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DEVELOPMENT AND DURABILITY OF PROSTHETIC LINER FOR TRANSTIBIAL AMPUTEE

Original Research

Hafeez Ul Rehman[1]*, Saad Saleem[2], Sobia Javeed[3], Awais Aslam[4], Raza Abbas[5]
[1]MS Scholar, Rehabilitation Sciences (Orthotics and Prosthetics), Superior University, Lahore (Main Campus), (Certified Orthotist And Prosthetist), Pakistan.
[2]Consultant/Senior Lecturer, Department of Prosthetics and Orthotics, Superior University, Lahore, Pakistan.
[3]MS Scholar, Rehabilitation Sciences (Orthotics and Prosthetics), Superior University, Lahore (Main Campus), Pakistan.
[4]Certified Prosthetist and Orthotist, Pakistan.
[5]Certified Prosthetist and Orthotist, Hope Rehabilitation Centre, Lahore, Pakistan.
Corresponding Author: Hafeez Ul Rehman, MS Scholar, Rehabilitation Sciences (Orthotics and Prosthetics), Superior University, Lahore (Main Campus), (Certified Orthotist and Prosthetist), Pakistan, hafeezul799@gmail.com
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ABSTRACT

Background: Prosthetic liners play a critical role in improving the comfort, mobility, and prosthesis management in lower-limb amputees, particularly among transtibial amputees. However, the high cost and limited availability of prefabricated liners often restrict access for patients in low-resource settings. Developing a cost-effective and durable prosthetic liner tailored to individual needs can significantly enhance user satisfaction and quality of life in this population.

Objective: To develop and evaluate a cost-effective, durable prosthetic liner that enhances mobility, comfort, and prosthesis usability in transtibial amputees over an 8-week period.

Methods: An experimental case study was conducted at the Pak Rehabilitation Center in Peshawar involving eight transtibial amputees with medium-length stumps. Participants were selected through non-probability convenient sampling and underwent assessments at baseline, 4th, and 8th week. Outcome measures included the Four-Square Step Test (FSST) for dynamic balance, Socket Comfort Score (SCS), Lower Extremity Function Scale (LEFS), and Prosthesis Donning and Doffing Score (PDDS). Data were analyzed using SPSS version 25, and repeated measures ANOVA was used to determine statistical significance, with $p < 0.05$.

Results: FSST time improved significantly from 18.15±1.72 seconds at baseline to 12.23±0.70 seconds at the 8th week ($p = 0.000$). The SCS increased from 4.78±0.52 to 7.00±0.49 ($p = 0.003$), while LEFS scores rose from 18.75±2.81 to 52.65±3.73 ($p = 0.003$). Prosthesis donning time reduced from 302.50±31.05 to 245.00±23.29 seconds ($p = 0.001$), and doffing time decreased from 218.75±20.31 to 177.50±21.21 seconds ($p = 0.003$).

Conclusion: The custom-fabricated, low-cost prosthetic liner demonstrated significant improvements in mobility, comfort, and prosthetic efficiency for transtibial amputees. These findings support the integration of affordable prosthetic solutions within rehabilitation programs to enhance functional outcomes and patient quality of life.

Keywords: Comfort, Durability, Lower Extremity Function Scale, Mobility, Prosthetic Liner, Transtibial Amputee, Usability.

