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Research Article

VACUUM SUSPENSION WITH AND WITHOUT SEALING SLEEVE IN TRANSTIBIAL PROSTHESES: COMPARISON OF MOBILITY AND SATISFACTION INDICATORS

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Keywords

Amputee,
Sealing,
Sleeve
Suspension,
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ABSTRACT

Purpose: The suspension system has a significant impact on user satisfaction and mobility, but it is not clear how suspension components affect these factors. The aim of this study was to investigate the effects of sealing sleeve in transtibial amputees who utilize either suction or elevated vacuum suspension systems in terms of balance, mobility and satisfaction.

Methods: Twenty-two participants were included in the study (age 40.18±14.75 years). Participants were divided into two groups according to the sealing type as 'with-sleeve' and 'without-sleeve'. The following tests were used: One Limb Stance Test for balance; Timed Up and Go test for functional mobility; the Mobility subcategory of the Prosthesis Evaluation Questionnaire for perceived mobility with a prosthesis; and the Satisfaction with Prosthesis Questionnaire for prosthetic satisfaction.

Results: There was no difference between the two groups in terms of functional mobility and satisfaction; without-sleeve group was found to be significantly better in terms of prosthetic limb balance and perceived mobility. There was a significant relationship between stump length and both prosthetic limb balance as well as perceived mobility.

Conclusion: The current study may provide important evidence for understanding the role of the sealing sleeve, optimizing prosthetic design, and personalizing prosthetic care for users.

INTRODUCTION

Prosthetic suspension systems are critical components that influence mobility, and user satisfaction in individuals with transtibial amputations. Among the various suspension options available, Suction Suspension (SS) and Elevated Vacuum Suspension (VS) have gained increasing attention due to their ability to remove air between the limb and socket, create a vacuum, reduce pistoning, and ensure that the socket fits securely. Previous studies have shown that vacuum systems can improve mobility and balance parameters by providing more consistent socket fit and improved proprioceptive feedback (1–3). Furthermore, prosthetic satisfaction is a multifaceted outcome that encompasses comfort, perceived stability, and confidence during ambulation—all of which may be influenced by the suspension method and the presence of prosthetic components like the sealing sleeve (4,5).

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Both SS and VS are based on the principle of creating negative pressure between the liner and the inner socket by expelling air via a distal one-way valve or vacuum pomp (6). The effectiveness of the vacuum depends on creating an airtight inner socket environment and a vacuum chamber that provides consistent suspension throughout the gait cycle. For this purpose, one of the suspension components used is the “sealing sleeve” on the proximal socket trim. While sleeves contribute to overall suspension integrity, their use may also introduce functional trade-offs, such as restrictions in knee range of motion or thermal discomfort, potentially influencing the user's mobility and satisfaction (2,7,8).

Another suspension component used for an airtight inner socket environment is silicone liners with sealing rings (or membranes) which are designed to provide vacuum suspension without a sleeve. The sealing rings of the liner isolate the distal region of the socket from the proximal section. The vacuum maintains negative pressure in the sealed distal chamber, thereby increasing socket fit and suspension in that region. The proximal region is not sealed, which provides greater freedom of movement and better heat distribution (9,10). There are no absolute criteria for choosing with- or without-sleeve options in vacuum suspension. However, for the use of without-sleeve system, it is recommended that the stump not be too short to provide a tight socket-liner interface in the distal limb region (11).

There has been no systematic comparison of the effects sealing sleeves in vacuum assisted prostheses in the literature. The aim of this study was to investigate the effects of with- and without-sleeve in transtibial amputees who utilize either suction or vacuum suspension systems in terms of balance, mobility and satisfaction. Also, the difference in stump length between with- vs without-sleeve system users and the relationship between stump length and mobility were also investigated. By comparing with- vs without-sleeve conditions in a controlled, cross-sectional design, this research seeks to provide evidence-based insights into the functional and subjective outcomes associated with sleeve use. The findings may inform clinical decisions regarding prosthetic suspension prescriptions and contribute to enhancing user-centered prosthetic care.

METHODS

This study was planned as a prospective case–control study and the level of evidence is III. This study was approved by the Gülhane Scientific Research Ethics Committee of Health Sciences University (2025-155). All participants provided written informed consent before taking part. The inclusion criteria were being between ages of 18-65 years, having unilateral transtibial amputation, using a carbon foot with solid ankle, and using SS or VS with- or

without-sleeve. Participants must also have to be using their current prosthetic system for at least six months. The same evaluation process was applied to all individuals included in the study.

