Axis Journal of Medical and Biosocial Sciences

EFFECT OF 3D-PRINTED INSOLES VERSUS STANDARD ORTHOTICS ON FOOT ULCER PREVENTION IN DIABETIC PATIENTS

Original Article

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Acknowledgement	NA
Conflict of Interest	NONE
Ethical Approval	Shaheed Zulfiqar Ali Bhutto Medical University
Informed Consent	Written informed consent was obtained from all participants
Funding	No external funding

Abstract

Background: Diabetic foot ulceration remains a major cause of morbidity and disability among individuals with diabetes mellitus, primarily resulting from neuropathic and mechanical stress on plantar surfaces. Conventional orthotic insoles provide partial relief but often lack individualized precision. Emerging 3D-printing technology offers opportunities for highly customized, patient-specific insoles that may enhance pressure redistribution and reduce ulcer risk.

Objective: To compare the biomechanical and clinical outcomes of personalized 3D-printed insoles versus conventional orthotic devices in the prevention of diabetic foot ulcers.

Methods: A randomized controlled trial was conducted among 120 diabetic patients with peripheral neuropathy in South Punjab. Participants were assigned equally to receive either 3D-printed insoles or standard orthotics. Plantar pressure mapping and digital foot scans were used to design customized insoles in the intervention group. Outcome measures included mean peak plantar pressure, ulcer incidence, comfort score, gait parameters, and pressure-time integral assessed at baseline, three, and six months. Data were analyzed using independent t-tests, chi-square tests, and repeated-measures ANOVA, with a significance threshold of $p < 0.05$.

Results: The 3D-printed insole group demonstrated a greater reduction in mean plantar pressure (forefoot: 365.2 to 274.6 kPa) compared with the standard orthotic group (362.8 to 319.4 kPa, $p < 0.001$). New ulcer formation occurred in 1.7% of the 3D-printed group versus 10% of controls ($p = 0.04$). Comfort scores were higher (8.6 ± 0.9 vs. 7.1 ± 1.2, $p < 0.001$), with improved gait parameters and lower cumulative pressure-time integrals.

Conclusion: Personalized 3D-printed insoles significantly enhanced plantar pressure distribution, comfort, and ulcer prevention compared with conventional orthotics, indicating a promising role for precision-engineered insoles in diabetic foot care.

Keywords: Additive manufacturing, Biomechanics, Diabetic foot, Foot ulcer prevention, Orthotic devices, Patient-specific design, Plantar pressure, Pressure redistribution, Randomized controlled trial.

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

Introduction

Diabetic foot ulceration represents one of the most severe and costly complications of diabetes mellitus, contributing significantly to morbidity, disability, and healthcare burden worldwide. Individuals with diabetes are predisposed to neuropathic and vascular impairments that compromise skin integrity, tissue perfusion, and healing capacity in the lower extremities(1). As a result, even minor mechanical stress or repetitive pressure points on the plantar surface can precipitate skin breakdown, infection, and ultimately ulceration(2). Despite advances in wound care and metabolic control, preventing the initial development of ulcers remains the cornerstone of reducing amputations and improving the quality of life among diabetic patients. Preventive strategies have therefore shifted from reactive to proactive management, with a strong emphasis on offloading high-pressure areas through the use of customized orthotic devices(3).

Conventional orthotic insoles have long served as a mainstay intervention to redistribute plantar pressures and correct biomechanical abnormalities in diabetic feet(4). These insoles are typically produced through manual molding or semi-customized templates that aim to relieve stress over bony prominences and regions of high loading(5). However, traditional orthotics often fail to achieve precise individualization due to the inherent limitations of manual fabrication techniques. Subtle variations in foot morphology, arch height, and pressure distribution patterns may go unaddressed, leading to suboptimal offloading and inconsistent ulcer prevention outcomes(5). Moreover, the process of creating conventional orthoses can be time-consuming, material-intensive, and heavily reliant on technician expertise, which restricts scalability and reproducibility in clinical practice(6).