INTRODUCTION

The development of prosthetic liners represents a significant advancement in the field of prosthetics, particularly for individuals with lower-limb amputations. Acting as an interface between the residual limb and the prosthetic socket, liners are essential for enhancing comfort, stability, and skin protection. Their importance is especially pronounced among transtibial amputees, where the residual limb's skin is highly sensitive and vulnerable to irritation, pressure sores, and mechanical damage caused by friction and impact during movement (1). Prosthetic liners have evolved from basic materials such as wool, leather, and rubber to more sophisticated, skin-friendly substances like silicone, thermoplastic elastomers (TPE), and polyurethane. These modern materials offer better elasticity, cushioning, and adaptability to environmental conditions, greatly improving the daily experience of prosthetic users (2,3). Silicone liners are particularly valued for their biocompatibility and ability to provide a stable, comfortable fit, especially for patients with fragile or damaged skin. However, their higher cost and susceptibility to tearing at stress points limit their widespread use (4). TPE liners, while more affordable, offer good flexibility and comfort, but tend to have a shorter lifespan. In contrast, polyurethane liners are known for their superior shock absorption and durability, though they may be less comfortable due to their rigidity (5,6). These varying material characteristics influence liner selection based on the user's activity level, budget, and individual stump conditions. Despite these advancements, access to high-quality liners remains a challenge in resource-limited settings, where the high cost of prefabricated options often places them out of reach for many patients in need (7,8).

A key challenge with prosthetic liner use involves managing fluctuations in residual limb volume caused by factors such as edema, weight change, or muscle atrophy. Such variations can compromise the fit and function of the prosthetic socket, leading to discomfort and potential skin breakdown (9). Some modern liners attempt to address this with adjustable or expandable features, though these solutions remain limited in scope and accessibility. In addition to maintaining comfort and fit, liners must integrate effectively with suspension systems like pin-lock and suction mechanisms. Each system places distinct demands on the liner, from resisting shear forces to maintaining airtight seals, necessitating material choices that can withstand mechanical stresses while protecting the skin (10,11). For instance, silicone liners are often preferred for suction systems due to their superior sealing capability, while TPE and polyurethane are more frequently used in dynamic, high-stress scenarios (12,13). Although the utility of prosthetic liners is well recognized, there is a growing need to address their affordability and long-term performance, particularly in low- and middle-income countries. Many patients are unable to afford imported liners, resulting in a gap between technological advancement and practical access. Addressing this disparity requires the development of cost-effective, durable alternatives that can be produced and maintained locally, without compromising on comfort or safety (14). Moreover, evaluating these liners through real-world patient use is essential to ensure their functional longevity and user satisfaction. This study was designed to develop a cost-effective and durable prosthetic liner specifically for transtibial amputees, with the goal of improving accessibility while maintaining high standards of comfort, skin protection, and usability over prolonged periods (15).

METHODS

This study employed an experimental case study design and was conducted at the Pak Rehabilitation Center in Peshawar. A total of eight participants were recruited using non-probability convenience sampling. Participants included individuals aged 40 years and above with transtibial amputations and medium-length residual limbs, who had been using prosthetic limbs for at least three years without the support of prosthetic liners. Individuals under 40 years of age, those who had never used a prosthesis, and patients with amputations other than transtibial were excluded from the study. All participants provided informed written consent before enrollment, and ethical approval was obtained from the institutional review board (IRB) of Pak Rehabilitation Center. Participant selection was guided by clinical evaluations and medical history assessments to confirm eligibility. The study prioritized individuals with medium-sized transtibial stumps to ensure a homogenous sample reflective of the majority population among lower-limb amputees. Once recruited, each participant underwent a detailed prosthetic preparation process. Initially, a custom mold of the residual limb was created using medical-grade casting material that offered precise anatomical detailing and easy removal. This negative cast was filled with either plaster or resin to generate a positive replica of the stump. The model was carefully rectified to eliminate rough edges or casting imperfections, ensuring accurate prosthetic alignment and liner fit. Subsequently, a silicone liner was fabricated over the model, tailored to match the individual contours of the residual limb. The liner was designed to optimize both comfort and durability, functioning as a stable interface between the limb and the prosthetic socket.

To evaluate the effectiveness and usability of the custom liners, four validated outcome measures were utilized. Dynamic balance and coordination were assessed using the Four-Square Step Test (FSST), which evaluates multidirectional stepping and postural transitions. The Socket Comfort Score (SCS) was employed to gauge subjective comfort and socket-liner interface quality. The Lower Extremity Function Scale (LEFS) provided a quantitative measure of functional ability in lower limb tasks, and the Prosthesis Donning and Doffing Score (PDDS) was used to assess the ease and independence with which participants could wear or remove the prosthesis. Data were analyzed using IBM SPSS Statistics for Windows, Version 25. Descriptive statistics, including means, standard deviations, frequency distributions, and visualizations such as pie charts and bar graphs, were used to summarize patient-reported outcomes. To detect any statistically significant changes over time, repeated measures analysis of variance (ANOVA) was conducted, with significance set at $p < 0.05$.

