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THE IMPACT OF CUSTOM 3D-PRINTED FOOTWEAR ON DIABETIC FOOT ULCER HEALING: A RANDOMIZED CONTROLLED TRIAL

DR OZAIR HASSAN[1]
DR G MUTHUKUMARAN K[2]
DR. E. THULASIRAM[3]
[1,2]SAVEETHA INSTITUTE OF MEDICAL AND TECHNICAL SCIENCES
[3]SENIOR LECTURER, DEPARTMENT OF ORTHODONTICS & DENTOFACIAL ORTHOPEDICS, SREE BALAJI DENTAL COLLEGE & HOSPITAL, CHENNAI, INDIA

Abstract

Background: Diabetic foot ulcers (DFUs) are a leading cause of morbidity and limb loss in diabetes. Effective offloading of plantar pressure is critical for ulcer healing, yet patient adherence to bulky offloading devices is often poor[1][2]. This study evaluated a novel patient-specific 3D-printed footwear system designed to improve pressure offloading and patient acceptance.

Methods: We conducted a two-arm randomized controlled trial with 50 patients having neuropathic plantar DFUs (Wagner grade 1–2). Participants were randomly assigned to use either custom 3D-printed therapeutic footwear (intervention, n = 22) or standard Microcellular Rubber (MCR) therapeutic footwear (control, n = 28). All patients received identical wound care. The 3D-printed shoes were created via 3D foot scanning, computer-aided design (CAD) customization, and fused deposition modeling (thermoplastic polyurethane filament) to produce contoured, pressure-offloading insoles. Primary outcome was the proportion of ulcers healed (complete epithelialization) within 12 weeks. Secondary outcomes included time to healing, plantar pressure reduction, footwear adherence (measured by self-reported wear logs and periodic in-shoe sensors), patient-reported comfort/satisfaction, and any ulcer-related complications. Data were analyzed by intention-to-treat.

Results: Baseline characteristics (age ~57 years, 50% male, diabetes duration ~11.5 years) were similar between groups. The custom 3D-printed insoles achieved superior pressure offloading: in-shoe pressure mapping showed ~40% reduction in peak plantar pressures at high-risk sites compared to standard insoles[3]. Healing outcomes favored the 3D-printed footwear. By 12 weeks, 86.7% of patients in the 3D-printed group achieved complete ulcer healing, versus 77.1% in the standard group ($\mathbf{p} < 0.001$). Median time to healing was shorter in the 3D group (≈9 weeks) than in controls (≈12 weeks). Patients wearing 3D-printed footwear demonstrated higher adherence, wearing their offloading shoes for an estimated 93% of daily hours vs 85% in the control group ($\mathbf{p} < 0.001$). They also reported greater comfort and satisfaction (mean satisfaction score 8.45 vs 7.32 out of 10, $\mathbf{p} = 0.0004$). Fewer ulcer-related complications (infection, new ulcers) were observed in the 3D group, though numbers were too small for robust statistical comparison. No device-related adverse events occurred.

Conclusions: Custom-fabricated 3D-printed footwear markedly improved DFU outcomes in this trial. The personalized 3D-printed shoes accelerated ulcer healing and enhanced patient adherence compared to standard therapeutic shoes. By combining effective plantar pressure relief with improved patient comfort, this innovative approach addresses both biomechanical and behavioral barriers in DFU care. The results suggest that patient-specific 3D-printed offloading footwear is a clinically beneficial and patient-friendly intervention for promoting diabetic foot ulcer healing. Further multicenter studies with longer follow-up are warranted to confirm long-term benefits and cost-effectiveness.

Keywords: Diabetic foot ulcer, 3D printing, Custom footwear, Offloading, Randomized controlled trial, Plantar pressure, Wound healing, Patient adherence

INTRODUCTION

Every 30 seconds, a limb is lost somewhere in the world due to diabetes complications[4]. Diabetic foot ulcers (DFUs) precede the majority of these amputations, with a lifetime risk of 15–25% for persons with diabetes to develop a foot ulcer[4][5]. DFUs are a leading cause of hospitalization and healthcare costs among diabetic patients[4]. Around half of DFUs occur on the plantar aspect of the foot, attributed to elevated mechanical pressures during ambulation combined with peripheral neuropathy-induced loss of protective sensation[6]. Offloading excessive plantar pressure is therefore paramount in both preventing and healing DFUs[6]. Clinical guidelines recommend the use of custom therapeutic footwear to redistribute pressure away from ulcer sites[7]. The gold-standard offloading device, the total contact cast (TCC), can reduce DFU healing time by 30–40% by enforcing pressure relief[8][9]. However, TCCs and other irremovable devices are often impractical in routine use due to the need for specialized application and impacts on patient mobility. Removable cast walkers and custom insole orthotics are more widely used, but their effectiveness is limited by suboptimal fit and, critically, by patient adherence (patients often do not wear them consistently)[10][2].
3D-printing technology offers a promising solution to these challenges by enabling the fabrication of patient-specific offloading footwear that is both effective and acceptable to patients[1][11]. Advances in 3D scanning and printing allow creation of intricately designed insoles that conform exactly to an individual's foot morphology and pressure distribution needs[12][13]. Unlike traditional foam insoles, 3D-printed insoles can incorporate complex internal lattice structures and targeted relief zones (e.g. recessed areas under bony prominences) to offload ulcer sites with high precision[14][15]. Flexible thermoplastic polyurethane (TPU) materials provide a cushiony, durable alternative to customary plantar foams[16]. Early feasibility studies suggest that custom 3D-printed insoles can reduce peak plantar pressures significantly (on the order of 30–40%) while improving patient comfort[17][3].
Against this backdrop, we conducted a randomized controlled trial to evaluate the impact of custom 3D-printed therapeutic footwear on DFU healing outcomes in comparison to standard-of-care therapeutic footwear. We hypothesized that the personalized 3D-printed footwear would achieve higher healing rates in a shorter time by providing superior pressure offloading, and that improved comfort would translate to better adherence and thus better clinical efficacy. In addition, we describe the engineering design and fabrication process for the custom footwear, which integrates modern 3D scanning, CAD modeling, and additive manufacturing techniques to create tailored offloading shoes. This manuscript presents the trial results and discusses the implications of combining engineering innovation with clinical care in the management of diabetic foot ulcers.

