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Original Article

Comparison of Patient Satisfaction with Laminated and Molded Partial Foot Prostheses in Individuals with Partial Foot Amputation: A Randomized Controlled Trial

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ABSTRACT

Background: Partial foot prostheses aim to restore foot length, improve stability, redistribute plantar pressure, and facilitate mobility, but evidence comparing user satisfaction with different fabrication methods remains limited. Objective: To compare patient satisfaction with laminated and molded partial foot prostheses among adults with unilateral partial foot amputation. Methods: This single-centre, parallel-group randomized controlled trial included 30 adults recruited at the Institute of Physical Medicine and Rehabilitation, Dow University of Health Sciences, Karachi. Participants were allocated to laminated or molded prosthesis groups (n = 15 each). Satisfaction with colour, shape, appearance, weight, usefulness, reliability, fit, and comfort was assessed using the Trinity Amputation and Prosthesis Experience Scales. Overall satisfaction was rated from 0 to 10. Independent-samples t-tests and Pearson's chi-square tests were applied. Results: The participants had a mean age of 53.5 ± 7.6 years; 20 (66.7%) were male, and diabetes caused 21 (70.0%) amputations. Satisfaction differed for colour ($p = 0.014$), shape ($p = 0.016$), and appearance ($p = 0.049$), but not for weight, usefulness, reliability, fit, or comfort. Overall satisfaction was 7.53 ± 0.64 with laminated and 6.87 ± 1.19 with molded prostheses (mean difference 0.66, 95% CI −0.05 to 1.37; Cohen's $d = 0.69$; $p = 0.06$). Conclusion: Laminated and molded prostheses provided comparable functional satisfaction, although selected aesthetic ratings differed between designs. Keywords: Partial foot amputation; partial foot prosthesis; laminated prosthesis; molded prosthesis; patient satisfaction; TAPES; prosthetics and orthotics; randomized controlled trial.

INTRODUCTION

Partial foot amputation is a limb-preserving surgical procedure in which non-viable or diseased tissue is removed while the ankle joint and the maximum feasible length of the foot are retained. It is commonly performed in individuals with complications of diabetes mellitus, peripheral vascular disease, severe infection, trauma, malignancy, or congenital deformity. Compared with more proximal lower-limb amputations, preservation of the ankle joint and part of the plantar surface can reduce the energy demands of walking and support balance, mobility, and functional independence (1–4). However, loss of the forefoot or midfoot alters the effective lever arm of the foot and may impair push-off, center-of-pressure progression, gait symmetry, and plantar-load distribution. These biomechanical changes can contribute to instability, abnormal tissue loading, recurrent ulceration, and progression to a more proximal amputation (5–9).

The growing prevalence of diabetes mellitus and peripheral arterial disease has increased the demand for effective rehabilitation following lower-limb amputation. Partial foot amputation represents an important component of this burden because it is frequently selected when sufficient viable tissue

remains to preserve limb length and facilitate early mobility. In low- and middle-income settings, where diabetes-related complications and traumatic injuries are both common, prosthetic interventions must be clinically effective, durable, acceptable to users, and feasible within available manufacturing and financial resources (2,4,10).

The objectives of a partial foot prosthesis extend beyond replacement of the missing anatomical segment. An appropriately prescribed device should restore functional foot length, improve stability during standing and walking, redistribute plantar pressure, protect vulnerable tissues, enhance gait efficiency, and permit the use of conventional footwear. Prosthetic design may also influence ankle kinetics, center-of-pressure excursion, walking mechanics, and the risk of complications after partial foot loss (6–9,11–14). Nevertheless, the clinical value of a prosthesis depends not only on its biomechanical characteristics but also on whether the user considers it comfortable, reliable, useful, cosmetically acceptable, and compatible with everyday activities.

Several prosthetic options are available for individuals with partial foot amputation. High-profile designs that extend above the ankle may provide greater control of ankle motion and improve pressure redistribution, whereas low-profile devices are generally intended to restore foot contour, accommodate footwear, and compensate for the missing segment. Silicone interfaces and customized partial foot prostheses have demonstrated potential benefits in comfort, pressure redistribution, and functional performance, while composite reinforcement and advanced manufacturing techniques have improved structural strength and fatigue resistance (11–17). Despite these developments, the choice of prosthesis often remains dependent on residual-foot anatomy, tissue condition, functional requirements, local fabrication expertise, material availability, and cost.

