

Qualitative Study of Prosthetic Suspension Systems on Transtibial Amputees' Satisfaction and Perceived Problems With Their Prosthetic Devices

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ABSTRACT. Ali S, Abu Osman NA, Naqshbandi MM, Eshraghi A, Kamyab M, Gholizadeh H. Qualitative study of prosthetic suspension systems on transtibial amputees' satisfaction and perceived problems with their prosthetic devices. *Arch Phys Med Rehabil* 2012;93:1919-23.

Objective: To investigate the effects of 3 dissimilar suspension systems on participants' satisfaction and perceived problems with their prostheses.

Design: Questionnaire survey.

Setting: A medical and engineering research center and a university biomedical engineering department.

Participants: Persons with unilateral transtibial amputation (N=243), using prostheses with polyethylene foam liner, silicone liner with shuttle lock, and seal-in liner.

Interventions: Not applicable.

Main Outcome Measures: Descriptive analyses were performed on the demographic information, satisfaction, and prosthesis-related problems of the study participants.

Results: The results showed significant differences between the 3 groups regarding the degree of satisfaction and perceived problems with the prosthetic device. Analyses of the individual items revealed that the study participants were more satisfied with the seal-in liner and experienced fewer problems with this liner. The silicone liner with shuttle lock and seal-in liner users reported significant differences in maintenance time compared with the polyethylene foam liner. Users of the silicone liner with shuttle lock experienced more sweating, while those who used the seal-in liner had greater problems with donning and doffing the device.

Conclusions: The results of the survey provide a good indication that prosthetic suspension is improved with the seal-in liner as compared with the polyethylene foam liner and silicone liner with shuttle lock. However, further prospective studies are needed to investigate which system provides the most comfort and the least problems for participants.

Key Words: Amputees; Prosthesis; Rehabilitation; Satisfaction.

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THE SUSPENSION SYSTEM and socket fitting in prosthetic devices significantly affect the amputee's comfort, mobility, and satisfaction.^{1,2} Secure suspension decreases residual limb movement within the prosthetic socket by firmly attaching the prosthesis to the residual limb.³ Conversely, inappropriate suspension can result in deterioration of the prosthetic socket fitting, and a poorly fit socket can cause pain and skin ulcers. These problems may result in an unwillingness or an inability of the amputee to use the prosthesis until the pain is relieved and the ulcers are healed.⁴⁻⁶

There are several methods of suspending a transtibial prosthesis to the residual limb.⁷ These include the following:

1. Belt and suprapatellar cuff, which is the most common suspension method and usually the most effective for most wearers⁸
2. Figure-of-8 belt, which is a variation of the suprapatellar cuff suspension⁹
3. Sleeve suspension, which can develop negative pressure between the socket and residual limb^{10,11}
4. Supracondylar-suprapatellar suspension¹²
5. Supracondylar suspension, which is a variation of supracondylar-suprapatellar suspension and is usually used for long residual limbs¹³
6. Thigh corset, which provides more mediolateral stability for the users¹⁴
7. Silicone liner suspension, such as distal locking pin, lanyard, and suction suspension¹⁵

Patellar tendon-bearing prostheses with polyethylene foam liners have been in use since 1950. They are fitted within the socket to provide the residual limb with a soft cushion.¹⁶ Polyurethane foam liners are still used in practice, but modern liners are generally made from silicone and other elastomers that offer better suspension and cushioning.¹⁷⁻¹⁹ Silicone and gel liners were introduced worldwide in the mid 1990s and were designed to lessen shear forces and produce a better interface bond.³ A new type of silicone liner, called the seal-in liner, uses a membrane lip, which is placed circumferentially around the distal end of the liner.²⁰

The efficiency of the suspension systems can be evaluated both objectively and subjectively with the use of questionnaires. Researchers have developed numerous questionnaires as a means of assessing consumers' satisfaction with prosthet-

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List of Abbreviations

JMERC	Janbazan Medical and Engineering Research Center
PTA	person with transtibial amputation

ics and orthotics.²¹⁻²⁴ The Prosthetic Evaluation Questionnaire has been used to investigate satisfaction and perceived problems among prosthetic users. Dillingham et al²⁵ carried out a survey regarding the use of and satisfaction with prosthetic devices in 146 participants, most of whom were not satisfied with their prostheses because of pain and skin problems. A study by Kark and Simmons²⁶ also demonstrated that their study participants were unsatisfied with their prostheses. A research study¹⁶ showed that 77% of participants were more satisfied with their pin and lock system compared with the polyethylene foam liner. On the contrary, in a prospective study,²⁷ almost all the participants (75%) preferred the polyethylene foam liner. Van de Weg and Van der Windt³ conducted a study on the effect of 3 transtibial interfaces on satisfaction and perceived problems. No significant differences were reported.

