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ORIGINAL ARTICLE

Satisfaction and Problems Experienced With Transfemoral Suspension Systems: A Comparison Between Common Suction Socket and Seal-In Liner

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Abstract

Objective: To compare a seal-in liner with the common suction socket with regards to patient satisfaction and problems experienced with the prosthesis.

Design: Retrospective survey.

Setting: A medical and engineering research center and a department of biomechanical engineering.

Participants: Men (N = 90) with traumatic transfemoral amputation who used both suspension systems participated in the study.

Intervention: Two prosthetic suspension systems: a seal-in liner and common suction socket.

Main Outcome Measures: Two questionnaires were completed by each subject to evaluate their satisfaction and problems experienced with the 2 suspension systems. Satisfaction and problems with the prosthetic suspension systems were analyzed in terms of fitting, donning and doffing, sitting, walking, stair negotiation, appearance, sweating, wounds, pain, irritation, pistoning, edema, smell, sound, and durability.

Results: The study revealed that the respondents were more satisfied with a seal-in liner with regards to fitting, sitting, and donning and doffing. Overall satisfaction increased with the use of a seal-in liner compared with the suction socket ($P<.05$). However, satisfaction with the prosthesis showed no significant differences in terms of walking (flat and uneven surfaces), appearance, and stair negotiation. Furthermore, problems experienced differed significantly between the 2 suspension systems ($P<.05$). Sweating, wounds, pain, irritation, pistoning, edema, smell, and sound were less problematic with the use of a seal-in liner, whereas durability was significantly better with the suction socket.

Conclusions: The results of the survey suggest that satisfaction and problems with prosthetic suspension in persons with transfemoral amputation can be improved with a seal-in liner compared with the suction socket, provided that the durability of the liner is enhanced.

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Choice of suspension system and socket fit have significant influence on a patient's comfort, mobility, and satisfaction with prosthetic devices.[1-3] The suspension system prevents rotation, translation, and vertical movement of the prosthesis in relation to the residual limb. Poor suspension can have negative effects on rehabilitation and can affect the mobility level and comfort of persons with transtibial amputation.[1,4] While this may also apply to individuals with transfemoral amputation, it has not yet been investigated.

Presently, a number of prosthetic suspension systems are used with transfemoral prostheses; among them are the Silesian belt, hip joint with pelvic band, suction socket, and silicone liners with or without a shuttle lock.[5-7] A Silesian belt and hip joint with pelvic band provide easier donning for geriatric users and good suspension for users with a short residual limb.[5,8,9] Conventional suction suspension consists of a hard socket with a 1-way valve at the distal end of the socket. A suction suspension system allows greater freedom of mobility, maximizes the use of the residual limb's remaining muscles, and provides more comfort and good

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cosmetic appearance when compared with the Silesian belt or hip joint with pelvic band.[5] However, suction sockets are not suitable for those prosthesis users who have volume fluctuation of their residual limb, because socket fit and suspension will diminish. Also, in geriatric users, or those with vascular disease, suction sockets may cause edema at the end of the residual limb.[5]

Silicone and polyurethane liners have been used in lower-limb prosthetics since the 1980s. These liners improve suspension, reduce shear forces between the residual limb and socket, and control residual limb volume in transtibial prostheses.[2,10] The silicone liner, which is rolled onto the residual limb, provides better suspension, stability, comfort, and cushioning compared with polyethylene foam liners and suction sockets.[11-13] Different techniques are used for fixation of the residual limb and liner in the socket. These include distal pin and shuttle lock, lanyard, and vacuum/suction seals (fig 1).[14,15] A new suspension system for lower-limb prostheses, called a seal-in liner, has been introduced (see fig 1), which has a hypobaric sealing membrane around the liner that ensures a firm attachment between the socket and the liner. This new suspension system fixes the residual limb inside the socket by creating vacuum and subsequently decreases the pistoning, translation, and rotation movements that occur inside the transtibial socket.[3,16] These enhanced qualities should be demonstrated not only objectively but also based on feedback of prosthetic users.

