

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.

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)⁸ 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.

List of abbreviations:

JMERC Janbazan Medical and Engineering Research Center
PEQ Prosthesis Evaluation Questionnaire



Fig 1 Transfemoral Seal-In Liner (with a hypobaric sealing membrane around the liner) used in this study.

The PEQ items were scored on a range between 0 and 100, where 0 indicated unsatisfied or extremely bothered and 100 represented completely satisfied or not bothered at all.¹⁹ Moreover, in order to determine the overall satisfaction and problems, average scores for the questions were calculated.¹⁹

Analysis procedures

Statistical analyses were performed with SPSS 17.0,^b and $P \leq 0.05$ was chosen to reflect statistical significance. Eighteen 2-tailed paired samples *t* tests (equal to the number of questions) with Bonferroni adjustment were employed to compare the effects of each suspension system on satisfaction with the prosthesis.

Results

Respondents' profile

Ninety subjects out of the 112 who were invited returned the completed questionnaires (a response rate of 80.35%). The mean age \pm SD of the respondents was 47.7 ± 7.0 years, and all participants were men. All of the selected participants had lost their limbs because of trauma. The average weight and height of

Table 1 Respondents' characteristics

Age (y)	47.77 \pm 7.0
Height (cm)	173.67 \pm 7.5
Years since amputation	23.80 \pm 4.2
Weight (kg)	80.63 \pm 12.2
Activity level	
K2	33 (36.7)
K3	57 (63.3)
Amputation side	
Right	36 (40.0)
Left	54 (60.0)
Daily prosthetic use (h)	11.80 \pm 3.34

NOTE. Values are mean \pm SD or n (%).

the respondents were 80.6 ± 12.2 kg and 173.6 ± 7.5 cm, respectively. Of the 90 subjects with unilateral transfemoral amputation, 54 subjects (60%) had their left leg amputated. The majority of the respondents (63.3%) had an activity level of K3. Table 1 provides detailed data about the study sample.

Use and satisfaction

The level of subjects' satisfaction between the Seal-In Liner and the common suction socket suspension system differed significantly in terms of fitting, sitting, and donning and doffing ($P < 0.05$). However, satisfaction with the prosthesis showed no significant differences in terms of walking (even and uneven surfaces), cosmetic appearance of the prosthetic devices, and stair negotiation (table 2). The overall mean satisfaction score \pm SD for the Seal-In Liner was 76.12 ± 8.9 , while it was 69.04 ± 8.3 for the common suction socket suspension. Table 2 presents the mean scores related to satisfaction and problems with the Seal-In Liner and common suction socket system.

Problems and complaints

The respondents indicated more problems with the common suction socket system compared with the Seal-In Liner, and there were significant differences between the 2 systems ($P < 0.05$). The subjects experienced more difficulties with the common suction socket in terms of sweating, wounds, pain, irritation, pistoning, swelling, smell, and sound. Nevertheless, durability of the suspension system was significantly higher with the common suction socket ($P = .000$) (see table 2). The overall mean scores \pm SD for problems experienced with the Seal-In Liner and the common suction socket system were 89.68 ± 3.2 and 78.37 ± 7.5 , respectively.

Discussion

Rehabilitation of persons with amputation is a challenge, because it requires teamwork and necessitates a person's willingness to accomplish time-consuming and costly prosthetic training. Prosthetic satisfaction is a multifactorial issue. Some of these factors are dependent on the level of amputation, prosthetic components and alignment, prosthetist's skills, level of activity, and socket fit.^{19,26-28} Level of amputation is one of the significant factors that can notably affect prosthetic use and user satisfaction.²⁶ Based on the literature, the majority of studies about satisfaction with

