

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-Dermo-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

school, and 3.7% had an elementary school education. The average number of years PTAs had been using a prosthesis was 22.01 ± 5.95 . The number of left-sided PTAs (60.9%) exceeded the number of right-sided PTAs (39.1%). Most of the participants (63.4%) reported an activity level of K3, followed by 18.9% reporting a level of K4 and 17.7% a level of K2. On average, PTAs had used their prosthesis for 11.67 ± 3.25 h/d. The average age of the liner was 21.02 ± 14.48 months. There was a significant difference ($P < .05$) between the maintenance time among the 3 suspension systems. The silicone liner with shuttle lock had the longest maintenance time of 2.98 ± 2.63 hours per year, followed by the seal-in liner with 2.53 ± 1.52 hours per year and the polyethylene liner with $.54 \pm .45$ hours per year. Most of the PTAs used the polyethylene foam liner (41.2%). Table 1 describes the characteristics of the participants.

Satisfaction and Use

Most of the PTAs used the prosthesis for more than 11.67h/d, and daily prosthetic use time was not significantly different between the 3 suspension systems. The mean overall satisfaction on a 0- to 100-point numerical rating scale was 63.14 for the polyethylene foam liner, 75.94 for the silicone liner with shuttle lock, and 83.10 for the seal-in liner. As shown in table 2, PTAs were more satisfied with the seal-in liner suspension. The P values in the test of between-participants effect showed that the suspension type had a significant correlation with all satisfaction items ($P < .05$ for all items). This can be further understood by looking at table 2, which shows the ranking according to the satisfaction ratings.

Problems/Complaints

The multivariate tests in table 3 show that there was a significant difference between the 9 complaint/problem items

Table 1: Characteristics of the Survey Respondents (N=243)

Characteristics	Values
Age (y)	44.02±6.26
Sex: male	243 (100)
Weight (kg)	85.09±15.54
Height (cm)	176.14±6.69
Education	
Elementary	9 (3.7)
High school	31 (12.8)
Diploma	84 (34.6)
Graduate	119 (49.0)
Years since first prosthesis	22.01±5.95
Cause of amputation	
Trauma	243 (100)
Amputation side	
Right	95 (39.1)
Left	148 (60.9)
Activity level	
K2	43 (17.7)
K3	154 (63.4)
K4	46 (18.9)
Prosthetics use every day (h)	11.67±3.25
Maintenance per year (hours)	1.88±2.07
Age of liner (mo)	21.02±14.48
Type of liner	
Silicone liner with shuttle lock	85 (35)
Silicone seal-in liner	58 (23.9)
Polyethylene foam liner	100 (41.2)

NOTE. Values are mean ± SD or n (%).

Table 2: Satisfaction and Use With 3 Studied Suspension Systems

Satisfaction Type/Liner Type	Mean*	P	Ranking [†]
Fitting satisfaction		.000	
Silicone liner with shuttle lock	79.59		2
Polyethylene foam liner	64.82		3
Seal-in liner	87.09		1
Donning and doffing satisfaction		.000	
Silicone liner with shuttle lock	71.44		2
Polyethylene foam liner	79.68		1
Seal-in liner	57.24		3
Sitting satisfaction		.000	
Silicone liner with shuttle lock	68.80		3
Polyethylene foam liner	76.44		2
Seal-in liner	79.41		1
Walking satisfaction		.000	
Silicone liner with shuttle lock	72.80		2
Polyethylene foam liner	65.21		3
Seal-in liner	84.66		1
Uneven walking satisfaction		.000	
Silicone liner with shuttle lock	63.91		2
Polyethylene foam liner	54.10		3
Seal-in liner	77.93		1
Stair satisfaction		.000	
Silicone liner with shuttle lock	68.75		2
Polyethylene foam liner	60.83		3
Seal-in liner	80.60		1
Suspension satisfaction		.000	
Silicone liner with shuttle lock	81.72		2
Polyethylene foam liner	55.20		3
Seal-in liner	93.71		1
Cosmetic satisfaction		.000	
Silicone liner with shuttle lock	69.05		3
Polyethylene foam liner	73.27		2
Seal-in liner	83.10		1
Overall satisfaction with prosthesis		.000	
Silicone liner with shuttle lock	75.94		2
Polyethylene foam liner	63.14		3
Seal-in liner	83.10		1

*Greater mean indicates more satisfaction and use.

†Satisfaction increases from the ranking 3 to 1.

($P < .05$) among the 3 suspension systems. The P values in the test of between-participants effect showed that the suspension type has a significant correlation with all complaint/problem items ($P < .05$). The only exception was the "sweat complaint," which had a P value of .074. Participants found donning and doffing to be more difficult with the seal-in liner, while pistoning was recorded the highest for the polyethylene foam liner (see table 3).

DISCUSSION

Prosthetic satisfaction is a multifactorial issue. These aspects mainly include prosthetic alignment, prosthetic components, prosthetist's skill, residual limb condition, level of activity, and socket fit.³⁰ We investigated different suspension systems as an influencing factor on PTA use and satisfaction with the prostheses. The findings supported our hypothesis that participants would be more satisfied with the seal-in liner compared with other 2 systems.