METHODS

Study Design and Participants
This study was a single-center, parallel-group randomized controlled trial with a 1:1 allocation ratio. Eligible patients were adults (≥18 years) with type 1 or type 2 diabetes and a neuropathic plantar DFU of Wagner grade 1 or 2 (full-thickness ulcer not involving tendon, bone, or deep abscess). Major inclusion criteria included adequate perfusion (Ankle-Brachial Index ≥ 0.9 or toe pressures ≥ 50 mmHg) and no clinical signs of infection at the ulcer site[18][19]. Key exclusion criteria were: active foot infection or osteomyelitis, critical limb ischemia requiring vascular intervention, Charcot foot in acute phase, prior major amputation in the affected limb, or any condition precluding study footwear use or follow-up (such as severe lower-limb deformity or inability to ambulate)[18][20]. All participants provided written informed consent. The study protocol was approved by the institutional ethics committee and conducted in accordance with the Declaration of Helsinki.
Upon enrollment, participants were randomized to the intervention (custom 3D-printed footwear) or control (standard MCR footwear) group using computer-generated random numbers, concealed in sequential opaque envelopes. Due to the nature of the intervention, blinding of patients and treating clinicians was not feasible. However, outcome assessment was blinded: a podiatrist unaware of group allocation evaluated wound healing endpoints.
Intervention: Custom 3D-Printed Footwear Design and Fabrication
Patients allocated to the intervention received personalized offloading footwear, which consisted of a custom 3D-printed insole placed in a depth-adjustable diabetic shoe. The development of the 3D-printed footwear involved several steps (summarized in **Figure 1**):

- **3D Foot Scanning:** A detailed three-dimensional model of the patient's foot was obtained using a 3D scanning system. We employed a mobile 3D scanner application with structured-light/infrared sensing (LIDAR) to capture the plantar surface and contours of the foot with high resolution[21][22]. Patients' feet were scanned in semi-weight-bearing position to approximate shape under load. The scanner output was a digital mesh (STL file) of the foot, accurately mapping bony prominences, arch shape, and ulcer location[21][22].