Table 2 Satisfaction and problems with Seal-In Liner and CSS

Satisfaction/Problem	Seal-In Liner	CSS	Significance (2-tailed)
Fitting*	92.33±9.1	85.89±7.7	.000
Donning and doffing*	83.33±9.4	54.83±17.5	.000
Sitting*	81.67±12.0	75.28±11.1	.000
Walking*	74.11±14.1	72.08±12.7	.068 [‡]
Walking (uneven surface)*	69.11±14.2	67.04±12.5	.064 [‡]
Stair negotiation*	61.17±11.2	59.17±10.8	.070 [‡]
Cosmetic appearance*	71.11±12.7	68.92±10.2	.053 [‡]
Overall satisfaction*	76.12±8.9	69.04±8.3	.000
Sweat [†]	78.40±14.6	66.60±17.7	.000
Wounds [†]	100.00±0.0	81.50±13.5	.000
Pain [†]	93.67±7.6	81.83±12.0	.000
Irritation [†]	100.00±0.0	96.50±5.1	.000
Pistoning [†]	97.67±3.1	88.50±7.7	.000
Swelling (edema) [†]	98.89±3.4	86.00±12.9	.000
Smell [†]	88.17±12.6	54.40±21.3	.000
Sound [†]	97.67±4.2	59.33±20.2	.000
Durability [†]	52.67±13.2	90.67±8.8	.000
Overall problems [†]	89.68±3.2	78.38±7.5	.000

NOTE. Values are mean ± SD or as otherwise indicated.

Abbreviation: CSS, common suction socket.

* Score of 0 indicates unsatisfied, and 100 represents completely satisfied.

[†] Score of 0 indicates extremely bothered, and 100 represents not bothered at all.

[‡] Nonsignificant differences.

prostheses have focused on patients with transtibial amputation.^{3,9,14} In a retrospective study, Dillingham et al²⁹ examined satisfaction of persons with lower-limb traumatic amputation, which included persons with amputation at the transfemoral level. The transfemoral subjects had used either a strap or suction suspension. While more than half of the participants (57%) were not satisfied with their prostheses, the correlation between the suspension system and patients' satisfaction was not investigated.²⁹

As hypothesized, the results of the current study revealed that the participants were more satisfied and experienced fewer problems with the Seal-In Liner. The only exception was durability, which was found to be higher with the suction system. Furthermore, there was no significant difference in walking on even and uneven surfaces, stair negotiation, and appearance between the 2 systems.

There is minimal study of the relation between the suspension system and satisfaction.^{15,30-32} The common suction socket system is said to cause discomfort and edema.³³ Koike et al³⁰ introduced a new transfemoral double socket. They reported that the participants were satisfied with the new system in comparison with the common suction socket, particularly for donning and doffing. The main reason for this finding was reported to be the flexibility of the inner socket, which they believed maintained close contact with the residual limb at all times and reduced edema associated with the common suction socket.³⁰ Our study concurs with these findings, because our participants were more satisfied with the Seal-In Liner, which also has a soft inner socket. Our subjects also experienced less swelling using the Seal-In Liner compared with the common suction socket system ($P<.000$).

In a prospective study, Trieb et al¹⁵ compared satisfaction with transfemoral prostheses when wearing a contour adducted

trochanteric controlled-alignment socket with and without a silicone liner. They reported that with the silicone liner the socket could be used for longer hours and reduce skin trauma, resulting in enhanced quality of life.¹⁵ Similarly, participants in the current study were more satisfied with the Seal-In silicone liner and experienced less problems.

Based on a study by Haberman et al³¹ on persons with transfemoral amputation, the silicone liner creates a negative pressure, resulting in concurrent movement of the liner and skin. Seal-In Liners also generate suction at the inner socket wall through a vacuum between the seals and socket. Therefore, the soft tissue is protected from the stresses associated with the common suction socket. Haberman³¹ concluded that silicone liners resulted in a level of suspension and comfort that is not possible with the common suction socket system. Heim et al³⁴ also claimed that the use of silicone liners greatly improved the function of the prosthesis because of enhanced suspension, skin protection, and cushioning.³⁴ Similarly, the respondents in the current study were more satisfied with the Seal-In Liner ($P<.000$).

Ease of donning and doffing has been reported to have a positive effect on a patient's experience with a prosthetic device.^{31,35-37} The results of the present study support this assertion. The participants involved in the current study were more satisfied with the process of donning and doffing of the Seal-In Liner than the common suction socket. An elastic bandage is used to lessen friction when the patient dons the residual limb into the hard socket in the common suction socket; however, our findings suggest that donning a suction socket using an elastic bandage is a challenge. The silicone liner can be donned in a sitting position with less effort and does not require balance skills normally associated with donning the common suction socket while standing.³¹ These findings are consistent with the study by Koike³⁰ on 440 transfemoral subjects. Koike³⁰ also observed easier donning while sitting with a flexible internal socket in comparison with the suction socket. The findings of our study with regard to the donning and doffing process were completely different from the results obtained from previous work on the transtibial Seal-In Liner.^{3,36,37} Individuals with transtibial amputation were not satisfied with the Seal-In Liner because of difficulty of donning and doffing, while those with transfemoral amputation stated fewer problems with this type of liner. One possible explanation is that transfemoral prostheses are heavier than transtibial prostheses; therefore, enhanced fit by the Seal-In Liner possibly resulted in higher satisfaction in the transfemoral subjects. Furthermore, soft tissue of the residual limb is less firm in persons with transfemoral amputation than transtibial amputation.