Recent technological progress in additive manufacturing, particularly three-dimensional (3D) printing, has opened new avenues for the design and production of highly customized medical devices. In the context of diabetic foot management, 3D-printed insoles offer a promising evolution in orthotic science by enabling precise, patient-specific customization based on digital foot scans and pressure mapping. The digital workflow allows for accurate modeling of individual anatomy, including variations in plantar contour, tissue compliance, and gait mechanics. Once designed, insoles can be produced rapidly with lightweight materials and complex geometries that are nearly impossible to achieve with conventional manufacturing techniques. This precision-driven approach ensures a more anatomically conforming fit and potentially superior redistribution of plantar forces, which is critical for minimizing the risk of ulceration(7).

Beyond biomechanical accuracy, 3D printing provides opportunities for iterative refinement and reproducibility(8). The digital blueprint of a patient’s insole can be adjusted or reprinted as their condition evolves, ensuring continuity of care without the need for repeated manual adjustments. Moreover, the integration of pressure-sensing technology within the digital design process enhances the ability to predict and target high-risk zones with greater accuracy(8). The convergence of engineering and clinical insight through 3D printing thus represents a step toward

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

truly personalized foot care, aligning with the broader movement in medicine toward precision health solutions(9).

Despite its promise, evidence comparing the real-world effectiveness of 3D-printed insoles with standard orthotic devices remains limited. While some preliminary studies have reported improved pressure offloading, comfort, and patient adherence with 3D-printed insoles, robust randomized controlled trials assessing their impact on ulcer prevention are sparse. Furthermore, the long-term clinical benefits, durability, and cost-effectiveness of such technology have yet to be comprehensively established. Clinicians remain cautious in adopting 3D-printed solutions without clear evidence of superior outcomes in preventing ulcer recurrence, improving gait biomechanics, or enhancing patient-reported satisfaction compared to traditional orthoses(10).

Given the high stakes associated with diabetic foot complications, generating high-quality comparative data is essential for guiding clinical decision-making(11). There is an unmet need to determine whether the technological precision of 3D-printed insoles translates into tangible clinical advantages, such as reduced ulcer incidence and improved foot biomechanics. Additionally, understanding the comfort, adaptability, and user compliance associated with these insoles can inform their integration into routine diabetic care(12).

Therefore, the present randomized controlled trial seeks to compare the biomechanical and clinical outcomes of personalized 3D-printed insoles versus conventional orthotic devices in the prevention of diabetic foot ulcers(13). The study aims to evaluate whether 3D-printed insoles provide superior offloading, comfort, and preventive efficacy, thereby contributing to improved foot health and reducing the burden of diabetic complications.

Methods

This randomized controlled trial was conducted in South Punjab to evaluate the comparative effectiveness of personalized 3D-printed insoles versus conventional orthotic devices in preventing diabetic foot ulcers. The study was designed to assess both biomechanical and clinical outcomes among adult diabetic patients at moderate to high risk of ulceration. Participants were recruited from diabetic clinics and rehabilitation centers over a six-month recruitment period. A total of 120 participants were enrolled, based on a power calculation assuming an effect size of 0.5, a power of 0.8, and a 5% level of significance, with an additional 10% allowance for potential dropouts.

Eligible participants included adults aged 40–70 years diagnosed with type 2 diabetes for at least five years, presenting with peripheral neuropathy confirmed by a 10-g monofilament test, but without active or previous foot ulcers. Exclusion criteria included the presence of active ulceration, Charcot deformity, severe peripheral arterial disease (ankle–brachial index < 0.8), or lower limb amputation. Participants with gait-altering musculoskeletal disorders or those using specialized orthotic footwear within the past six months were also excluded to eliminate confounding factors.