Outcome Measurements

Within the scope of the study, participants' age, height, weight, date of amputation, and the type of foot, socket, suspension used in the prosthesis were recorded. Stump length (Medial Tibial Plateau - Stump Distal) and intact limb leg length (Medial Tibial Plateau - Floor) were recorded in centimeters. Stump length was recorded as a percentage relative to the intact limb ((stump length*100)/intact limb length). Then, the following assessments were done to find out about mobility parameters and satisfaction.

The *One Limb Stance Test* (OLST) was used for balance assessment. In the OLST, participants were asked to stand on one leg for as long as possible and the amount of time they could stand on one limb was recorded in seconds. The test began when they stood up, lifted one limb, and placed their hands on their iliac crest. During the test, participants were instructed to look at a mark on the wall. If they lost their balance or changed their foot or hand position, the time was stopped and recorded. The test ended for participants who could stand for more than 30 seconds. The test was first applied to the intact limb (IL), then to the prosthetic limb (PL), and repeated three times for each limb (12–14).

The *Timed Up and Go* (TUG) test was used for functional mobility assessment. The TUG measures the basic motor skills of subjects, including walking, transferring, and turning abilities. The test started with the participant in a seated position on a chair. When the test began, the subject was asked to stand up from the chair, walk 3 meters, turn 180 degrees, return to the starting point, and sit back down in the chair. The test was considered complete when the subject returned to the initial position. The total time was recorded in seconds. Lower time indicated better functional mobility level. Previous studies have assessed physical mobility and the risk of falls using this test and have confirmed the validity and reliability of the TUG test for subjects with transtibial amputation (15,16).

The *"Mobility" subcategory of the "Prosthesis Evaluation Questionnaire"* (PEQ-M) was used to evaluate the mobility level with the prosthesis. The PEQ-M assesses the perceived mobility potential of amputated individuals using a prosthesis in the last 4 weeks. It is a mobility scale consisting of 13 items that evaluates ambulation with prosthesis (8 items) and transfers (5 items). It uses a visual analog scale expressed in millimeters (0–100mm) for scoring and a high score indicates high mobility with the prosthesis (17).

The *Satisfaction with Prosthesis Questionnaire* (SATPRO) was used to assess prosthetic satisfaction. SATPRO is a 15-item, self-administered test aimed at determining satisfaction with the prosthesis used. For each item, participants mark the number that best describes their satisfaction with their current prosthesis (3: totally agree, 2: rather agree, 1: rather disagree, 0: totally disagree). Items 6, 12, and 14 are scored in reverse. Higher total scores indicate higher satisfaction. The maximum possible score is 45, indicating 100% satisfaction, whereas a score of 0 indicates 0% satisfaction. The satisfaction score was obtained as a percentage (%) by dividing the total score of the participants by the maximum score they could get from the questions they marked, multiplied by 100 (18).

Statistical Analysis

A priori power analysis was performed using G*Power Version 3.1 software for sample size estimation based on data from published studies. In the study by Çerezci-Duygu et al., the mobility scores of the independent intervention and control groups after follow-up, assessed using PEQ-M, were taken as the reference and the effect size was estimated as 1.67 (19). The minimum sample size required with this effect size was 22 participants (11 participants per group), using two-tailed hypothesis and independent sample t-test with at least 95% power and a significance level of 0.05.

The conformity of outcome measurements (including OLST, TUG, PEQ-M, SATPRO) to normal distribution was determined by analytical method (Skewness-Kurtosis) (20). Frequency distributions for categorical variables and descriptive statistics (Mean ± Standard Deviation) for quantitative continuous variables were calculated. The t-test was used to compare quantitative continuous data between two groups. Pearson's correlation coefficient was used to determine the strength of non-causal relationships among two numerical variables. Statistical comparisons were made using the *Statistical Package for the Social Sciences* (SPSS) software. Type 1 error level of 5% was accepted for statistical significance.

RESULTS

Twenty-two participants with transtibial amputation were recruited as volunteers (age 40.2±14.8 years; body mass index, 25.49±3.78 kg/m^2). Participants had an average stump length of 16.09±3.89 cm, and a stump length percentage relative to intact limb length of 35.41±8.73 %. The mobility and satisfaction scores of the participants are presented in **Table 1**.