With the exception of the "sweat complaint," significant differences were found between different suspension systems with respect to perceived problems. Sweating was reported

Table 3: Comparison Between 3 Different Suspension Systems With Regard to Complaints/Problems

Problem/Liner Type	Mean*	P	Ranking [†]
Sweat complaint		.074	
Silicone liner with shuttle lock	55.00		3
Polyethylene foam liner	60.16		2
Seal-in liner	64.78		1
Wound complaint		.000	
Silicone liner with shuttle lock	81.85		2
Polyethylene foam liner	75.04		3
Seal-in liner	95.17		1
Irritation complaint		.000	
Silicone liner with shuttle lock	81.28		2
Polyethylene foam liner	75.10		3
Seal-in liner	94.66		1
Pistoning within the socket		.000	
Silicone liner with shuttle lock	84.18		2
Polyethylene foam liner	63.95		3
Seal-in liner	96.47		1
Rotation within the socket		.000	
Silicone liner with shuttle lock	80.18		3
Polyethylene foam liner	81.65		2
Seal-in liner	99.57		1
Inflation complaint		.021	
Silicone liner with shuttle lock	86.75		3
Polyethylene foam liner	89.64		2
Seal-in liner	94.91		1
Smell complaint		.000	
Silicone liner with shuttle lock	72.49		2
Polyethylene foam liner	63.94		3
Seal-in liner	77.83		1
Sound complaint		.000	
Silicone liner with shuttle lock	70.21		3
Polyethylene foam liner	80.28		2
Seal-in liner	96.81		1
Pain complaint		.000	
Silicone liner with shuttle lock	80.62		3
Polyethylene foam liner	81.18		2
Seal-in liner	92.67		1

*Greater mean indicates fewer complaints/problems.

†Problems/complaints decrease from the ranking 1 to 3.

more often by PTAs with the locking liner (55 score) than by those with the polyethylene foam and seal-in liners. In addition, we registered significant differences between different suspension liners with respect to participant use and satisfaction. However, the overall satisfaction rating was higher with the seal-in liner (83.10 score) when compared with the locking liner (75.94%) and the polyethylene foam liner (63.14 score).

In this study, the participants preferred the silicone liner with shuttle lock and seal-in liner over the polyethylene liner. These results contradict the findings of Coleman et al¹⁶ and Boonstra et al,²⁷ whose studies showed the polyethylene foam liner to be more favorable. The findings of both crossover studies were considerably less positive toward locking liners; however, the study by McCurdie et al² clearly demonstrated the preference for locking liners. Van der Linde et al³¹ indicated that professionals in the field of rehabilitation preferred a locking liner in their research study. Vacuum suspension is said to improve proprioception in prosthetic users,³² and this may be one possible explanation of preference for the seal-in liner.

Hatfield and Morrison³³ revealed that their participants who used locking liners felt more comfortable. Aström and Sten-

ström³⁴ stated that locking liners delivered improved socket comfort when compared with polyethylene liners. The same was true with our study, as the participants were more satisfied with the locking liner and seal-in liner during activities that involved walking, walking on uneven ground, and walking on stairs.

Enhanced suspension and cosmesis of the prostheses had a positive effect on prosthetic function and the participant's satisfaction.¹³ Our study showed improved suspension with the silicone liner with shuttle lock and seal-in liners when compared with the polyethylene foam liner. Cluitmans et al³⁵ and Baars and Greetzen³⁶ found improved suspension with the locking liners.

The ease of donning and doffing has an important effect on prosthetic use.^{37,38} Our results showed that participants who used the polyethylene and locking liners found donning and doffing easier than those who used the seal-in liner. The data revealed that the polyethylene liner was the most durable of the 3 suspension systems. This is compatible with the findings of Van de Weg and Van der Windt³ and Coleman et al.¹⁶

The only study on the effect of seal-in liners on participant satisfaction revealed that the participants were more satisfied with the seal-in liner than the locking liner.²⁸ However, this study did not purely examine satisfaction and perceived problems. Similarly, we found that all the satisfaction parameters were higher for the seal-in liners than they were for the locking system and the polyethylene foam liner. Furthermore, statistical analyses revealed that the participants had fewer problems with the seal-in liner than they did with the 2 other liners. Nevertheless, donning and doffing the seal-in liner was difficult, which is also consistent with the findings of Gholizadeh et al.²⁸

Study Limitations

One limitation of this study was that we could not fabricate 3 individual prostheses with 3 different suspension systems for each of the participants to give equal chance for the comparison. Furthermore, the trajectory of prosthetic suspension systems, including the timing and extent of prostheses used under each, was not determined. Future research should determine the factors affecting the prescription or selection of the suspension type by the prosthetist and PTA.

CONCLUSIONS

In this study, the participants reported significant differences in their experiences with different suspension systems. There is clear evidence in this study that supports the view that the seal-in liner has higher participant satisfaction. There is also good reason to believe that the prosthetic suspension may be improved with the seal-in liner. A further study with a larger number of participants is needed to compare the seal-in liner with other suspension systems.

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