RESULTS

A total of eight participants were included in the study, with a mean age of 46.00 ± 3.25 years. The age range of the participants was between 40 and 51 years. Gender distribution was presented using a pie chart to depict participant demographics, though specific percentages were not detailed. In terms of functional mobility, the Four-Square Step Test (FSST) showed a statistically significant improvement across the three assessment points. The mean time at baseline was 18.15 ± 1.72 seconds, which improved to 15.81 ± 1.54 seconds at the fourth week and further to 12.23 ± 0.70 seconds by the eighth week ($p = 0.000$). This reflects a consistent enhancement in dynamic balance and coordination over the intervention period. Socket comfort, measured through the Socket Comfort Score (SCS), also showed significant improvement. At baseline, the mean score was 4.78 ± 0.52, which increased to 6.00 ± 0.49 at the fourth week and 7.00 ± 0.49 at the eighth week ($p = 0.003$), indicating increased participant satisfaction and improved socket-liner interface. Lower limb function was assessed using the Lower Extremity Functional Scale (LEFS), where a marked improvement was observed. The baseline mean score was 18.75 ± 2.81, which significantly increased to 39.00 ± 3.29 at the fourth week and reached 52.65 ± 3.73 at the eighth week ($p = 0.003$). This indicated enhanced functional independence and mobility in participants. Regarding donning time, a statistically significant reduction was noted over time. At baseline, participants required an average of 302.50 ± 31.05 seconds, which decreased to 268.00 ± 25.87 seconds at the fourth week and 245.00 ± 23.29 seconds by the eighth week ($p = 0.001$), reflecting improved ease and efficiency in applying the prosthesis. Similarly, the prosthesis doffing score demonstrated significant improvement. At the initial assessment, the mean time to remove the prosthesis was 218.75 ± 20.31 seconds, which decreased to 195.00 ± 17.28 seconds at the fourth week and 177.50 ± 21.21 seconds by the eighth week ($p = 0.002$).

Table 1: Statistics of age

Statistics of age	
N	8
Mean	46.0000
Std. Deviation	3.25137
Minimum	40.00
Maximum	51.00

Table 2: Repeated measure ANOVA test between four square step tests at baseline, 4th and 8th week

Variables	Treatment	Interquartile range (IQR)	Mean± Standard deviation	P value
Four square step tests	Baseline	2	18.15±1.72	0.000
	4th week	2	15.81±1.54	
	8th week	2	12.23±.70	

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Table 3: Repeated measure ANOVA test between socket comfort score at baseline, 4th and 8th week

Variables	Treatment	Interquartile range (IQR)	Mean± Standard deviation	P value
Socket comfort score	Baseline	2	4.78±.52	0.003
	4^{th} week	2	6.00±.49	
	8^{th} week	2	7.00±.49	

Table 4: Repeated measure ANOVA test between lower extremity function scale at baseline, 4th and 8th week

Variables	Treatment	Interquartile range (IQR)	Mean± Standard deviation	P value
Lower extremity function scale	Baseline	2	18.75±.2.81	0.003
	4^{th} week	2	39.00±.3.29	
	8^{th} week	2	52.65±.3.73	

Table 5: Repeated measure ANOVA test between prosthesis donning score at baseline, 4th and 8th week

Variables	Treatment	Interquartile range (IQR)	Mean± Standard deviation	P value
Prosthesis donning score (seconds)	Baseline	2	302.50±31.05	0.001
	4^{th} week	2	268.00±25.87	
	8^{th} week	2	245.00±23.29	

Table 6: Repeated measure ANOVA test between prosthesis doffing score at baseline, 4th and 8th week