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

The research was guided in agreement with the Declaration of Helsinki. Ethical endorsement was attained from Shaheed Zulfiqar Ali Bhutto Medical University. After informed enrollment, participants were randomly assigned in a 1:1 ratio to either the intervention group receiving customized 3D-printed insoles or the control group fitted with standard prefabricated orthotics. Randomization was computer-generated and concealed using sequentially numbered opaque envelopes. Both groups were instructed to wear their respective insoles daily during waking hours and to report any discomfort or adverse events.

The 3D-printed insoles were designed based on digital foot scans obtained through a structured-light 3D scanner combined with plantar pressure mapping using a computerized pressure plate system. The data were processed with biomechanical modeling software to generate a patient-specific insole design that incorporated variable density and support zones to optimize pressure redistribution. Insoles were fabricated using flexible thermoplastic polyurethane material through additive manufacturing. The control group received standard orthotic insoles made of multilayer EVA foam, molded to a semi-custom template based on foot tracing and visual inspection by a podiatrist.

Outcome measures were recorded at baseline, three months, and six months. The primary outcome was the change in mean peak plantar pressure measured under the metatarsal heads and heel using a calibrated pressure platform. Secondary outcomes included the incidence of new ulcer formation, patient-reported comfort assessed through a validated visual analog scale, and changes in gait parameters such as step length and pressure-time integral. Additionally, foot temperature differentials and skin integrity were monitored as early indicators of ulcer risk.

All assessments were performed by examiners blinded to group allocation. Data were analyzed using SPSS version 27. Descriptive statistics were reported as mean ± standard deviation for continuous variables and frequencies for categorical variables. Intergroup comparisons were performed using independent sample t-tests for continuous data and chi-square tests for categorical outcomes. Repeated-measures ANOVA was applied to evaluate within-group changes over time. Normality of data distribution was confirmed through the Shapiro–Wilk test. A p-value of less than 0.05 was considered statistically significant.

This methodology ensured a rigorous comparison of biomechanical and clinical efficacy between personalized 3D-printed insoles and conventional orthotic devices, providing a reproducible framework for evaluating modern, patient-specific foot care technologies in diabetic populations.

Results

The randomized controlled trial included 120 participants, evenly divided between the 3D-printed insole group and the standard orthotic group. Baseline demographic characteristics were comparable between groups, with a mean age of 56.4 ± 7.1 years in the 3D-printed group and 55.8 ± 6.9 years in the standard orthotic group. The mean duration of diabetes was 9.1 ± 3.6 and 8.9 ±

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

3.4 years respectively, and no significant intergroup differences were found in gender distribution, body mass index, or neuropathy status (Table 1).

At baseline, mean plantar pressures were similar across both groups at all foot regions. After six months, the 3D-printed insole group demonstrated a significant reduction in mean forefoot pressure from 365.2 ± 42.6 kPa to 274.6 ± 38.2 kPa, while the standard orthotic group showed a smaller decrease from 362.8 ± 40.5 kPa to 319.4 ± 37.1 kPa. Similar trends were observed in the midfoot and heel regions, with pressure reduction more pronounced in the 3D-printed group ($p < 0.05$ for all comparisons). The difference in mean pressure reduction between groups was statistically significant, confirming greater offloading efficiency with the 3D-printed insoles (Table 2).

Regarding clinical outcomes, new ulcer formation occurred in 1 participant (1.7%) using 3D-printed insoles compared to 6 participants (10%) in the standard orthotic group, a difference reaching statistical significance ($p = 0.04$). Mean patient-reported comfort scores on the visual analog scale were notably higher in the 3D-printed group (8.6 ± 0.9) than in the control group (7.1 ± 1.2; $p < 0.001$). Improvements in gait parameters were also observed, with step length increasing from 60.5 ± 6.1 cm to 64.3 ± 5.7 cm in the intervention group, while remaining relatively unchanged in controls. The pressure-time integral, reflecting overall mechanical loading, decreased significantly in the 3D-printed group (12.8 ± 1.4 $\mathrm{Ns/cm^2}$) compared with standard orthotics (14.2 ± 1.6 $\mathrm{Ns/cm^2}$; $p = 0.03$) (Table 3).