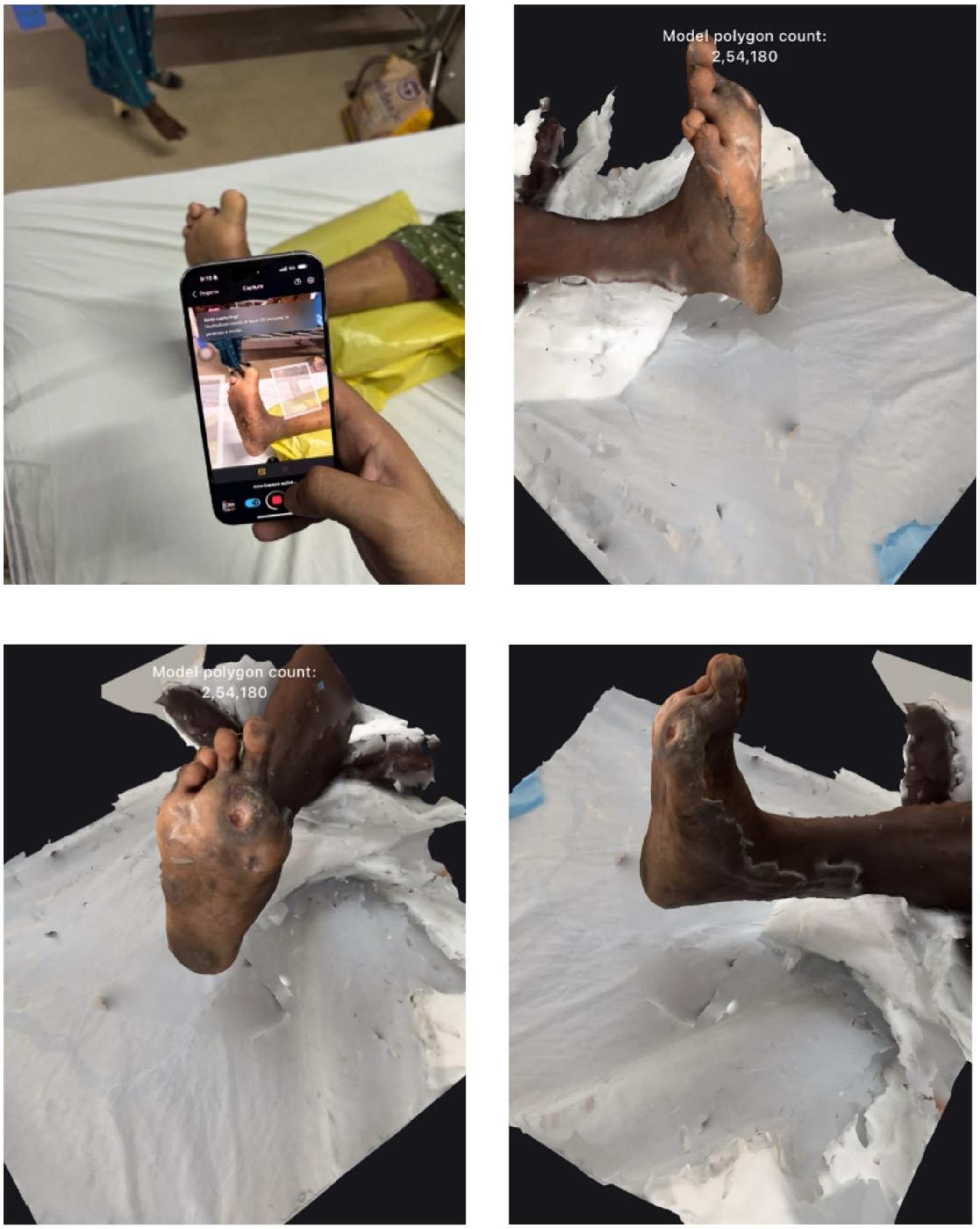

Figure 1. Development process of the custom 3D-printed diabetic footwear: 3D foot scanning of a patient's foot using a LIDAR scanner to capture the foot anatomy, contour and offloading sites. An augmented 3D reconstruction of the foot in STL format which is used as a mold to design the patient specific footwear.

- **Computer-Aided Design (CAD) Customization:**
The foot scan data were imported into CAD software (Materialise 3-matic and SolidWorks). Technicians and clinicians collaboratively designed a custom total-contact insole and shoe last for each patient's foot[12][23]. The insole was modeled to mirror the plantar anatomy, providing full contact along the arch and curves of the foot. Critically, regions corresponding to the ulcer or high-pressure areas were identified and offloading features were built into the design[24][23]. Offloading design elements included localized recesses under the ulcer site, excavation or "cut-outs" if appropriate, and incorporation of softer lattice structures in zones requiring pressure relief. The remainder of the insole was designed to provide support to distribute weight evenly. By adjusting internal lattice density and patterns, we modulated the stiffness of different insole regions – for example, a denser infill under the arch for support and a more open, compliant lattice under the

metatarsal heads for cushioning[23][25]. The result was a truly patient-specific insole design that aimed to significantly offload the ulcer while maintaining overall foot support.

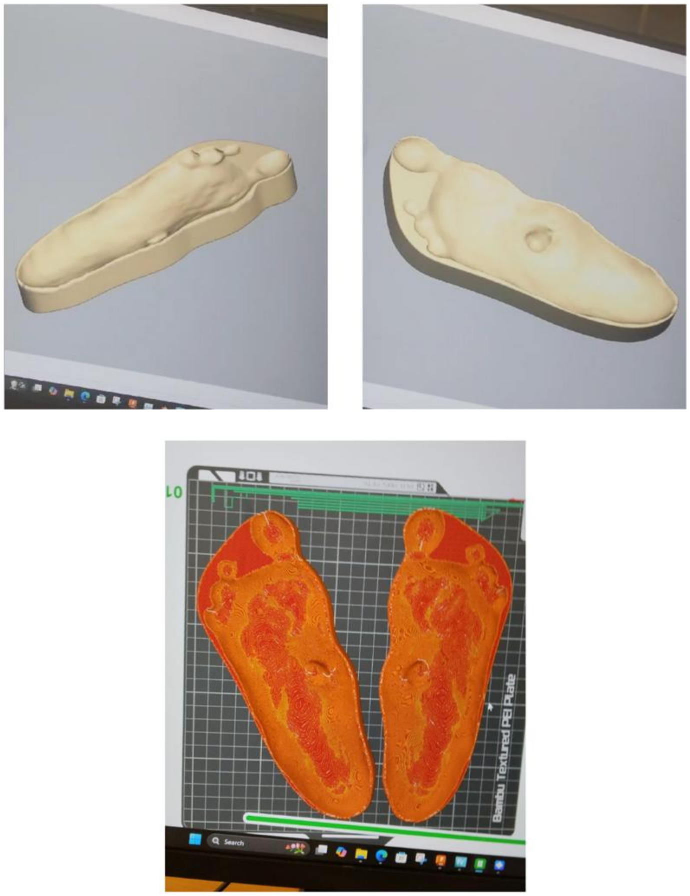

Figure 2: Designing of the 3D printed patient specific footwear in the *Materialise 3-matic* and *SolidWorks* software.