The participants were more satisfied with the static items of satisfaction: no significant difference was seen in satisfaction during ambulation (walking on level ground, walking on uneven surface, and stair negotiation). Yet it does not undermine the improved results with the Seal-In Liner in comparison with the common suction socket, because static scenarios are critical in activities of daily living.

Durability of silicone liners has long been debated. Because the liner is constantly under compressive and tensile loading, its longevity is a concern.³⁸ Research has shown the Alpha cushion and locking liners to have a durability of 6.6 and 6.7 months, respectively.³⁹ Similarly, Össur¹⁶ provides a warranty of 6 months for its Seal-In Liners. Low durability necessitates frequent replacements of the liners, which will be costly for users. Thus, the question is raised of how durability might be enhanced. Some

authors have addressed this issue by the addition of cloth and matrix material to the surface of liners.^{13,38} In the current study, participants reported significantly less durability for the Seal-In Liner than the common suction socket ($P<.000$). Despite low durability, participants were more satisfied with the Seal-In Liner than the common suction socket. Further research and development is needed to help enhance the liner's longevity. Or, if the liners must be replaced frequently,¹³ they must be made of cheaper material, such as plant-based substances. Another alternative is to provide 2 liners to each prosthetic user, and therefore alternating use may increase each liner's lifetime.

It has previously been reported that the Seal-In Liner decreases pistoning inside the socket and increases patient confidence during walking.^{37,40} The participants in our study reported less problems with pistoning in the Seal-In Liner compared with the common suction socket. This may be attributed to total contact between the seals and the socket wall. The participants in this study also experienced less pain in their residual limb, possibly as a result of better skin protection, volume control, less friction, suction, and edema at the end of the residual limb because of full contact between the liner and skin when wearing the Seal-In Liner.^{36,37} Although both suspension systems in this study are considered suction suspension, one applies suction to the skin (common suction socket) whereas the other creates suction mostly between the liner and socket wall. Silicone liners are used to reduce skin irritation or breakdown that is a common problem with prostheses.³³ Participants in this study also stated less irritation, pain, and wounds using the Seal-In Liner. This may be another possible reason why they preferred the Seal-In Liner.

The subjects reported fewer problems with sound in the common suction socket during walking. This finding is consistent with our previous study on subjects with transtibial amputation.⁴⁰ Moreover, sweating and smell decreased with use of the Seal-In Liner compared with the common suction socket, possibly because of the enhanced fitting between the skin and the liner in this system.

Study strengths

Despite the fact that the Seal-In Liner has only been recently introduced, this study provides qualitative data on a large number of transfemoral prosthetic users having experienced Seal-In Liner use. Furthermore, because all participants have used both systems, they were able to compare the common suction socket and the Seal-In Liner. Because the mean time since amputation was 23.8 years in this study sample, they could by virtue of their experience provide better subjective feedback than new prosthesis users.

Study limitations

We acknowledge that all the participants were men with traumatic amputation; therefore, the findings cannot be generalized to women with transfemoral amputation or those with peripheral vascular disease. Another drawback of this retrospective survey might be the fact that the participants had to recall their experience with the common suction socket system, because they were all using Seal-in Liners at the time the study was conducted. Furthermore, the study approach was not mechanistic, because it only relied on the participants' subjective statements regarding the suspension system. Further objective exploration is needed.

Conclusions

Overall, this study revealed that the majority of participants with transfemoral amputation were more satisfied with the Seal-In Liner than the common suction socket. If the durability of the Seal-In Liner were increased in some way, it would address the main issue with Seal-in Liners.

Suppliers

- a. Össur Inc, Grjothals 5, 110 Reykjavik, Iceland.
- b. SPSS Inc, 233 S Wacker Dr, 11 Fl, Chicago, IL 60606-6412.

Keywords

Amputation; Patient satisfaction; Prostheses and implants; Rehabilitation

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