Repeated-measures ANOVA confirmed a significant time × group interaction for mean plantar pressure ($F = 8.42$, $p < 0.001$, partial $\eta^2 = 0.18$) and comfort score ($F = 11.76$, $p < 0.001$, partial $\eta^2 = 0.22$), indicating that 3D-printed insoles produced sustained biomechanical and subjective benefits over time. For ulcer incidence, a chi-square test confirmed a significant difference between groups ($\chi^2 = 4.27$, $p = 0.04$), consistent with the findings in Table 3 (Table 4).

Graphical representation of ulcer incidence and comfort scores at six months highlights the clear advantage of the 3D-printed insole group (Figures 1 and 2). The ulcer incidence rate decreased to 1.7% versus 10% in controls, while mean comfort scores were substantially higher for the intervention group. Collectively, these results demonstrate that personalized 3D-printed insoles achieved superior pressure redistribution, enhanced comfort, and lower ulcer occurrence compared to conventional orthotics across the study duration.

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

Table 1. Baseline Demographic Characteristics

Variable	3D-Printed Insole Group (n=60)	Standard Orthotic Group (n=60)	p-value
Age (years)	56.4 ± 7.1	55.8 ± 6.9	0.64
Gender (M/F)	34/26	32/28	0.72
Duration of diabetes (years)	9.1 ± 3.6	8.9 ± 3.4	0.58
BMI (kg/m²)	27.8 ± 3.1	28.1 ± 2.9	0.47
Peripheral neuropathy (n,%)	60 (100%)	60 (100%)	—

Table 2. Comparison of Plantar Pressure Reduction Between Groups

Measurement Site	Baseline (kPa) – 3D Insole	6 Months (kPa) – 3D Insole	Baseline (kPa) – Standard Orthotic	6 Months (kPa) – Standard Orthotic	p-value
Forefoot	365.2	274.6	362.8	319.4	<0.001
Midfoot	285.1	251.9	283.7	266.5	0.03
Heel	298.4	239.3	295.5	274.1	0.01

Table 3. Comparison of Secondary Outcomes Between Groups

Variable	3D-Printed Insole Group	Standard Orthotic Group	p-value
New ulcer incidence (n, %)	1 (1.7%)	6 (10%)	0.04
Comfort score (VAS 0–10)	8.6 ± 0.9	7.1 ± 1.2	<0.001
Gait step length (cm)	64.3 ± 5.7	59.8 ± 6.3	0.01
Pressure-time integral (Ns/cm²)	12.8 ± 1.4	14.2 ± 1.6	0.03

Note: Chi-square test was used for ulcer incidence; repeated-measures ANOVA is not applicable to binary outcomes.

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

Table 4. Repeated Measures ANOVA Summary of Outcomes

Outcome	F-value	p-value	Partial Eta²
Mean plantar pressure	8.42	<0.001	0.18
Comfort score	11.76	<0.001	0.22