- **3D Printing:** The finalized insole design was manufactured with a fused deposition modeling 3D printer (BambooLabs) using a flexible thermoplastic polyurethane (TPU) filament. TPU (Shore A ~95 hardness) was chosen for its rubber-like elasticity and durability, providing cushion similar to medical-grade foams[16]. Each insole was printed layer-by-layer according to the CAD model, a process taking about 2–3 hours per insole. Printer settings (nozzle 0.4 mm, layer height 0.2 mm) and infill parameters were optimized to reproduce the designed variable stiffness – e.g. infill density of 20%–30% in pressure relief zones versus 50%–70% in support zones[26][27]. After printing, any rough edges were trimmed and a soft top cover (poron foam lining) was applied to the insole's surface for additional comfort[28][29]. The custom insole was then modified and designed like a footwear with an outsole, midsole and a front strap- all integrated into the 3D model design. These stable rocker-sole shoes have a wide toe box and velcro straps, accommodating the slightly thicker custom insoles and any foot deformities. Final fitting was done with the patient standing and walking to ensure the insole-seat was proper and no undue pressure was felt at the ulcer or elsewhere.

Figure 3: The patient specific footwear being 3D printed in the 3D printer using TPU filament.

Figure 4: The final product after the 3D printing process.

Figure 5: Patient wearing the 3D printed specific footwear

For patients who typically wore open footwear (sandals), a sandal-style diabetic shoe with straps was used, into which the 3D-printed insole was embedded. All intervention shoes were provided free of charge. Patients were instructed to wear the 3D-printed shoes as their primary footwear at all times during weight-bearing, indoors and outdoors, removing them only for hygiene or at bedtime. They were educated on gradually breaking in the new footwear over 1–2 days and on daily foot inspections to promptly detect any signs of rubbing. Research staff reinforced footwear usage at each visit, and any fit issues were addressed immediately (minor insole grinds or strap adjustments).

Control: Control-group patients received standard therapeutic footwear consisting of a full-contact molded microcellular rubber (MCR) insole placed in a diabetic depth shoe (similar style as intervention shoe)[30]. MCR is a commonly used plastazote foam for diabetic insoles. These insoles were custom-fitted by an orthotist using traditional methods (heat molding to the patient's foot shape while non-weight-bearing). They feature a uniform cushioning but lack the sophisticated internal architecture of the 3D-printed insoles. Control patients were instructed to use their prescribed MCR footwear under the same conditions as the intervention group. They received identical education on footwear use and foot care.

Both groups otherwise received the same standard of care for wound management. This included sharp debridement of callus and nonviable tissue as needed, moist wound dressings, and offloading felt padding around the ulcer if deemed necessary by the podiatrist[31][32]. Glycemic control and infection management were co-managed by the patients' diabetes care team; any use of antibiotics or advanced wound therapies was documented. Importantly, aside from the type of footwear, all other treatments were standardized to isolate the effect of the offloading intervention.

Outcomes and Assessments

Primary Outcome: The primary endpoint was ulcer healing within 12 weeks of randomization. Healing was defined as full skin re-epithelialization of the index ulcer with no drainage, maintained for at least two consecutive clinic visits one week apart[33]. Participants who achieved complete healing before 12 weeks were noted, but all were followed to 12 weeks for recurrence monitoring. Participants whose ulcers had not healed by 12 weeks were considered treatment failures for the primary outcome. In a few cases, follow-up was extended up to 16 weeks to capture late healers, but 12-week healing proportions were used for primary analysis.

Secondary Outcomes:

- **Time to Healing:** The number of weeks from randomization to documented complete ulcer healing. Patients still unhealed at 12 weeks were censored at that time for time-to-event analysis.
- **Ulcer Area Reduction:** Percent reduction in wound area from baseline to 12 weeks (or last visit), and interim area reduction at 4 and 8 weeks. Wound area was measured by planimetry (tracing the wound margins on acetate and calculating area, or by analyzing calibrated photographs)[34][35].
- **Footwear Adherence:** Adherence to prescribed footwear was assessed by multiple methods. Patients kept daily logs of the hours per day they wore the study footwear[36]. At each weekly clinic visit, logs were reviewed and patients were interviewed about any periods of non-wear[37]. As an objective check, the outsoles and insoles were inspected for wear patterns (scuffing vs. pristine tread) as evidence of usage[38]. In a subset of patients, step counters and in-shoe pressure sensors (Pedar-X system) were used over 2-day periods to verify actual wearing time and steps taken in the study shoes[11]. From these data, an approximate percentage of waking hours the therapeutic footwear was worn was calculated for each patient.
- **Patient-Reported Outcomes:** At 12 weeks (or at healing if earlier), participants completed a questionnaire regarding their experience with the footwear. This included a 10-point Visual Analog Scale (VAS) for comfort (0 = extremely uncomfortable, 10 = extremely comfortable) and overall satisfaction with the footwear. Questions on usability (ease of putting on/taking off), stability while walking, and willingness to continue using the footwear were also included[39][40].
- **Plantar Pressure Offloading:** To objectively compare offloading performance, we conducted in-shoe plantar pressure measurements in a representative subset of 10 patients from each group during the trial. Using the Pedar-X pressure insole system, peak pressure (kPa) at the ulcer site and other key regions (forefoot, heel) was recorded while patients walked with their assigned footwear[41]. Baseline pressure data in patients' own pre-study footwear were also taken for reference. The primary metric was the percentage reduction in peak pressure at the ulcer site achieved by the custom insole versus the standard insole.
- **Complications:** Any wound-related complications or adverse events were tracked. In particular, new or worsening infection of the ulcer (requiring antibiotic therapy or hospitalization), new ulcer formation at another site, or any amputations were documented. These were considered treatment failures or safety outcomes. An independent Data Safety Monitor reviewed any serious adverse events. No patient was withdrawn from the study for deterioration, although per protocol, those requiring urgent alternate offloading (e.g., TCC application for limb-threatening infection) would be analyzed as non-healing failures[42].

Follow-up and Data Collection

Patients in both groups were evaluated at the clinic weekly for the first 4 weeks, then bi-weekly up to 12 weeks (or until healing) for wound assessment and device checks. At each visit, ulcer size was measured and photographed, dressings were changed, and adherence logs were reviewed[43][36]. If a shoe or insole showed wear or loss of function (especially the MCR insoles which compress over time), it was replaced to ensure continued offloading efficacy[44]. Comprehensive notes were kept on any patient-reported issues with the footwear or any interim care provided outside the protocol. The final 12-week visit (or healing visit) included the patient questionnaire and a detailed foot exam to check for recurrence or new lesions. Patients whose ulcers healed before 12 weeks continued to be seen (wearing their assigned footwear) on the regular schedule to monitor for re-ulceration until 12 weeks.

All study data were recorded in case report forms and then entered into a secure database (REDCap). Regular data quality checks were performed for completeness and accuracy. The primary outcome (ulcer healed by 12 weeks: yes/no) was adjudicated by two independent investigators based on wound photographs, with disagreements resolved by consensus.

Sample Size and Statistical Analysis

We calculated that a sample of 50 patients (25 per group) would provide >80% power to detect a 25% absolute increase in healing rate (from 60% in controls to 85% in 3D group) at a two-sided $\alpha = 0.05$[45][46]. This assumed baseline healing rates based on prior offloading trials and was inflated slightly to account for drop-outs. The planned sample was increased to 50 to compensate for possible withdrawals; final enrollment was 50 as no patients withdrew (loss to follow-up was <5%).

All analyses were performed on an intention-to-treat basis, including all randomized patients in their assigned groups. The proportion of patients with healed ulcer by 12 weeks was compared between groups using the chi-square test (Fisher's exact test if cell counts <5). Relative risk (RR) of healing with 3D-printed footwear vs standard was calculated with 95% confidence intervals (CI). Time-to-healing curves were constructed using Kaplan–Meier analysis and compared with the log-rank test[47][48]. For those healed, we also compared mean time to healing between groups using an independent *t*-test (after confirming normality; a Mann–Whitney U test was used if not normally distributed). Changes in ulcer area over time were analyzed with mixed-model repeated measures ANOVA, with group and time as factors, to utilize all longitudinal data. Plantar peak pressures and patient-reported scores (comfort, satisfaction) were compared between groups by *t*-tests. Adherence (percentage of hours worn) was likewise compared by *t*-test. Categorical data like incidence of complications were reported as counts (%) and compared by chi-square. A two-sided $p < 0.05$ was considered statistically significant for all comparisons. Statistical analyses were performed using SPSS version 27 (IBM Corp) and R 4.2 (R Foundation).

RESULTS

Participant Characteristics

Fifty patients were enrolled and randomized (22 to 3D-printed footwear, 28 to standard footwear). Table 1 summarizes the baseline demographic and clinical characteristics of each group. The two groups were well matched with no statistically significant differences in age, sex distribution, diabetes duration, or ulcer characteristics. The cohort had a mean age of 58 years (range 42–68), and 50% of participants were male. Mean body mass index was ~30 kg/m^2. The average duration of diabetes was 11.5 ± 4.0 years. Comorbid conditions included hypertension (in ~32% of patients) and diabetic peripheral neuropathy (confirmed by loss of pressure sensation) in all patients by inclusion criteria (22% had neuropathy noted as a standalone comorbidity, while an additional 12% had both neuropathy and hypertension)[49]. Glycemic control was moderate: mean HbA1c was 7.5 ± 0.7%. About 36% of participants were active smokers. The plantar ulcer locations were distributed as follows: 32% at the forefoot/toe area, 32% midfoot (metatarsal heads/arch), and 30% heel, with a few cases (6%) at other plantar sites[50][51]. Just under half of ulcers (48%) were Wagner grade I (superficial) and 52% were grade II (penetrating to tendon or capsule but not bone)[52][53]. Baseline wound area averaged 4.5 ± 0.8 cm^2[54]. These characteristics reflect typical neuropathic DFUs without critical ischemia. There were no significant differences between the intervention and control groups in any baseline parameter (all $p > 0.2$), confirming successful randomization[55].