Variables	Treatment	Interquartile range (IQR)	Mean± Standard deviation	P value
Prosthesis doffing score (seconds)	Baseline	2	218.75±20.31	0.002
	4^{th} week	2	195.00±17.28	
	8^{th} week	2	177.50±21.21	

Figure 1 Four Square Step Test Over Time

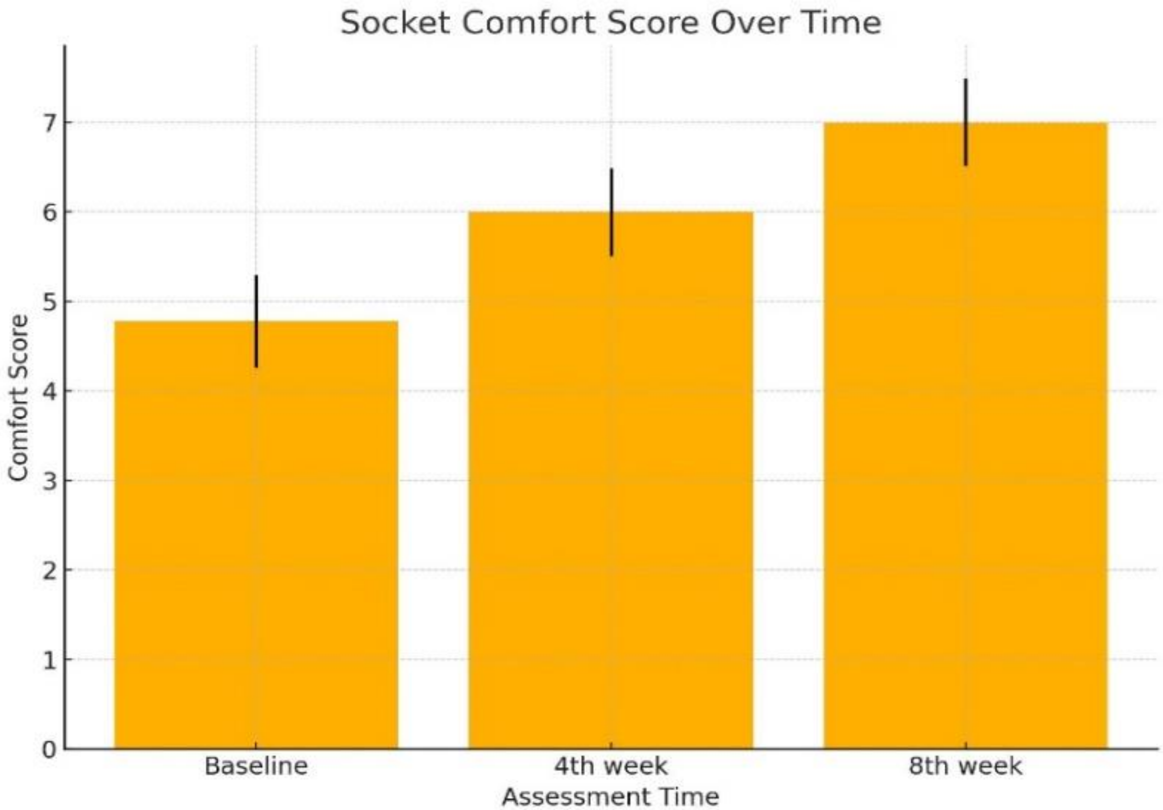

Figure 2 Socket Comfort Score Over Time

DISCUSSION

The findings of this study demonstrated significant improvements in mobility, comfort, functional ability, and prosthesis management among transtibial amputees over an eight-week intervention period. These outcomes support the growing body of evidence highlighting the benefits of prosthetic liners and rehabilitation programs in enhancing patient outcomes. The marked reduction in Four Square Step Test (FSST) time suggests enhanced dynamic balance and agility, key indicators of postural control and environmental navigation. Improvements in FSST performance reflected a notable gain in neuromuscular coordination, likely facilitated by a more stable and comfortable prosthetic interface. These results are consistent with previous studies where structured prosthetic rehabilitation led to measurable gains in mobility among individuals with lower limb amputations (14,15). The increase in the Socket Comfort Score (SCS) over time emphasized the critical role of prosthetic interface optimization in user satisfaction. Comfort at the socket-limb junction is a cornerstone of prosthetic success, influencing not only wear-time compliance but also functional independence. As observed in earlier investigations, participants reported a gradual increase in comfort, often attributed to improved liner conformity, individualized adjustments, and enhanced adaptation to the prosthetic system during the rehabilitation process (16,17). The current findings reinforced that consistent use of a well-fitted liner contributed to greater prosthetic acceptance and reduced interface-related complications.

Similarly, the substantial improvement in the Lower Extremity Function Scale (LEFS) scores illustrated meaningful gains in physical function, with participants demonstrating better performance in walking, climbing stairs, and completing other daily living activities. These improvements are attributed to the combined effects of targeted rehabilitation exercises, enhanced prosthetic fit, and increased confidence in prosthetic use. Prior research has also documented the positive impact of rehabilitation on lower limb functionality, particularly when therapy is closely aligned with prosthetic training and adaptation (18,19). The present study extends this understanding by affirming that measurable functional recovery can be achieved within a relatively short time frame when patient-centered prosthetic

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care is provided. Efficiency in donning and doffing the prosthesis significantly improved during the study period. These gains are indicative of greater ease of use, improved prosthesis control, and possibly enhanced liner-socket integration. Such improvements are particularly relevant in the context of daily living, where prolonged or difficult prosthesis handling can hinder independence and reduce quality of life. The observed decline in donning and doffing time underlines the value of custom-fitted liners in facilitating smoother transitions in prosthetic use and reducing fatigue and frustration associated with device management (20).

