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Original Article

Comparative Evaluation of Quality of Life in Patients Using Laminated and Molded Transtibial Prostheses

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ABSTRACT

Background: Transtibial amputation substantially affects physical function, pain, emotional wellbeing, social participation, and general health perception. Prosthetic rehabilitation is central to recovery, yet comparative evidence regarding the effect of laminated and molded transtibial prostheses on quality of life remains limited. Objective: To evaluate and compare quality of life among patients using laminated and molded transtibial prostheses. Methods: A pretest-posttest comparative interventional study was conducted at the Institute of Physical Medicine and Rehabilitation, Dow University of Health Sciences. Twenty male patients aged 20-60 years with transtibial amputation were recruited through convenience sampling and allocated into two groups: laminated prosthesis (n=10) and molded prosthesis (n=10). Quality of life was assessed before prosthetic fitting and again after six weeks using the SF-36 questionnaire. Data were analyzed in SPSS version 20 using descriptive statistics and t-tests, with $p<0.05$ considered statistically significant. Results: Significant pretest-posttest improvement was observed in all eight quality-of-life domains, including limitation of activities ($p=0.001$), social activities ($p<0.001$), energy ($p=0.001$), emotion ($p<0.001$), role limitation due to physical health ($p<0.001$), role limitation due to emotional health ($p<0.001$), pain ($p<0.001$), and general health ($p<0.001$). Between-group comparison showed significant differences only for limitation of activities ($p=0.002$) and social activities ($p=0.010$), while the total quality-of-life score did not differ significantly between groups (92.30 ± 8.72 vs 97.00 ± 3.94; $p=0.138$). Conclusion: Both laminated and molded transtibial prostheses were associated with significant improvement in quality of life after rehabilitation, with no statistically significant difference in overall post-intervention quality-of-life score between groups. Keywords: transtibial amputation, prosthesis, laminated prosthesis, molded prosthesis, quality of life, rehabilitation.

INTRODUCTION

Lower-limb amputation is a major life-changing event that results in substantial physical, psychological, and social consequences for affected individuals. Transtibial amputation, involving loss of the lower limb between the knee and ankle, is one of the most common levels of amputation and is generally associated with better functional potential than transfemoral amputation because preservation of the knee joint facilitates gait training, mobility, and prosthetic rehabilitation (1,10,11). Amputation may be performed because of trauma, vascular compromise, infection, tumor, or other severe pathology when limb salvage is not feasible or when removal of the affected segment is necessary to preserve life and improve overall function (1-7). Although amputation eliminates a diseased or nonviable limb, long-term outcomes depend heavily on rehabilitation quality, prosthetic fitting, and the individual's ability to adapt physically and emotionally to limb loss (3,13-16).

A prosthesis is an artificial device designed to replace a missing body part and restore function to the greatest extent possible (9). In transtibial amputation, prosthetic rehabilitation aims not only to improve ambulation and independence in activities of daily living but also to enhance broader health-related quality of life. Health-related quality of life is a multidimensional construct that includes physical functioning, emotional wellbeing, social participation, pain, vitality, and general health perception rather than survival alone (13-16). For individuals with lower-limb amputation, quality of life is influenced by multiple factors, including level of amputation, pain, prosthetic use, mobility, comorbidities, social support, and rehabilitation outcomes (17-37). Previous studies have shown that prosthetic rehabilitation can improve mobility and daily functioning, although many amputees continue to experience pain, restricted participation, emotional distress, and reduced overall quality of life compared with the general population (17-21,28-32).

Published literature has also shown that prosthesis use is generally associated with better function and improved adjustment following lower-limb amputation, but the degree of improvement varies across patient groups and prosthetic systems (18,19,24,26,28,37). Some evidence suggests that functional restoration and quality of life may depend not only on wearing a prosthesis but also on prosthetic comfort, socket fit, structural durability, and the individual's ability to use the device effectively in everyday life (22,25,27,33,34). Laminated and molded transtibial prostheses are both commonly used in clinical practice, yet comparative evidence regarding their relative impact on quality of life remains limited in the local rehabilitation setting. Much of the available literature has focused on prosthesis use in general, amputation level, or rehabilitation outcomes, while fewer studies have directly evaluated whether one transtibial prosthetic fabrication method offers superior patient-reported benefit over another.