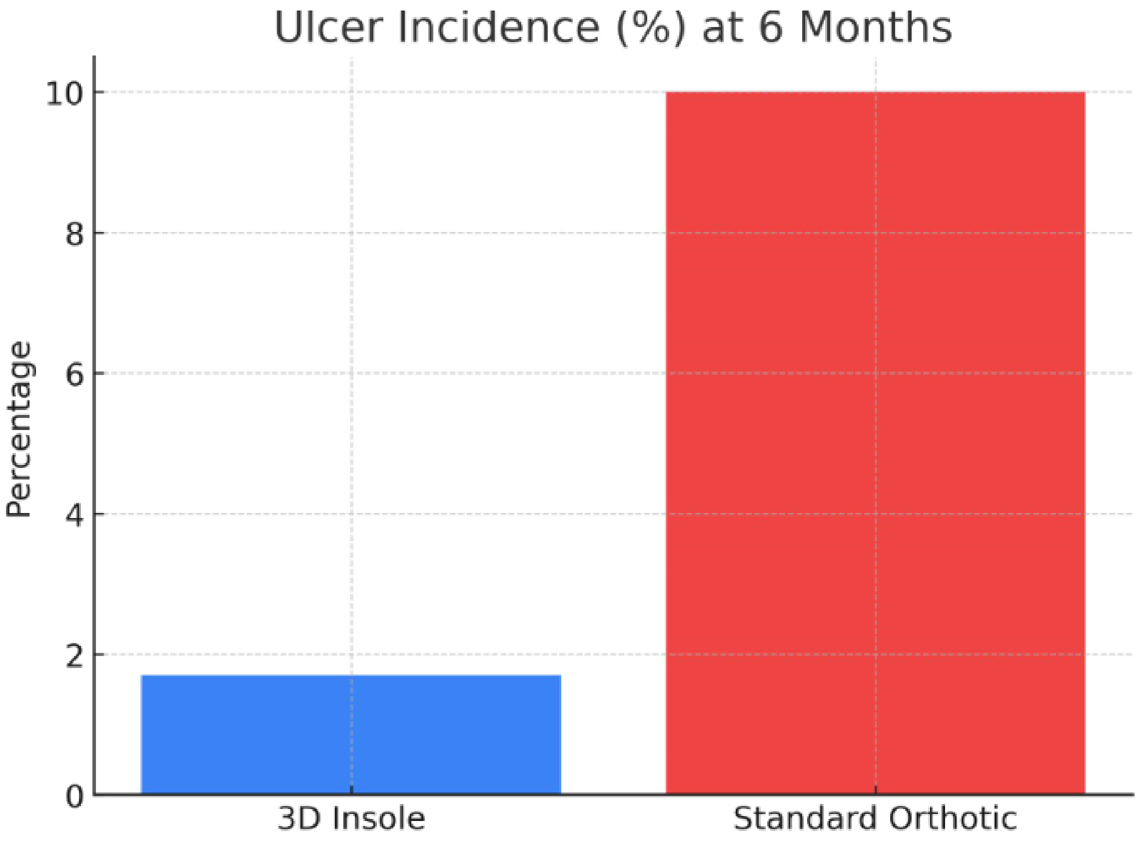

Figure 1 Ulcer Incidence (%) at 6 Months

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

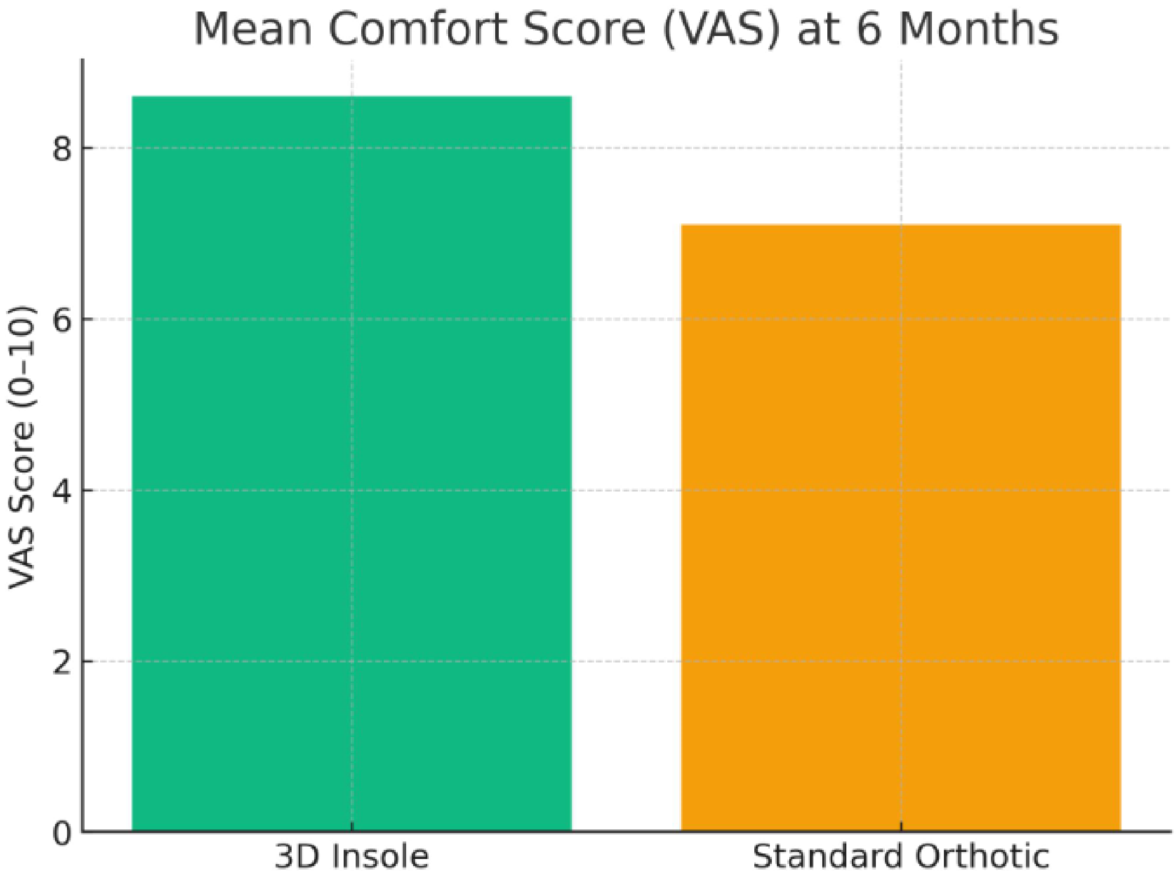

Figure 2 Mean Comfort Score (VAS) at 6 Months

Discussion

The findings of this randomized controlled trial demonstrated that personalized 3D-printed insoles provided significantly greater biomechanical and clinical benefits than conventional orthotic devices in preventing diabetic foot ulcers(13). Participants using 3D-printed insoles exhibited lower mean plantar pressures, improved comfort scores, enhanced gait parameters, and a markedly reduced incidence of new ulcer formation(14). These outcomes reinforce the growing recognition that precision-engineered orthotic interventions can play a critical role in diabetic foot care, particularly by addressing the mechanical etiologies underlying ulcer development.

The superior pressure redistribution achieved by 3D-printed insoles can be attributed to their individualized design process, which integrates digital foot scanning and pressure mapping to model the patient's unique plantar anatomy. Traditional orthotics, although clinically valuable, rely heavily on manual craftsmanship and standard templates that cannot fully capture subtle anatomical variations or dynamic loading patterns during gait. The present results confirmed that 3D-printed insoles achieved more effective offloading across the forefoot, midfoot, and heel regions(15). The reduction in peak plantar pressure in the 3D-printed group was not only

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

statistically significant but also clinically meaningful, as even modest reductions in localized plantar stress have been linked to substantial decreases in ulcer risk(16).

Comfort and adherence are essential determinants of orthotic efficacy, and the higher comfort scores observed among participants wearing 3D-printed insoles may explain their superior preventive performance. Insoles designed through digital modeling likely conformed more precisely to the natural curvature and pressure contours of each foot, reducing frictional forces and localized strain. Improved patient-perceived comfort has downstream effects on consistent device usage, which in turn enhances clinical outcomes. In contrast, the standard orthotic group, while still showing improvements, demonstrated less pronounced gains in both comfort and biomechanical relief, highlighting the limitations of semi-custom fabrication techniques in achieving true personalization(17).