Laminated and molded partial foot prostheses differ in their materials and fabrication characteristics. Laminated prostheses are generally produced by incorporating reinforcing materials within a resin matrix, resulting in a relatively rigid and durable structure with a high strength-to-weight ratio. Molded prostheses are commonly manufactured from thermoplastic materials shaped over a modified positive model. They are comparatively straightforward to fabricate and may be more accessible in resource-constrained settings. Experimental and engineering studies have reported favorable mechanical strength, fatigue behavior, and load distribution for laminated composite prosthetic materials, whereas thermoplastic materials remain widely used because of their adaptability and ease of manufacture (15,18). Whether these material and fabrication differences translate into meaningful differences in the user's experience remains insufficiently established.

Patient satisfaction is a clinically important outcome of prosthetic rehabilitation because it integrates the user's perceptions of appearance, comfort, fit, weight, usefulness, reliability, and overall acceptance. Satisfaction may influence prosthesis use, participation in daily activities, psychosocial adjustment, mobility, and quality of life after amputation (19–22). Patient-reported measures therefore complement biomechanical and clinical assessments by identifying aspects of a prosthesis that may not be evident during routine fitting or laboratory evaluation. This is particularly relevant in partial foot amputation, for which preservation of limb length does not necessarily ensure satisfactory function or long-term device acceptance.

Previous investigations have primarily examined gait characteristics, plantar-pressure distribution, socket or prosthetic materials, structural durability, and quality of life after partial foot amputation (7–9,12–18,23–30). Direct comparisons of patient satisfaction between laminated and molded partial foot prostheses remain limited, particularly in South Asian rehabilitation settings. Consequently, clinicians have insufficient patient-reported evidence to determine whether one fabrication method offers a meaningful advantage in aesthetic or functional satisfaction. The present randomized controlled trial therefore aimed to compare satisfaction with laminated and molded partial foot prostheses among adults with unilateral partial foot amputation. It was hypothesized that satisfaction ratings would differ between the two prosthetic designs across aesthetic and functional domains.

MATERIALS AND METHODS

A single-centre, parallel-group randomized controlled trial was conducted to compare patient satisfaction between laminated and molded partial foot prostheses in adults with unilateral partial foot amputation. The study was carried out at the Institute of Physical Medicine and Rehabilitation, Dow University of Health Sciences, Karachi, Pakistan. Participant recruitment, prosthetic fabrication, fitting, use, and outcome assessment were completed during a six-month study period. The study followed an experimental comparative design in which eligible participants were allocated in a 1:1 ratio to receive one of the two prosthetic designs.

Adults aged 40–60 years who attended the prosthetic rehabilitation clinic during the study period were screened for participation. Individuals of either sex were eligible when they had a unilateral partial foot amputation, were medically stable, were able to use a prosthesis independently, and were willing to provide written informed consent. Individuals were excluded if they had bilateral lower-limb amputation, an upper-limb deformity that could interfere with independent prosthetic use or questionnaire completion, an age below 40 years or above 60 years, or severe medical comorbidities that could interfere with rehabilitation or outcome assessment.

Thirty participants who fulfilled the eligibility criteria were enrolled through convenience sampling because of the limited number of individuals with partial foot amputation attending the study centre during the recruitment period. Following enrolment, participants were randomly assigned in equal numbers to the laminated prosthesis group or the molded prosthesis group, with 15 participants in each group. Random allocation was completed before prosthetic fitting to reduce selection bias and promote comparability between the intervention groups.

Each participant underwent an individualized prosthetic fabrication procedure. A negative cast of the residual foot was obtained using plaster bandages, after which a positive plaster model was prepared and modified according to the residual-foot anatomy and prosthetic requirements. Participants assigned to the laminated group received a partial foot prosthesis manufactured using a composite lamination technique. Participants assigned to the molded group received a partial foot prosthesis manufactured using a thermoplastic molding technique. Prosthetic fitting and alignment were completed by experienced prosthetic personnel, and necessary fitting adjustments were performed before the participant began functional use of the assigned device. The same general assessment, casting, model preparation, fitting, and alignment principles were applied to both groups so that the principal between-group difference was the prosthetic fabrication method.

