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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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ARTICLE INFO ABSTRACT Background: Transtibial amputees encounter stairs and steps during their daily activities. The excessive pressure Article history: Received 6 March 2013 between residual limb/socket may reduce the walking capability of transtibial prosthetic users during ascent and Accepted 9 September 2013 descent on stairs. The purposes of the research were to evaluate the interface pressure between Dermo (shuttle lock) and Seal-In X5 (prosthetic valve) interface systems during stair ascent and descent, and to determine their Keywords: satisfaction effects on users. Satisfaction Methods: Ten amputees with unilateral transtibial amputation participated in the study. Interface pressure was Prosthetic interface systems recorded with F-socket transducer (9811E) during stair ascent and descent at self-selected speed. Each partici-Pressure pant filled in a questionnaire about satisfaction and problems encountered with the use of the two interface Transtibial prosthesis systems. Amputee Findings: The resultant mean peak pressure (kPa) was significantly lower for the Dermo interface system compared to that of the Seal-In X5 interface system at the anterior, posterior and medial regions during stair ascent (63.14 vs. 80.14, 63.14 vs. 90.44, 49.21 vs. 66.04, respectively) and descent (67.11 vs. 80.41, 64.12 vs. 88.24, 47.33 vs. 65.11, respectively). Significant statistical difference existed between the two interface systems in terms of satisfaction and problems encountered (P < 0.05). Interpretation: The Dermo interface system caused less pressure within the prosthetic socket compared to the Seal-In X5 interface system during stair negotiation. The qualitative survey also showed that the prosthesis users experienced fewer problems and increased satisfaction with the Dermo interface system. © 2013 The Authors. Published by Elsevier Ltd. Open access under CC BY-NC-SA license.

1. 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

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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, still many 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

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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 to minimize the chances of pressure ulcers with 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 system is 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 socket walls. 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 doffing with 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 socket wall, providing an airtight seal. The Seal-In X5 interface system is 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 claim motivated 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. It was our hypothesis that the subjects will experience less interface pressure and will be more satisfied with the Dermo interface system during stair negotiation compared to the Seal-In X5 interface system.

2. Methods

Ten amputees (seven males and three females) with transtibial amputation contributed to this study. All the participants had undergone unilateral amputation 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

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Particulars of the participants.

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 plastic was applied and it was insured that all the areas were 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 of Malaya (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 the mid 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 stump with 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,

Subjects	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
Age (year)	37	50	24	41	71	63	62	51	49	32
Height (cm)	175	171	170	180	180	173	160	163	165	171
Sex	Male	Male	Male	Male	Male	Male	Female	Female	Female	Male
Body mass (kg)	90	65	60	101	80	76		49	50	62
Cause of amputation	Trauma	Trauma	Trauma	Diabetes	Diabetes	PVD	Diabetes	PVD	Diabetes	Trauma
Amputation side	Left	Right	Left	Right	Left	Right	Left	Left	Right	Right
Activity level	3–4	3–4	3–4	3-4	2-3	2-3	2-3	3-4	3–4	3-4
Years since amputation	4	4	4	4	9	6	3	8	8	5
Stump length (from mid patella to stump end)	16	15.5	15.5	17	16.5	15.5	15	16.5	16.5	15.8

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