This lack of comparative evidence is clinically relevant because prosthetic prescription and fabrication influence comfort, function, patient satisfaction, and long-term rehabilitation success. A clearer understanding of whether laminated or molded transtibial prostheses are associated with better quality of life may support more evidence-based decisions in prosthetic management and rehabilitation planning. Therefore, the present study was conducted to evaluate the quality of life of patients using laminated and molded transtibial prostheses and to compare outcomes between these two prosthetic groups.

MATERIALS AND METHODS

This study was designed as a pretest-posttest comparative interventional study to evaluate quality of life among individuals with transtibial amputation before and after provision of two different types of prostheses. The study was conducted at the Institute of Physical Medicine and Rehabilitation, Dow University of Health Sciences, after obtaining institutional permission. The duration of the study was six months following approval of the synopsis. Ethical permission to conduct the study was obtained from Isra University, and confidentiality of participant data was maintained throughout the research process. Data were coded before analysis to support privacy and data protection.

A total of 20 patients with transtibial amputation were included in the study through convenient non-probability sampling. Eligible participants were males aged 20 to 60 years with transtibial-level amputation. Patients were excluded if they had any additional amputation in the body, known comorbidities, or psychosocial issues that could interfere with the assessment of quality of life. After recruitment, participants were allocated into two equal groups. Group A received a laminated transtibial prosthesis, whereas Group B received a molded transtibial prosthesis. Each group therefore comprised 10 participants.

Quality of life was assessed using the Short Form-36 (SF-36) questionnaire. Baseline assessment was performed before prosthetic provision. After fabrication and fitting of the assigned prosthesis, participants were reviewed again at six weeks, and the SF-36 questionnaire was re-administered to evaluate post-intervention quality of life. The questionnaire was used to assess multiple domains of health-related quality of life, including limitations in physical activities, role limitations due to physical health, role limitations due to emotional health, pain, emotional wellbeing, energy, social functioning, and general health perception. The primary outcome of the study was change in quality-of-life status following prosthetic use, with secondary comparison between the laminated and molded prosthesis groups.

The fabrication process for both transtibial prostheses began with casting of the residual limb. A negative cast was obtained from the patient and then filled with a mixture of plaster of Paris and water to create the positive model. After hardening, the plaster bandage was removed and the model was modified according to prosthetic requirements. The prepared model was then used for the fabrication of either a laminated or molded transtibial prosthesis. In the laminated prosthesis group, the prosthesis incorporated a socket, ankle block for height adjustment, and SACH foot. In the molded prosthesis group, the prosthesis incorporated components including a socket cylinder for height adjustment, a convex ankle disc, and a foot component.

Figure 1 Comparison of laminated and molded transtibial prostheses demonstrating structural design and clinical application in amputee rehabilitation

The main study variables included prosthesis type and quality-of-life outcomes measured before and after intervention. To reduce procedural variation, all participants underwent the same assessment schedule and were evaluated using the same questionnaire at the same two time points. Because the study used a pretest-posttest design with two intervention groups, comparisons were made both within participants over time and between groups after treatment. Data were entered and analyzed using Statistical Package for the Social Sciences (SPSS) version 20. Descriptive statistics were used to summarize participant characteristics and questionnaire responses. Continuous variables such as age, height, and weight were reported using means and standard deviations, while categorical responses were presented as frequencies and percentages. Inferential analysis was performed using the t-test, as specified in the original study protocol, to assess differences in quality-of-life scores. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 20 male participants with transtibial amputation were enrolled and completed the study, with 10 assigned to the laminated prosthesis group and 10 to the molded prosthesis group. The overall sample had a mean age of 31.90 ± 8.43 years, mean weight of 59.60 ± 10.91 kg, and mean height of 5.24 ± 0.25 ft. At baseline, the laminated group was slightly younger and lighter than the molded group, with mean ages of 30.10 ± 7.55 and 33.70 ± 9.26 years, respectively, while mean weights were 55.70 ± 8.34 kg and 63.50 ± 12.16 kg. Mean height was comparable between groups at 5.20 ± 0.18 ft for the laminated group and 5.27 ± 0.31 ft for the molded group.