Table 1. Mobility and satisfaction scores of the participants

	Min - Max	**Mean ± SD**
Amputation duration, year	1 – 32	12.3 ± 11.8
Stump length, cm	9 – 25	16.09 ± 3.89
Stump length, %	13.16 – 50	35.41 ± 8.73
OLST-IL, s	6.6 – 30	24.75 ± 8.47
OLST-PL, s	1.33 – 30	9.13 ± 9.41
TUG, s	7 – 12.6	9.56 ± 1.79
PEQ-M	5.39 – 9.63	7.83 ± 1.35
SATPRO, %	60 – 95	79.29 ± 8.98

Min–Max, minimum–maximum: SD, standart deviation: s, second: OLST, One Limb Stance Test: IL, Intact Limb: PL, Prosthetic Limb: TUG, Timed Up and Go Test: PEQ-M, Prosthesis Evaluation Questionnaire Mobility Subcategory: SATPRO, Satisfaction with Prosthesis Questionnaire.

In terms of the prosthetic systems used, 11 participants used a vacuum system with-sleeve (n=10 VS; n=1 SS), and 11 participants used a vacuum system without-sleeve (n=7 VS; n=4 SS). The comparison of outcome measurements between groups formed according to sealing sleeve utilization is presented in **Table 2**. The relationship between stump length and outcome measurements is presented in **Table 3**.

Table 2. Comparison of outcome measurements between groups

	With-sleeve (n=11)	**Without-sleeve (n=11)**	**Between-group difference (95%CI)**
Amputation duration, year	12.2 ± 12.4	12.5 ± 11.8	-0.3 (-11, 10.5)
Stump length, cm	13.18 ± 2.36	19 ± 2.76	**-5.82* (-8.1, -3.54)**
Stump length, %	29.49 ± 7.87	41.32 ± 4.58	**-11.83* (-17.65, 6.01)**
OLST-IL, s	22.37 ± 9.56	27.13 ± 6.84	-4.76 (-12.2, 2.68)
OLST-PL, s	4.61 ± 4.98	13.67 ± 10.79	**-9.06* (-16.71, -1.34)**
TUG, s	9.8 ± 2.16	9.31 ±1.39	0.49 (-1.13, 2.1)
PEQ-M	6.97 ± 1.2	8.7 ± 0.85	**-1.73* (-2.65, -0.8)**
SATPRO, %	79.39 ± 11.38	79.19 ±6.31	0.2 (-8.13, 8.53)

CI, confidence interval: s, second: OLST, One Limb Stance Test: IL, Intact Limb: PL, Prosthetic Limb: TUG, Timed Up and Go Test: PEQ-M, Prosthesis Evaluation Questionnaire Mobility Subcategory: SATPRO, Satisfaction with Prosthesis Questionnaire. *Statistically significant.

Tablo 3. Relationship between stump length and outcome measurements

	OLST-IL	**OLST-PL**	**TUG**	**PEQ-M**	**SATPRO**

Stump length, cm	0.326	**0.438***	0.086	**0.6****	-0.128
Stump length, %	0.375	0.168	0.047	**0.624****	-0.344

OLST, One Limb Stance Test: IL, Intact Limb: PL, Prosthetic Limb: TUG, Timed Up and Go Test: PEQ-M, Prosthesis Evaluation Questionnaire Mobility Subcategory: SATPRO, Satisfaction with Prosthesis Questionnaire. *. Correlation is significant at the 0.05 level (2-tailed). **. Correlation is significant at the 0.01 level (2-tailed).

DISCUSSION

In current study, the perceived level of mobility and static balance of the prosthetic limb were found to be better at the without-sleeve condition. Additionally, no difference was found in functional mobility or prosthetic satisfaction between with- or without-sleeve condition. Regarding the stump length, it was found that the stump length was shorter in the with-sleeve condition; and a positive, significant relationship was identified between stump length and perceived mobility and static balance on the prosthetic limb, suggesting that stump length may influence mobility and balance outcomes.

Mobility and balance are very important for individuals with amputation to perform their daily activities safely and efficiently. Although there are many determinants of mobility and balance, the present study findings indicate that the perceived mobility and static balance levels of the prosthetic limb are better in the without-sleeve condition. A previously noted disadvantage of the sealing sleeve is that it had to be worn up to the upper thigh. This limited knee range of motion and created excessive pressure on the patella (2,21). One reason why better mobility and static balance can be observed during without-sleeve condition is that the sealing sleeve restricts the knee range of motion, reducing flexibility and comfort during walking.