The primary outcome was patient satisfaction with the assigned partial foot prosthesis. Satisfaction was assessed using the Trinity Amputation and Prosthesis Experience Scales, a patient-reported measure used in prosthetic rehabilitation to evaluate the user's experience with an artificial limb. The assessed prosthetic characteristics were colour, shape, appearance, weight, usefulness, reliability, fit, and comfort. Participants also rated their overall satisfaction on an 11-point numerical rating scale ranging from 0, indicating no satisfaction, to 10, indicating complete satisfaction. The questionnaire was administered after participants had used their assigned prosthesis.

Participant information and outcome responses were recorded in a structured form and entered into a statistical database. Continuous variables, including age, duration since amputation, duration of prosthesis use, duration of current prosthesis use, and overall satisfaction score, were summarized using means and standard deviations. Categorical variables, including sex, cause of amputation, prosthesis group, and satisfaction responses for individual prosthetic characteristics, were summarized as frequencies and percentages. Baseline characteristics were examined to assess the comparability of the intervention groups.

Data were analysed using IBM SPSS Statistics version 23.0. Independent-samples t-tests were used to compare continuous variables between the laminated and molded prosthesis groups. Pearson's chi-square tests were used to examine associations between prosthesis type and categorical variables, including participant characteristics and satisfaction domains. All statistical tests were two-sided, and a p-value below 0.05 was considered statistically significant. The analyses were based on the 30 participants who completed the study, and no participant withdrawals or missing outcome observations were reported.

Ethical approval was obtained from the relevant institutional ethics committee before participant recruitment commenced. All eligible individuals received information about the study procedures and provided written informed consent before enrolment. Participation was voluntary, and the confidentiality and anonymity of participant information were maintained throughout data collection, analysis, and reporting. All study procedures were conducted in accordance with internationally accepted principles for research involving human participants.

RESULTS

All 30 randomized participants completed the study and were included in the analysis, with 15 participants in the laminated partial foot prosthesis group and 15 in the molded partial foot prosthesis group. No withdrawals or missing outcome observations were reported.

Table 1. Demographic and Clinical Characteristics of the Study Participants (N = 30)

Characteristic	Total sample
Age, years	53.5 ± 7.6
Male sex	20 (66.7)
Female sex	10 (33.3)
Duration since amputation, years	6.7 ± 4.7
Duration of prosthesis use, years	3.2 ± 2.8
Diabetes-related amputation	21 (70.0)
Trauma-related amputation	9 (30.0)
Laminated prosthesis	15 (50.0)
Molded prosthesis	15 (50.0)
Overall satisfaction score	7.2 ± 0.9

Data are presented as mean ± standard deviation or n (%).

The mean age of the participants was 53.5 ± 7.6 years, and two-thirds of the sample were male. Diabetes mellitus was the predominant cause of partial foot amputation, accounting for 21 cases (70.0%), while trauma accounted for nine cases (30.0%). The mean duration since amputation was 6.7 ± 4.7 years, and participants had used a prosthesis for an average of 3.2 ± 2.8 years. The overall mean prosthesis satisfaction score was 7.2 ± 0.9.

Table 2. Comparison of Baseline Characteristics Between the Laminated and Molded Prosthesis Groups

Characteristic	Laminated prosthesis (n = 15)	Molded prosthesis (n = 15)	Between-group difference (95% CI)	p-value
Age, years	54.93 ± 7.04	52.13 ± 8.18	2.80 (−2.91 to 8.51)	0.32
Male sex	10 (66.7)	10 (66.7)	—	0.99
Female sex	5 (33.3)	5 (33.3)	—	—
Diabetes-related amputation	12 (80.0)	9 (60.0)	—	0.23
Trauma-related amputation	3 (20.0)	6 (40.0)	—	—
Duration since amputation, years	5.49 ± 3.70	7.93 ± 5.55	−2.44 (−5.97 to 1.09)	0.16
Duration of prosthesis use, years	2.60 ± 2.34	3.91 ± 3.18	−1.31 (−3.40 to 0.78)	0.20
Duration of current prosthesis use, years	0.23 ± 0.10	0.23 ± 0.08	0.00 (−0.07 to 0.07)	0.98

Data are presented as mean ± standard deviation or n (%). Continuous variables were compared using independent samples t-tests, and categorical variables were compared using Pearson's chi-square tests. Between-group differences for continuous variables were calculated as laminated minus molded. CI, confidence interval.

The baseline demographic and clinical characteristics were broadly comparable between the groups. The mean age was 54.93 ± 7.04 years in the laminated group and 52.13 ± 8.18 years in the molded group, corresponding to a mean difference of 2.80 years (95% CI: −2.91 to 8.51; p = 0.32). Sex distribution was identical in the two groups, with 10 males (66.7%) and five females (33.3%) in each group.