Table 1. Baseline Characteristics of the Study Participants

Variable	Overall (n=20) Mean ± SD	Laminated (n=10) Mean ± SD	Molded (n=10) Mean ± SD
Age, years	31.90 ± 8.43	30.10 ± 7.55	33.70 ± 9.26
Weight, kg	59.60 ± 10.91	55.70 ± 8.34	63.50 ± 12.16
Height, ft	5.24 ± 0.25	5.20 ± 0.18	5.27 ± 0.31

Before prosthetic intervention, perceived health status was generally low. In the full cohort, 65% of participants rated their health as somewhat worse than one year earlier and only 20% rated it as somewhat improved. After six weeks of prosthetic use, this pattern reversed: 55% reported their health as much improved and 40% as somewhat improved compared with one year earlier, while only 5% continued to report poorer health. General health status also improved substantially, with posttest ratings showing 90% of participants reporting excellent health and 10% reporting very good health, compared with pretest values of 40% good, 35% fair, and 25% poor.

Within-group pretest-posttest analysis demonstrated statistically significant improvement across all eight analyzed quality-of-life domains. The largest mean change was observed in role limitation due to emotional health, with a mean difference of -85.00 ± 27.52 and a highly significant paired t-value of -13.813. This was followed by role limitation due to physical health, which improved by -73.75 ± 47.62, and general health, which improved by -47.00 ± 25.10. Social activities also improved markedly, with a mean difference of -47.50 ± 32.35, while limitation of activities improved by -39.25 ± 47.11. All domains reached statistical significance, with p-values ranging from 0.001 to <0.001.

Table 2. Pretest–Posttest Comparison of Quality-of-Life Domains in the Overall Sample (n=20)

Domain	Mean Difference	SD	t	df	p-value
Limitation of activities	-39.250	47.108	-3.726	19	0.001
Social activities	-47.500	32.353	-6.566	19	<0.001
Energy	78.500	84.684	4.146	19	0.001
Emotion	-34.469	24.601	-6.266	19	<0.001
Role limitation due to physical health	-73.750	47.624	-6.925	19	<0.001
Role limitation due to emotional health	-85.000	27.519	-13.813	19	<0.001
Pain	-46.625	33.749	-6.178	19	<0.001
General health	-47.000	25.100	-8.374	19	<0.001

At the between-group level, comparison of post-intervention domain scores showed that most quality-of-life domains did not differ significantly between participants using laminated and molded transtibial prostheses. No statistically significant between-group differences were found for role limitation due to physical health, role limitation due to emotional health, energy, emotion, pain, or general health, with all p-values exceeding 0.05. However, limitation of activities differed significantly between groups, with a mean difference of -7.10 points (95% CI: -11.32 to -2.88; p = 0.002), and social activities also showed a significant between-group difference, with a mean difference of 1.30 points (95% CI: 0.35 to 2.25; p = 0.010). These findings indicate that although both prosthetic types improved quality of life, differences between fabrication types were domain-specific rather than global.

Table 3. Between-Group Comparison of Post-Intervention Quality-of-Life Domains

Domain	Mean Difference (Laminated – Molded)	95% CI	p-value
Limitation of activities	-7.10	-11.32 to -2.88	0.002
Role limitation due to physical health	-0.40	-1.24 to 0.44	0.331
Role limitation due to emotional health	0.10	-0.11 to 0.31	0.331
Energy	-0.20	-2.20 to 1.80	0.836
Emotion	0.80	-1.74 to 3.34	0.517
Social activities	1.30	0.35 to 2.25	0.010
Pain	1.00	-1.09 to 3.09	0.328
General health	-0.20	-1.34 to 0.94	0.717

When total quality-of-life scores were compared between the two prosthesis groups, the molded group had a numerically higher mean posttest score than the laminated group (97.00 ± 3.94 vs 92.30 ± 8.72), but this difference was not statistically significant. The mean difference in total quality-of-life score was -4.70 points, with a 95% confidence interval from -11.06 to 1.66 and a p-value of 0.138, indicating that the overall quality-of-life benefit was comparable between groups despite minor numerical advantage in favor of the molded prosthesis.

Table 4. Between-Group Comparison of Total Quality-of-Life Score

Group	n	Mean ± SD	Mean Difference	95% CI	p-value
Laminated prosthesis	10	92.30 ± 8.72			
Molded prosthesis	10	97.00 ± 3.94	-4.70	-11.06 to 1.66	0.138

At the item level, the post-intervention distribution also reflected broad functional improvement. For example, in the full sample, 80% of participants reported no limitation in vigorous activities after intervention, 80% reported no limitation in moderate activities, 75% reported no limitation in carrying groceries, and 90% reported no limitation in climbing several flights of stairs. Similarly, role restrictions improved sharply: 95% of participants reported no reduction in work or other activities due to physical health, and 100% reported no reduction in work time due to emotional health. These descriptive changes are consistent with the statistically significant domain-level improvements shown in the paired analysis.