Stump length, its implications and biomechanics of remaining limb after amputation have been frequently discussed. It has been emphasized that there is a significant loss of strength, which may be related to stump length. This loss of strength may lead to changes in gait, decreased energy efficiency, increased walking resistance, altered joint loading, and an increased risk of osteoarthritis and chronic back pain (22,23). In addition to the predicted biomechanical effects on the remaining limb, the relationship between suspension selection, comfort, and stump length is unclear. One manufacturer's instructions state that their without-sleeve system cannot be used on stumps shorter than 11 cm; however, there is no such restriction for the with-sleeve systems. In our study, individuals using the without-sleeve system appear to have a more stump length. Based on these results, stump length appears to be a determining factor in choosing between the two systems. This is reasonable because a

vacuum forms in the distal region of the liner's ring/membrane in without-sleeve options. The shorter the distal stump region, the less the vacuum will affect it. Another reason for the improved mobility and static balance observed in individuals using without-sleeve system may be the longer stump length. The current study supports this notion by demonstrating that as stump length increases, perceived mobility and balance on the prosthetic limb improve.

The sleeve insulates the proximal end and creates a vacuum over the entire inner surface of the socket. This vacuum area is wider than that created by the without-sleeve design, but sleeve may negatively affect long-term mobility due to thermal discomfort such as sweating and heat intolerance, as well as difficulties in donning and doffing (21). Previous studies have shown that using prostheses significantly increases skin surface temperature, which can lead to discomfort (24). While using a sealing sleeve increases heat and the area of affected skin due to the increased surface area of the non-porous material (such as copolymer, rubber, or neoprene) in contact with the skin, the current study showed that it has no overall effect on prosthetic satisfaction.

Donning and doffing is also considered one of the important factors determining overall satisfaction and comfort with prostheses, and it appears to contribute to increased overall satisfaction (25,26). Previous studies have shown a direct relationship between suspension type and ease of donning and doffing (27). The present study demonstrated that sealing sleeves do not affect prosthetic satisfaction, despite the fact that they can complicate donning and doffing. As prosthetic satisfaction is a multidimensional concept incorporating factors such as perceived stability, comfort, ease of use and confidence, it is reasonable to assume that users evaluate their overall satisfaction by considering the advantages and disadvantages. In the current study, the fact that no difference was found between the satisfaction levels of users of both systems is surely due to the multiform nature of the satisfaction variable.

The functional mobility indicator did not show a statistically significant difference between the groups, which may be related to the nature of the test. TUG test used for this purpose is a combined test that focuses on short-term, basic functional mobility and transition movements. It may not be sensitive enough to detect more subtle changes in gait dynamics or long-term mobility limitations caused by the suspension system or the usage of a sealing sleeve. Previous studies, particularly in individuals using lower extremity prostheses, have shown that endurance-based assessments such as the 6-Minute Walk Test are more effective in detecting such subtle differences (28). Therefore, the inconclusive findings regarding the TUG test in our study may be related to the limited sensitivity of the test rather than the absence of functional effect and should be carefully evaluated in this context.

The current study has some limitations. First, the difference in the stump length of the two groups is a limiting factor in determining the isolated effect of sealing sleeve. Second, the vacuum option used was not standardized between the two groups (VS and SS). Third, tests with higher sensitivity could have been used for mobility assessment. Lastly, the present study examined the duration of amputation, but not the duration of use of the final prosthesis (vacuum suspension). Further studies could investigate the relationship between the duration, and outcome measures for different prosthetic components. Also, further studies with larger sample sizes, long-term follow-ups, and objective motion analyses are needed to improve clinical guidelines.

CONCLUSION

Current results suggest that sealing sleeve impacts not only suspension security, but also fundamental mobility and stability parameters. Specifically, stump length has been identified as a key determinant of these outcomes, emphasizing the necessity of considering individual anatomical characteristics when prescribing prosthetics. Additionally, balancing the mechanical benefits with the comfort-related drawbacks of cuff use highlights the importance of user-focused clinical evaluations. There is limited empirical data on the specific contribution of the sleeve component to vacuum systems' overall effects on functional outcomes. Despite the theoretical benefits, few studies specifically examine the sealing sleeve's effect on vacuum system users. Understanding the role of the sealing sleeve is important for optimizing prosthetic design and personalizing care for users.

Ethics Committee Approval: This study was approved by the Gülhane Scientific Research Ethics Committee of Health Sciences University (2025-155).

Informed Consent: All participants provided written informed consent before taking part.

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