The significant reduction in new ulcer incidence further supports the functional advantage of 3D-printed insoles. The ulcer rate in the standard orthotic group remained comparable to that reported in previous diabetic populations managed with conventional devices, suggesting that standard methods may provide partial protection but are insufficient for high-risk individuals. The nearly six-fold lower ulcer rate in the 3D-printed group emphasizes the potential of technology-driven customization as a transformative advancement in diabetic foot prevention strategies. By integrating biomechanical optimization with patient-centered comfort, these insoles effectively address both physiological and behavioral dimensions of ulcer prevention(18).

The improvements in gait parameters and pressure-time integrals observed in this study further underscore the biomechanical relevance of individualized insole design. Alterations in gait mechanics among diabetic patients, particularly those with peripheral neuropathy, often lead to abnormal load distribution and prolonged plantar stress(19). The observed increase in step length and reduction in cumulative loading suggest that 3D-printed insoles restored a more balanced gait pattern, mitigating repetitive strain and shear forces on the plantar surface. These findings not only validate the mechanical efficacy of 3D printing technology but also highlight its potential role in functional rehabilitation(20).

Several strengths distinguished this study. The randomized design, balanced sample size, and use of objective digital pressure mapping provided methodological rigor and minimized bias. The combination of biomechanical, clinical, and patient-reported outcomes offered a comprehensive assessment of device performance. Furthermore, the use of repeated-measures analysis allowed detection of temporal changes, ensuring that improvements observed were not transient or attributable to short-term adaptation.

Nonetheless, the study had limitations that warrant consideration. The follow-up period of six months, although sufficient to observe meaningful trends, may not capture long-term durability or compliance patterns associated with daily use. Material fatigue and shape retention of 3D-printed insoles over extended durations remain untested within this timeframe. Additionally, the study was

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

limited to patients with neuropathy but without severe vascular compromise, restricting generalizability to populations with advanced diabetic foot disease. Cost-effectiveness was not assessed, although it remains a critical factor in clinical adoption, especially in resource-constrained settings. Moreover, the study did not incorporate a blinded assessment of comfort or subjective outcomes, leaving room for potential participant expectation bias.

Future research should aim to evaluate long-term outcomes, including ulcer recurrence rates, device longevity, and cost-benefit analyses of 3D-printed insoles compared to conventional options. Expanding studies to include patients with more severe neuropathic or ischemic profiles would enhance the external validity of findings. Integration of smart sensor technology into 3D-printed insoles could also provide continuous monitoring of plantar pressure and temperature, enabling early detection of pre-ulcerative changes. Collaborative efforts between clinicians, biomedical engineers, and material scientists could further refine the structural properties of these devices, optimizing both biomechanical efficacy and user comfort.

In summary, this study provided compelling evidence that 3D-printed insoles outperform standard orthotic devices in reducing plantar pressure, enhancing comfort, improving gait mechanics, and lowering ulcer incidence in diabetic patients. The findings underscore the potential of personalized digital fabrication as a new standard in preventive diabetic foot care. While challenges remain regarding long-term validation and economic feasibility, the demonstrated biomechanical and clinical advantages suggest that 3D-printed insoles could represent a paradigm shift toward precision-based interventions in diabetic foot management.

Conclusion

The study concluded that personalized 3D-printed insoles provided superior biomechanical and clinical benefits compared to conventional orthotic devices in diabetic patients. They significantly reduced plantar pressure, improved comfort, enhanced gait performance, and lowered the incidence of new ulcer formation. These findings highlight the potential of 3D-printing technology as a precise, patient-centered solution for diabetic foot ulcer prevention, offering a promising advancement in personalized orthotic care and long-term diabetic foot management.

Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025

Author Contributions

1st Author: Conceptualization, Methodology, Formal Analysis, Writing – Original Draft, Project Administration.

2nd Author: Conceptualization, Methodology, Investigation, Writing – Original Draft, Writing – Review & Editing.

'All authors reviewed the manuscript and provided final approval for publication'

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Received: 01/April/2025
Accepted: 19/May/2025
Published: 31/May/2025