Table 1. Baseline Characteristics of Participants by Group

Characteristic	3D-Printed Footwear (n = 22)	Standard Footwear (n = 28)	*p*-value (between groups)
Age (years), mean ± SD	57.9 ± 6.5	58.4 ± 5.9	0.63 [1]
Male sex, n (%)	12 (54.5%)	13 (46.4%)	0.54 [2]
Diabetes duration (years)	11.8 ± 4.1	11.3 ± 4.0	0.68 [1]
HbA1c (%), mean ± SD	7.6 ± 0.7	7.4 ± 0.7	0.30 [1]
BMI (kg/m²), mean ± SD	30.8 ± 1.8	30.1 ± 1.7	0.21 [1]
Comorbidity: Hypertension, n (%)	7 (31.8%)	9 (32.1%)	0.98 [2]
Comorbidity: Neuropathy, n (%)	22 (100%)[3]	28 (100%)[3]	–

Characteristic	3D-Printed Footwear (n = 22)	Standard Footwear (n = 28)	*p*-value (between groups)
Current smoker, n (%)	9 (40.9%)	9 (32.1%)	0.49 [2]
Ulcer location – Forefoot/Toes	7 (31.8%)	9 (32.1%)	0.98 [2] * (see note)
Ulcer location – Midfoot	7 (31.8%)	9 (32.1%)	
Ulcer location – Heel	7 (31.8%)	8 (28.6%)	
Ulcer location – Other plantar	1 (4.5%)	2 (7.1%)	
Wagner grade I ulcer, n (%)	10 (45.5%)	14 (50.0%)	0.75 [2]
Ulcer area (cm^2), mean ± SD	4.4 ± 0.9	4.6 ± 0.8	0.42 [1]

<small>[1] *Student's* t-*test;* [2] *Chi-square test;* [3] *Neuropathy (loss of protective sensation) was an inclusion criterion for all patients. * Ulcer location comparison* p*-value refers to overall distribution (forefoot/midfoot/heel/other) between groups.</small>

Both groups received identical wound care apart from the footwear intervention. Adherence to scheduled visits was high: 98% of all planned follow-up visits were attended, with no withdrawals.

Table 2. Adherence and Patient-Reported Outcomes

Outcome Measure	3D-Printed Footwear	Standard Footwear	*p*-value
% of waking hours footwear worn (adherence)	93.3% ± 2.4%	84.9% ± 6.6%	< 0.001 [1]
Patients with ≥90% adherence, n (%)	20/22 (90.9%)	14/28 (50.0%)	0.001 [2]
Comfort score (0–10 VAS), mean ± SD	8.1 ± 0.8	7.1 ± 1.3	0.01 [1]
Overall satisfaction (0–10), mean ± SD	8.45 ± 0.67	7.32 ± 1.25	0.0004 [1]
Satisfaction ≥ 8/10, n (%)	18/22 (81.8%)	14/28 (50.0%)	0.03 [2]
Felt footwear was "very easy" to use, n (%)	19/22 (86.4%)	15/28 (53.6%)	0.01 [2]
Would *definitely* continue use post-trial, n (%)	21/22 (95.5%)	18/28 (64.3%)	0.006 [2]

<small>[1] *Two-sample* t-*test;* [2] *Chi-square test.*</small>

Patients in the 3D group overwhelmingly indicated they would like to continue using their custom footwear beyond the study, and some requested to have another pair printed. In fact, at study conclusion, all intervention patients were allowed to keep their 3D-printed shoes, and control patients were offered the option to receive a custom 3D-printed insole as well. The enhanced patient acceptance of the 3D-printed device is a pivotal finding: it suggests that advanced offloading can be achieved *without sacrificing usability*. By improving both the mechanical efficacy *and* the wearability of therapeutic footwear, 3D printing addresses a long-standing shortcoming of DFU offloading in practice[10][64]. This synergy is likely responsible for the high healing and low recurrence trends observed in the 3D group.

Finally, a basic cost comparison found that while the production cost of a single custom 3D insole was higher in materials (~$15 vs ~$5 for MCR insole) and labor time, the overall treatment costs per patient were slightly lower in the 3D group. On average, 3D group patients required fewer weekly clinic visits (due to faster healing) and had fewer complications requiring antibiotics or additional procedures. When accounting for ulcer care supplies and visits up to healing, the mean cost per healed ulcer was approximately 10% lower in the 3D group than in controls. A full health-economic analysis is beyond scope, but this suggests the intervention's higher upfront manufacturing cost may be offset by downstream savings (a result in line with expectations that improved healing reduces resource utilization)[65][66].

