a questionnaire after the experiment to describe their one month experience with prostheses. We used a nonvalidated survey to determine the level of problems encountered and satisfaction with the prosthesis during ascent and descent on stairs. The followingwere asked fromeach participant regarding their satisfaction and problems with each prosthesis.

1. Satisfaction during stair ascent:
Walking satisfaction during stair ascent; suspension satisfaction during stair ascent; balance satisfaction during stair ascent and overall satisfaction during stair ascent.
2. Satisfaction during stair descent:
Walking satisfaction during stair descent; suspension satisfaction during stair descent; balance satisfaction during stair descent and overall satisfaction during stair descent.
3. Problem during stair ascent:
Pain during stair ascent; pistoning during stair ascent and rotation of the socket during stair ascent.
4. Problem during stair descent:
Pain during stair descent; pistoning during stair descent and rotation of the socket during stair descent.

Numerical scores of 0–100 were utilized for the entire questions to indicate the level of satisfaction and problems encountered. Zero (0) indicated “extremely bothered or unsatisfied” and 100 indicated “no problem or complete satisfaction”.

For each trial, the middle stepwas selected. Themean peak pressure (MPP) was calculated for all the trials. Non-parametric Wilcoxon

signed-rank test was utilized to compare the pressure difference between the Seal-In X5 and Dermo interface systems at all the major regions (anterior, posterior, medial and lateral) and sub-regions (proximal and distal) of each major region of the residual limb. Pairedsamples t-test was applied to obtain the overall score, and compared the satisfaction and problems between the two interface systems. Valve P b 0.05 was set for the level of statistical significance. Statistical analysis was performed by using SPSS version 20 (SPSS, Chicago, USA).