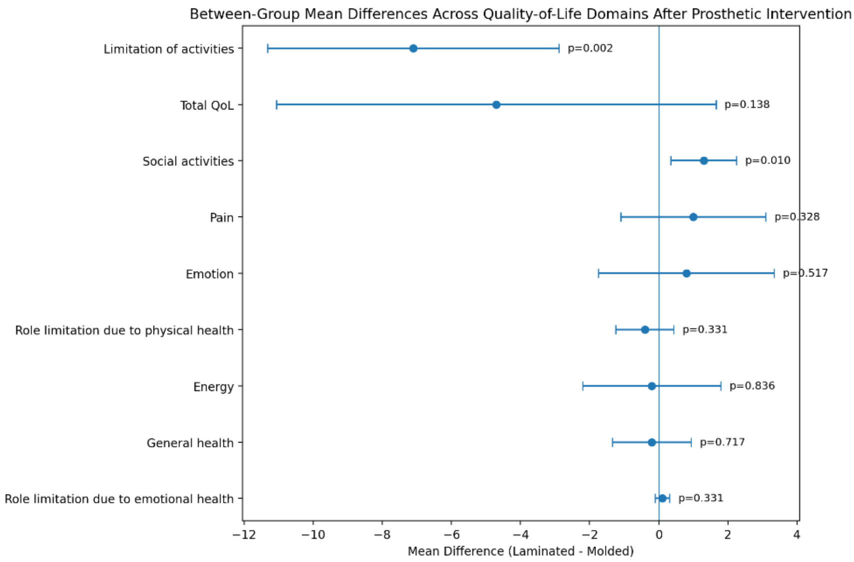

Figure 2 total quality of life, pain, emotion, energy, role limitations, and general health

The between-group effect profile showed that most domain-specific confidence intervals crossed the null, confirming the absence of statistically reliable differences between laminated and molded prostheses for total quality of life, pain, emotion, energy, role limitations, and general health. The two exceptions were limitation of activities, where the mean difference favored the molded group by 7.10 points (95% CI: -11.32 to -2.88; p = 0.002), and social activities, where a smaller but statistically significant 1.30-point difference was observed (95% CI: 0.35 to 2.25; p = 0.010). Total quality-of-life score remained numerically higher in the molded group by 4.70 points, but the confidence interval was wide and crossed zero, indicating that this overall difference was not statistically conclusive.

DISCUSSION

The present study evaluated quality of life in patients with transtibial amputation following rehabilitation with laminated and molded transtibial prostheses. The findings showed that prosthetic intervention was associated with statistically significant improvement across all measured quality-of-life domains, including limitation of activities, social functioning, energy, emotional wellbeing, pain, role limitation due to physical health, role limitation due to emotional health, and general health perception. These findings support the broader rehabilitation literature showing that provision of a functional transtibial prosthesis can substantially improve post-amputation adjustment, mobility, and perceived health status in lower-limb amputees (17-21,24,26,28,30,31). In the current study, improvement was evident not only in inferential testing but also in descriptive health ratings, as participants shifted from predominantly fair or poor self-rated health at baseline to overwhelmingly excellent or very good health after six weeks of prosthetic use.

The observed overall improvement is biologically and clinically plausible. Restoration of limb function through transtibial prosthetic fitting can reduce dependency, improve basic mobility, support reintegration into routine activities, and enhance confidence in social participation. Previous studies have similarly reported that prosthetic rehabilitation contributes to better functional status and quality of life, particularly when the residual limb is adequately fitted and rehabilitation is initiated appropriately (17,19,25,26,30,31). Transtibial amputees generally achieve better rehabilitation outcomes than more proximal amputees because preservation of the knee joint reduces energy expenditure during ambulation and allows more efficient gait retraining (10,11,20,21). The current results are therefore consistent with established biomechanical and rehabilitation principles, as well as with earlier work showing that prosthesis use itself is an important determinant of quality of life in amputee populations (18,24,28,37).