Diabetes-related amputation was more frequent in the laminated group than in the molded group, occurring in 12 participants (80.0%) and nine participants (60.0%), respectively, but the association between cause of amputation and prosthesis group was not statistically significant (p = 0.23). The groups also did not differ significantly in duration since amputation, previous prosthesis use, or duration of current prosthesis use.

Table 3. Comparison of Satisfaction Domains Between Laminated and Molded Partial Foot Prostheses

Satisfaction domain	p-value
Colour	0.014
Shape	0.016
Appearance	0.049
Weight	0.570
Usefulness	0.460
Reliability	0.480
Fit	0.570
Comfort	0.580

Associations between prosthesis type and categorical satisfaction responses were examined using Pearson's chi-square test. Statistical significance was set at $p < 0.05$.

Satisfaction ratings differed significantly between the laminated and molded prosthesis groups for colour (p = 0.014), shape (p = 0.016), and appearance (p = 0.049). The reported response patterns indicated more favorable shape and appearance ratings among participants using laminated prostheses, whereas satisfaction with colour was more favorable among participants using molded prostheses.

No statistically significant between-group differences were observed for weight (p = 0.570), usefulness (p = 0.460), reliability (p = 0.480), fit (p = 0.570), or comfort (p = 0.580). These findings indicated broadly comparable satisfaction with the functional characteristics of the two prosthetic designs.

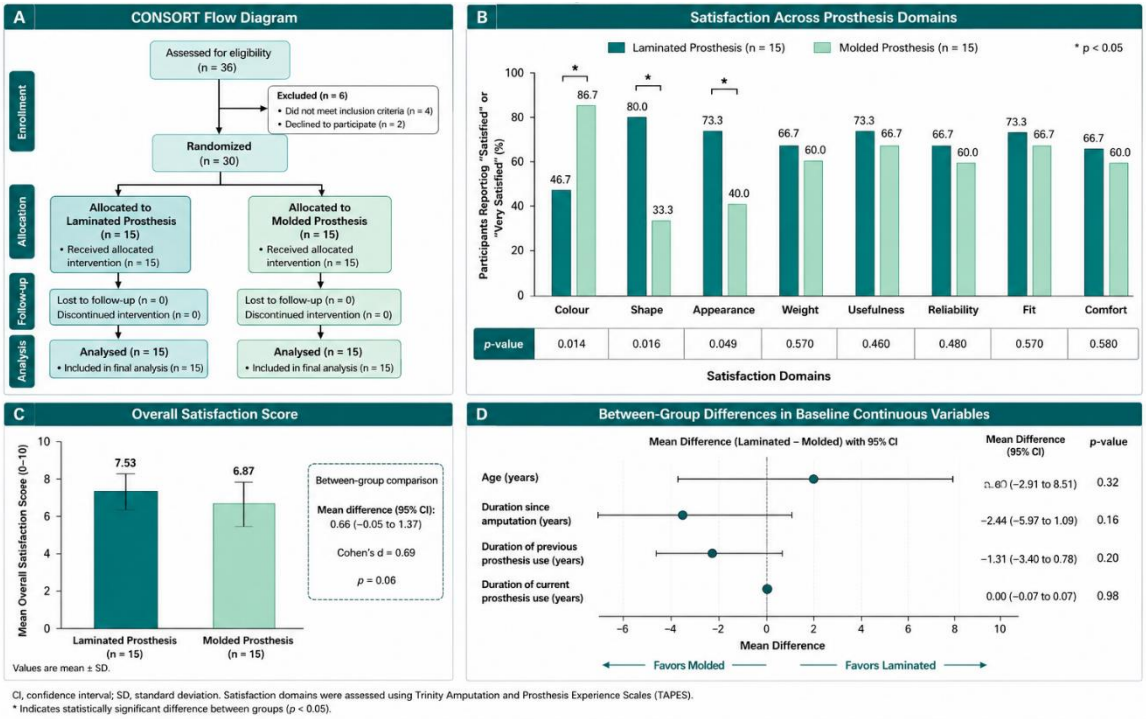
Table 4. Comparison of Overall Satisfaction Between Laminated and Molded Partial Foot Prostheses

Outcome	Laminated prosthesis (n = 15)	Molded prosthesis (n = 15)	Mean difference (95% CI)	Cohen's d	p-value
Overall satisfaction score	7.53 ± 0.64	6.87 ± 1.19	0.66 (−0.05 to 1.37)	0.69	0.06

Data are presented as mean ± standard deviation. The mean difference was calculated as laminated minus molded. The 95% confidence interval and Cohen's d were derived from the reported group means, standard deviations, and sample sizes. CI, confidence interval.