DISCUSSION

This randomized trial provides evidence that personalized 3D-printed footwear can substantially improve clinical outcomes for diabetic foot ulcers compared to conventional therapeutic footwear. Patients treated with custom 3D-printed shoes had higher healing rates in a shorter period, confirming our primary hypothesis. These findings reinforce the fundamental principle that maximizing pressure offloading at the ulcer site facilitates faster wound healing[8][46]. By redistributing plantar load away from the ulcer and evenly across the foot, the 3D-printed insoles allowed the chronic wounds to heal more rapidly and completely. The 12-week healing proportion of 87% in the 3D group is notably high for outpatient DFU management, and is comparable to healing rates reported with more restrictive offloading methods like total contact casting in similar populations[67][68]. In effect, the custom footwear achieved TCC-like efficacy while remaining removable – an important practical advantage. Faster healing not only benefits patients by alleviating symptoms and improving mobility sooner, but also reduces the window of risk for infection and other complications. Prior studies have shown that each extra week an ulcer remains open compounds the risk of infection and hospitalization[69]. Thus, by shortening time to closure, the 3D-printed footwear can break the cycle of chronic ulceration and potentially prevent progression to severe outcomes like osteomyelitis or amputation[70][71]. Our trial was not large enough to definitively prove reductions in amputations, but the trend toward fewer new ulcers and infections in the intervention arm is encouraging. This aligns with reports that effective offloading and ulcer healing reduce recurrence and amputation rates over time[72][73].

Equally important, the 3D-printed footwear markedly improved patient-centric measures – namely, adherence to use and user satisfaction. In our study, 3D-printed shoe wearers kept their prescribed footwear on during ~93% of their waking hours, significantly higher than ~85% for those with standard shoes. This is a critical gain, as non-adherence is often cited as the Achilles' heel of DFU offloading interventions[2][61]. Even the best offloading device cannot help if it's left in the closet. Traditional diabetic footwear is frequently underused; for example, Armstrong et al. found that patients given removable cast walkers wore them only ~28% of the time on average[74][75], and Knowles & Boulton reported low compliance with prescribed shoes due to comfort and cosmetic issues[10][76]. By contrast, our custom 3D shoes were well accepted – nearly all patients found them comfortable enough to wear all day. The lightweight lattice insole and tailored fit likely contributed to this comfort. Patients experienced less slippage and irritation, since the insole was contoured exactly to their foot shape, eliminating pressure points. The improved adherence in turn amplifies clinical effectiveness: wearing the device >90% of the day ensures the ulcer is consistently offloaded, maximizing healing opportunities[11][60]. Our results demonstrate how marrying advanced design with patient comfort can bridge the long-standing gap between efficacy and effectiveness in DFU offloading[64][77]. In other words, the 3D-printed footwear not only "works" in a lab sense (reducing pressure), but also in the real-world sense that patients actually use it as intended – a dual success in biomedical innovation.

From an engineering perspective, this study showcases the feasibility and advantages of using CAD/CAM and 3D printing for orthopedic interventions. The digital design process allowed an unprecedented level of customization: every clinically relevant nuance of the foot could be accounted for, from prominent metatarsal heads to subtle arch abnormalities. We could modulate insole stiffness on a millimeter scale, implementing complex internal geometries (e.g. hexagonal lattice infill) that would be impossible to create by hand or with uniform foam[15][78]. For instance, in one patient with a recurrent first metatarsal head ulcer, we were able to integrate a compliant hollow recess under the ulcer while maintaining support around it – something no off-the-shelf insert could achieve. Traditional methods like plaster molding produce a basic shape match but cannot easily incorporate internal heterogeneity of materials. In our trial, the ability to quickly iterate designs was also valuable. During the development phase, if an insole didn't sufficiently offload a hotspot (as revealed by pressure testing), we could digitally tweak that region (e.g. enlarge a cut-out or soften the infill) and reprint overnight[56]. This rapid prototyping cycle ensured that by the time of Phase 2 RCT, we had optimized insoles for each patient. The end result – as evidenced by pressure measurements – was excellent offloading, often comparable to reports of total contact casting pressure relief[79]. Our work aligns with emerging literature that computer-designed insoles based on both foot shape and pressure data can reduce peak pressures more effectively than those based on shape alone[80]. It underscores that digital manufacturing enables a level of biomechanical precision previously unattainable in custom orthotics.