Despite the promising results, this study was subject to several limitations. The small sample size (n=8) reduced the statistical power and limits the generalizability of the findings to broader amputee populations. Moreover, the duration of eight weeks, though adequate to observe short-term functional improvements, was insufficient to evaluate long-term outcomes such as liner durability, resistance to mechanical wear, or skin-related complications. The absence of data on skin integrity outcomes represented a critical gap, as preventing stump dermatological issues was a key objective of the study. Furthermore, the study sample was restricted to transtibial amputees with medium-length stumps, excluding individuals with transfemoral amputations, varied stump lengths, or multiple comorbidities. These factors may significantly influence prosthetic outcomes and should be considered in future research to broaden clinical applicability. Nonetheless, the study offered several strengths. It incorporated multiple validated outcome measures to assess various aspects of mobility, comfort, and functional independence, ensuring a comprehensive evaluation of patient progress. Additionally, the use of a custom-fabricated, cost-effective liner model provided preliminary evidence that locally developed solutions may serve as viable alternatives to expensive commercial liners in resource-limited settings. The integration of standardized assessment tools with patient-centered prosthetic customization added methodological robustness and clinical relevance to the findings. Future investigations should aim to include larger, more diverse populations and extend the duration of follow-up to evaluate long-term outcomes, including liner degradation, skin health, and prosthetic satisfaction. Incorporating objective skin assessment tools and qualitative feedback from users may further enrich understanding of the user experience and guide improvements in liner design and prosthetic management protocols.

CONCLUSION

This study concluded that targeted rehabilitation combined with the use of a custom-fabricated prosthetic liner led to meaningful improvements in mobility, comfort, lower limb function, and overall prosthetic management in transtibial amputees. The intervention enhanced dynamic balance, functional independence, and ease of prosthetic use, reinforcing the value of individualized prosthetic fitting and consistent rehabilitation. These findings underscore the practical significance of accessible, patient-centered prosthetic solutions in improving quality of life and supporting long-term adaptation for individuals with lower limb amputations.

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AUTHOR CONTRIBUTION

Author	Contribution
Hafeez Ul Rehman*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Saad Saleem	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Sobia Javeed	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Awais Aslam	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Raza Abbas	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published

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