An important finding of this study was that both laminated and molded prostheses produced improvement, but the overall total quality-of-life score did not differ significantly between groups. Although the molded prosthesis group demonstrated a numerically higher posttest total score than the laminated group, the mean difference was not statistically significant. This suggests that, at least within the small sample and short follow-up used in this study, the broader rehabilitation benefit may be related more to successful prosthetic provision and use than to fabrication type alone. This interpretation is aligned with prior literature indicating that functional recovery and quality of life are influenced by multiple interacting factors, including prosthetic use, mobility, pain, social support, and adaptation, rather than any single design feature in isolation (22,24,26-29,34,37). From a clinical perspective, these findings imply that both laminated and molded transtibial prostheses can be acceptable rehabilitation options when appropriately fitted and prescribed.

At the domain level, significant between-group differences were identified for limitation of activities and social activities, while other domains remained comparable. This pattern suggests that prosthetic type may influence certain functional or participation-related outcomes more than global quality of life. However, these domain-specific differences should be interpreted cautiously. The sample size was small, each group contained only 10 participants, and the study did not report standardized domain scoring procedures in sufficient detail to support strong mechanistic conclusions. In addition, several raw response tables in the source manuscript contain wording inconsistencies and category-label irregularities, which reduce confidence in item-level interpretation even though the reported inferential results were retained. Accordingly, the safest interpretation is that both prosthesis types improved quality of life substantially, with only limited evidence of differential benefit between them.

The findings of this study also reinforce the multidimensional nature of quality of life after amputation. Improvement was seen in physical, emotional, and social domains, indicating that prosthetic rehabilitation should not be viewed solely as a mechanical restoration process. Studies by Sinha et al., Asano et al., Samuelsson et al., and others have shown that employment status, mobility, pain burden, prosthesis-related problems, comorbidities, and psychosocial support all influence perceived quality of life after lower-limb amputation (26,28,37). The current results similarly indicate that improved mobility and reduction in role restriction may translate into better social engagement, emotional stabilization, and stronger general health perception. This supports a holistic model of amputee rehabilitation in which the prosthesis is one component of a broader physical and psychosocial adjustment process.

The study has several strengths. It directly compared two commonly used transtibial prosthetic fabrication approaches within the same clinical setting, used the same assessment instrument before and after intervention, and included complete follow-up for all recruited participants. These features allowed straightforward within-group and between-group comparisons. However, important limitations must be acknowledged. The study used convenience non-probability sampling, included only male participants, and had a very small sample size, all of which limit external validity. The follow-up period was only six weeks, which may be insufficient to evaluate longer-term adaptation, durability, and sustained quality-of-life change. The study also did not describe randomization procedures clearly, did not report blinding, and did not address potential confounding factors such as cause of amputation, residual limb condition, socioeconomic status, prior prosthesis exposure, or rehabilitation intensity. These methodological limitations likely reduced the precision of group comparisons and may have obscured true differences between prosthetic types.

Another limitation is the quality of reporting in the original manuscript dataset. Several questionnaire response categories appear linguistically distorted, and some domain labels are inconsistently described across the narrative and tables. Although the statistical tables provided sufficient information to support the main conclusions, clearer reporting of SF-36 scoring, domain transformation, and clinical meaning of score direction would have improved interpretability. Future studies should use larger and more representative samples, include both sexes, apply more rigorous allocation procedures, extend follow-up duration, and report standardized scoring and effect estimates more transparently. Comparative studies incorporating comfort, gait performance, prosthetic satisfaction, and cost-effectiveness would also be valuable in determining whether one transtibial prosthetic fabrication technique offers clinically meaningful long-term advantage over another.

Overall, the present findings indicate that prosthetic rehabilitation in transtibial amputees is associated with substantial short-term improvement in quality of life, while the comparative advantage of laminated versus molded prostheses remains limited and domain-specific in this dataset. The results therefore support the clinical value of timely prosthetic fitting and rehabilitation, while also highlighting the need for better-designed comparative studies to guide evidence-based prosthetic prescription.

CONCLUSION

Both laminated and molded transtibial prostheses were associated with significant short-term improvement in quality of life among male patients with transtibial amputation, with marked gains across physical, emotional, social, pain, and general health domains after six weeks of rehabilitation. Although the molded prosthesis group showed a numerically higher total post-intervention quality-of-life score, the overall between-group difference was not statistically significant, indicating that both prosthetic approaches may provide comparable overall benefit in routine rehabilitation settings. These findings support the importance of prosthetic fitting as a central component of transtibial amputee rehabilitation while suggesting that prosthesis type alone may not be the primary determinant of overall quality-of-life outcome.

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