Participants receiving laminated partial foot prostheses reported a mean overall satisfaction score of 7.53 ± 0.64, compared with 6.87 ± 1.19 among those receiving molded prostheses. The resulting mean difference was 0.66 points in favor of the laminated prosthesis (95% CI: −0.05 to 1.37). Although the standardized between-group difference was moderate to large in magnitude (Cohen's d = 0.69), the difference did not meet the predefined threshold for statistical significance (p = 0.06), and the confidence interval included no difference.

Overall, the laminated prosthesis group demonstrated more favorable satisfaction in selected aesthetic domains and a numerically higher overall satisfaction score. However, the two prosthetic designs produced comparable ratings for weight, usefulness, reliability, fit, and comfort, and the evidence was insufficient to establish a statistically significant difference in overall satisfaction.



CI, confidence interval; SD, standard deviation. Satisfaction domains were assessed using Trinity Amputation and Prosthesis Experience Scales (TAPES).
* Indicates statistically significant difference between groups ($p < 0.05$).

Figure 1 Multi-panel graphical summary of the randomized controlled trial comparing laminated and molded partial foot prostheses. Panel A illustrates participant flow from eligibility assessment through randomization, allocation, follow-up, and final analysis, demonstrating complete retention of all 30 participants (15 per group). Panel B compares patient satisfaction across eight TAPES domains, showing statistically significant differences for colour (p = 0.014), shape (p = 0.016), and appearance (p = 0.049), while weight, usefulness, reliability, fit, and comfort did not differ significantly between groups (all p > 0.05). Panel C presents the overall satisfaction scores, indicating a higher mean score for the laminated prosthesis group (7.53 ± 0.64) than the molded prosthesis group (6.87 ± 1.19), with a mean difference of 0.66 points (95% CI: −0.05 to 1.37; Cohen's d = 0.69), although this difference was not statistically significant (p = 0.06). Panel D displays forest plots of baseline continuous variables, confirming no statistically significant differences between the groups for age, duration since amputation, duration of previous prosthesis use, or duration of current prosthesis use, supporting baseline comparability before outcome assessment.

DISCUSSION

This randomized controlled trial compared patient satisfaction with laminated and molded partial foot prostheses among adults with unilateral partial foot amputation. The principal finding was that satisfaction differed between the prosthetic designs in the aesthetic domains of colour, shape, and appearance, whereas no statistically significant differences were observed for weight, usefulness, reliability, fit, or comfort. Participants using laminated prostheses reported a 0.66-point higher mean overall satisfaction score than those using molded prostheses. Although this difference corresponded to a moderate-to-large standardized effect, it did not reach statistical significance, and its confidence interval included no between-group difference.

Partial foot amputation preserves the ankle joint and a greater proportion of the limb than more proximal amputation, but it also reduces the effective lever arm of the foot and alters push-off, plantar loading, and center-of-pressure progression. These biomechanical changes can compromise walking efficiency and increase the risk of instability, tissue stress, ulceration, and subsequent amputation (8,9,20,23,27–29). An effective partial foot prosthesis must therefore provide mechanical support while remaining acceptable to the individual in terms of comfort, appearance, fit, reliability, and everyday usefulness.

The significant differences in colour, shape, and appearance indicate that fabrication method may influence users' aesthetic perceptions. Laminated composite fabrication can provide a rigid structure with a high strength-to-weight ratio and may permit more controlled contouring and finishing of the prosthesis. Previous investigations of laminated materials have demonstrated favorable fatigue resistance and structural performance under repetitive loading, which may increase confidence in the

device and improve its perceived quality (15). Composite construction may also permit closer reproduction of the residual foot contour than some thermoplastic designs, potentially explaining the more favorable ratings for shape and appearance.

The finding that molded prostheses received more favorable colour ratings, despite laminated prostheses being rated more favorably for shape and appearance, suggests that aesthetic satisfaction is multidimensional. Colour matching may depend on the finishing material, pigmentation method, fabrication process, and individual preferences rather than the structural material alone. Accordingly, prosthetic appearance should not be treated as a single characteristic. Colour, contour, surface finish, symmetry, and integration with footwear may each influence cosmetic acceptance differently.