To our knowledge, only 1 study²⁸ has been conducted on the satisfaction with the seal-in suspension concept. However, the study sample was small. Moreover, some of the existing findings on the satisfaction with different suspension systems had contradictory results. Therefore, the aim of this study was to investigate the effects of 3 different suspension systems on participants' satisfaction and perceived problems with their prostheses. The 3 systems included the polyethylene foam liner, the silicone liner with shuttle lock, and the seal-in liner. We hypothesized that participants would be more satisfied with the seal-in liner compared with the other 2 systems.

METHODS

Study Participants

The research team carried out a questionnaire survey among persons with transtibial amputation (PTAs) in Janbazan Medical and Engineering Research Center (JMERC), Tehran, Iran. We selected 303 men with unilateral transtibial (traumatic) amputation from the JMERC database and distributed the questionnaire among them. Participants were required to have used their prostheses for a minimum of 1 year. The satisfaction and perceived problems with the following suspension systems were compared: the polyethylene foam liner, the silicone liner with shuttle lock, and the seal-in liner (the Iceross-Seal-In liner^a) (fig 1).

The study was approved by the JMERC and the University Malaya Medical Centre ethics committees.

Questionnaire

To study the effect of the 3 different suspension systems on participant's satisfaction and to identify the perceived problems with the use of the prosthesis, we adopted some elements of the Prosthetic Evaluation Questionnaire. A Persian version of the questionnaire was produced to be used for the participants at JMERC. The survey was composed of demographic variables (age, sex, education level, marital status, weight, height), cause of amputation, amputation side, and time since last prosthesis. In addition, we asked some questions related to the use and maintenance of the prosthesis, and activity levels of the participants. The activity level was defined based on the Medicare Functional Classification Level.²⁹ Four activity levels were as follows: household ambulator (K1), limited community ambulator (K2), community ambulator (K3), and high level user (K4). The questionnaire also included questions about the participant's satisfaction and asked for details of any prosthetic-related problems that the participant experienced with each liner. In the satisfaction section of the questionnaire, participants were asked about the prosthetic fit, their ability to walk



Fig 1. Three different suspension systems: polyethylene foam liner (A), silicone liner with shuttle lock (B), and seal-in liner (C).

with the prosthesis, their ability to walk up and down stairs, their ability to don and doff the prosthesis, their ability to walk on diverse surfaces, the appearance of the prosthesis, the appearance of the suspension, their ability to sit with the prosthesis, and their overall satisfaction. Problems with the prosthesis consisted of sweating, skin irritation, wounds, ulcers, blisters, pistoning within the socket, rotation within the socket, unpleasant smell of the prosthesis or residual limb, unwanted sounds, and pain in the residual limb. A scale from 0 to 100 was used to score overall satisfaction with the prosthesis, with 0 indicating that a participant was "unsatisfied" with the liner and 100 indicating that a participant was "completely satisfied." For the variables related to problems/complaints, each item was also measured on a scale from 0 to 100, where 0 meant "extremely bothered" and 100 meant "not at all bothered."²¹

Analysis Procedures

Descriptive analyses were used to analyze the demographic information of the participants. To analyze participants' satisfaction and examine problems related to the liners, we used multivariate analysis of variance to compute the means of the items related to each type of liner and determine the significance. All data analyses were done using SPSS 16.0.^b

RESULTS

Participants' Profiles

A total of 243 questionnaires (80.19%) were returned. The mean age, weight, and height of the participants were 44.02 ± 6.26 years, 85.09 ± 15.54 kg, and 176.14 ± 6.69 cm, respectively. Forty-nine percent of the participants were university graduates, 34.6% had a diploma, 12.8% had attended high

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