Several questionnaires have been developed to evaluate patients' satisfaction with prostheses and orthoses. These include the Attitude to Artificial Limb Questionnaire, Amputation Related Body Image Scale, Body Image Questionnaire, Orthotics and Prosthetics National Outcomes Tool, Orthotics and Prosthetics Users' Survey, Prosthesis Evaluation Questionnaire (PEQ), Perceived Social Stigma Scale, Socket Comfort Score, and the Trinity Amputation and Prosthesis Experience Scales.[17-23] To date, the majority of researchers have evaluated differences in function, performance, and satisfaction between different prosthetic components or techniques using the PEQ.[3,19,23] The PEQ measures prosthetic-related quality of life.[19] It consists of 82 items grouped into 9 subscales. In addition, there are a number of individual questions pertaining to satisfaction, pain, ambulation, prosthetic care, and self-efficacy, which are not contained in the subscales. The PEQ scales are not dependent on each other, and therefore it is reasonable to use only those scales that are of interest to a given study. The questions are scored using a visual analog scale (100mm line). Testing has shown the PEQ to have good reliability (internal consistency and test-retest) and good-to-excellent construct validity in people with lower-limb amputation.[19]

In our previous work, individuals with transtibial amputation were found to be mostly satisfied with a seal-in liner, except for difficulty in donning and doffing.[3] As transtibial and transfemoral amputation levels differ in terms of residual limb size and shape, gait pattern, pistoning, appearance, and function, we assumed that effect of suspension systems on satisfaction would be different. This qualitative study, using the PEQ, aimed to compare satisfaction of users of transfemoral prostheses with the transfemoral seal-in liner suspension system and a common suction socket, and to identify problems perceived with these systems. We hypothesized that persons with transfemoral amputation would be more satisfied and would experience fewer problems with a seal-in liner compared with the common suction socket.

List of abbreviations:

JMERC **Janbazan Medical and Engineering Research Center**
PEQ **Prosthesis Evaluation Questionnaire**

Methods

Participants

We invited 112 persons with transfemoral amputation who met the inclusion criteria from Janbazan Medical and Engineering Research Center (JMERC), Tehran, Iran and the Prosthetic Laboratory, Department of Biomedical Engineering, University of Malaya, Malaysia to participate in this study. The inclusion criteria required that individuals with transfemoral amputation had used both suspension systems for at least a period of 2 years prior to commencement of this project. In addition, they were required to be using the Seal-In Liner (Iceross Dermo Seal-In Liner)[a] at the time of entry to the study. This was a retrospective study, because the prostheses had already been fabricated, and subjects were asked to recall their experiences. All participants had first experienced using the common suction socket and then had elected to transition to using the Seal-In Liner system, because it was introduced years after the common suction socket.

JMERC and the University of Malaya ethics committees granted ethical approval for the study. After written consent, the subjects were asked to complete a questionnaire based on the PEQ, which measured their level of satisfaction with both suspension systems.[4] All the participants filled in 1 questionnaire for each suspension system. The questionnaires were either mailed to the participants or were distributed to them on visiting either center.

Questionnaire

In order to study the effect of different suspension systems on the satisfaction of prosthesis users, a questionnaire was prepared based on the PEQ and a study by Van de Weg and Van Der Windt.[4] The questionnaire is available in both English and Persian languages.[3,24] The first section incorporated demographic questions, such as age, height, weight, amputation side, time since amputation, hours of daily prosthetic use, and activity level. This section of the forms was completed by a registered prosthetist. Activity levels (K level) were based on the Medicare Functional Classification Level.[25] This classification system determines the following activity levels: no ability or potential to ambulate (K0), limited and unlimited household ambulator (K1), limited community ambulator (K2), community ambulator (K3), and high-level user (K4). It was also sent to the participants to update the data at the time of entry to the study.

Section 2 of the questionnaire consisted of questions related to satisfaction, including ability to don and doff the prosthesis, perception of prosthetic fit, ability to sit with the prosthesis, ability to walk with the prosthesis, ability to walk on different surfaces, and perception of prosthetic appearance. In the third section, in order to examine possible problems with the prosthetic suspension mechanism, participants were also asked whether they suffered from any of the following problems when using each suspension system: sweating, skin irritation, wounds, swelling (edema) of the residual limb, pistoning within the socket, unpleasant smell of the prosthesis or residual limb, unwanted sound, pain in the residual limb, and durability of the suspension systems.