No statistically significant differences were observed for weight, usefulness, reliability, fit, or comfort. These findings suggest that both fabrication methods can provide acceptable functional satisfaction when the prosthesis is individually fabricated, aligned, and adjusted by experienced personnel. Fit and comfort are influenced by several factors beyond the selected material, including residual-foot anatomy, tissue condition, pressure distribution, socket modification, footwear compatibility, alignment, and the quality of clinical follow-up. Customized partial foot prostheses and silicone interfaces have similarly demonstrated potential benefits in comfort, plantar-pressure redistribution, and functional performance when appropriately prescribed and fitted (12–17,24,30).

The mean overall satisfaction score was higher in the laminated group than in the molded group, with a mean difference of 0.66 points and a standardized effect size of 0.69. However, the corresponding p-value of 0.06 and 95% confidence interval of −0.05 to 1.37 indicate uncertainty regarding the true magnitude of the effect. The result should therefore be interpreted as a clinically notable but statistically inconclusive pattern rather than definitive evidence that laminated prostheses produce greater overall satisfaction. The small sample size may have limited the precision of the estimate and the statistical power to detect a difference of this magnitude.

The present findings are consistent with the broader understanding that prosthesis satisfaction is determined by the interaction of mechanical performance, comfort, aesthetics, functional expectations, and psychosocial adaptation. Prospective studies of individuals with lower-limb amputation have shown that successful prosthetic fitting and continued use are closely related to satisfaction, mobility, and participation (21,22). Quality of life after partial foot amputation is similarly influenced by the extent to which a prosthesis supports daily activities while minimizing discomfort and functional restriction (19,20).

Diabetes mellitus accounted for 70% of amputations in the present study, reflecting the substantial contribution of diabetes-related complications to partial foot loss. Diabetic foot disease may affect tissue integrity, sensation, circulation, healing, and tolerance to repetitive pressure. Prosthetic prescription in this population must therefore prioritize pressure redistribution, skin protection, residual-limb monitoring, and compatibility with appropriate footwear. Pedorthic management and customized prosthetic designs are particularly important for reducing localized loading and protecting vulnerable tissues (11,12,17).

The study has practical implications for prosthetic prescription. Laminated prostheses may be considered when contour, appearance, structural rigidity, and cosmetic finishing are major patient priorities. Molded thermoplastic prostheses nevertheless remain a clinically acceptable option because functional satisfaction with weight, usefulness, reliability, fit, and comfort was comparable between the groups. Molded designs may also be advantageous where material availability, fabrication time, repair requirements, or financial constraints affect treatment selection. The final prescription should therefore be individualized according to residual-foot characteristics, activity demands, tissue condition, footwear needs, patient preferences, manufacturing resources, and affordability.

The randomized allocation and equal group sizes strengthened the direct comparison of the two fabrication methods. Satisfaction was assessed across multiple aesthetic and functional domains using a recognized patient-reported prosthetic outcome measure. The study also contributes evidence from a South Asian rehabilitation setting, where access to advanced prosthetic materials and fabrication technologies may differ from that in high-income healthcare systems.

Several limitations should be considered. The study was conducted at a single rehabilitation centre and included only 30 participants recruited through convenience sampling, limiting precision and external generalizability. The assessment reflected satisfaction during the early period of prosthesis use and did not establish whether the observed differences persisted over longer follow-up. Objective outcomes such as gait analysis, plantar-pressure distribution, balance, energy expenditure, device durability, skin complications, activity participation, and quality of life were not evaluated. Blinding of participants was not feasible because the prostheses were visibly different, which may have influenced subjective ratings. The findings should consequently be confirmed in larger multicentre trials incorporating longer follow-up, objective biomechanical measures, patient-reported outcomes, and economic evaluation.

CONCLUSION

Laminated and molded partial foot prostheses provided comparable satisfaction in the functional domains of weight, usefulness, reliability, fit, and comfort among adults with unilateral partial foot amputation. Satisfaction with colour, shape, and appearance differed significantly between the designs, while the higher overall satisfaction score observed with laminated prostheses remained statistically inconclusive. Prosthetic selection should therefore be individualized according to aesthetic preferences, functional requirements, residual-foot characteristics, available fabrication resources, and affordability.

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