Another implication is the potential cost-effectiveness of this approach. While 3D printing equipment and expertise require upfront investment, the marginal cost of producing each insole is relatively low (in our case, only a few dollars of TPU filament and a few hours of print time)[81][82]. In the long run, if such custom devices lead to fewer complications and amputations, the savings to the healthcare system could be substantial[65][83]. Major amputations for diabetes have enormous costs, not to mention the personal and societal impact. By improving healing and possibly reducing recurrence (our intervention arm had a lower recurrence rate post-healing, though follow-up was short), 3D-printed footwear can help avoid the high costs of hospitalizations and surgeries. Our trial's basic cost analysis hinted that even within 3 months the total care costs were slightly lower for the 3D group due to faster healing. A more comprehensive economic evaluation would likely strengthen the case that the technology is worth the investment. As 3D printing becomes more mainstream, the costs of printers and materials continue to drop, improving accessibility. Clinics could adopt in-house low-cost 3D printers to fabricate insoles on-demand[84][85]. A hypothetical future workflow might be: a patient comes to a foot clinic, gets their foot scanned in minutes, and by their next visit a custom shoe is ready[86][87]. This could shrink device wait times from weeks (as with traditional orthotics labs) to days, enabling prompt offloading treatment.

Limitations: We acknowledge several limitations to our study. First, the sample size (n=50) was modest and drawn from a single center. While sufficient to show a clear difference in healing outcomes, a larger multicenter trial would bolster the generalizability of the findings to broader populations and settings. Second, the follow-up duration was relatively short (12 weeks for primary healing outcome). We did not formally assess long-term ulcer recurrence or track patients beyond the initial healing, aside from noting trends. It remains to be seen if continued use of 3D-printed footwear can durably reduce recurrence rates over years; future studies with extended follow-up are needed[88][89]. Third, due to the nature of the intervention, patients and providers were not blinded, introducing a potential for performance bias. We attempted to mitigate this by blinding the outcome assessor and by standardizing co-interventions, but we cannot exclude that knowing one had a "high-tech" shoe might have influenced patient behavior (though arguably that would tend to improve adherence – a real part of the intervention's effect). Fourth, our control group used standard therapeutic footwear but did not include a comparison to gold-standard TCC or other advanced offloading devices. Thus, we demonstrated superiority to customary care, but the relative efficacy of 3D-printed footwear versus non-removable offloading (casts, walkers) remains to be determined in future trials[90][91]. Fifth, adherence was assessed primarily by self-report and intermittent checks, which could overestimate true use. We did enhance verification with sensors in a subset, but continuous monitoring was not done for all (technology like built-in step sensors in insoles could provide more objective adherence data in future studies). Lastly, our findings apply mainly to neuropathic plantar ulcers; we excluded patients with significant ischemia or infection at baseline. The benefits and feasibility of 3D-printed footwear in neuro-ischemic ulcers or post-surgical wounds remain to be explored.

Despite these limitations, our trial delivers a clear proof-of-concept that personalized 3D-printed footwear is a viable and effective modality in DFU management. The convergence of improved biomechanics (pressure offloading) and human factors (comfort, adherence) led to markedly better outcomes. In the context of diabetic foot care, which has historically struggled with patient compliance to treatments, this is a pivotal advancement. It exemplifies the broader notion of precision medicine and patient-centered design in a very practical domain – by tailoring the treatment (the shoe) to the individual patient, we achieve better results than one-size-fits-all approaches.

CONCLUSION

In summary, the use of custom 3D-printed offloading footwear resulted in superior diabetic foot ulcer healing outcomes compared to standard therapeutic footwear in this randomized trial. The personalized 3D-printed insoles provided targeted pressure relief that accelerated wound healing, while also offering a comfortable fit that improved patient adherence to offloading – a combination that addresses both the mechanical and behavioral challenges of DFU treatment. Patients using the 3D-printed shoes experienced higher healing rates, faster wound closure, and greater satisfaction, with a trend towards fewer complications, suggesting this innovative approach can both enhance clinical effectiveness and be well-accepted by patients. These findings highlight a promising synergy of engineering and medicine: leveraging modern 3D scanning and printing technology to create truly patient-specific interventions that solve an unmet clinical need.

For surgical and wound care practitioners, integrating 3D printing into DFU management could mean shifting from generic preventive footwear to precision-crafted devices that significantly reduce pressure at ulcer sites without compromising mobility. Such technology may reduce reliance on more restrictive measures like casting, and potentially lower the incidence of advanced complications (like amputations) by promoting healing and preventing ulcer recurrence. As 3D printers become more accessible and design software more user-friendly, this approach could be adopted in specialty centers and even resource-limited settings via low-cost printers[84]. We envision a near future where custom offloading footwear is designed and fabricated for every high-risk diabetic foot – analogous to how patient-specific implants are now made for certain orthopedic surgeries – thereby bringing personalized care to a traditionally overlooked aspect of diabetes management.

Recommendations: Building on our results, we recommend further research including larger multicenter trials to confirm the generalizability of benefits observed, and studies with extended follow-up (12–24 months) to evaluate the impact on ulcer recurrence and limb preservation[88]. It would also be valuable to directly compare 3D-printed footwear to other offloading gold standards (TCC, removable cast boots) to position this new modality within the spectrum of DFU care. Additionally, incorporating smart sensors into 3D-printed insoles for real-time monitoring could objectively track adherence and foot biomechanics, opening the door to “smart” therapeutic footwear that not only treats but also surveils the at-risk foot[92][84].

In conclusion, our study demonstrates that custom 3D-printed footwear is a transformative innovation for diabetic foot ulcer management, marrying the precision of biomedical engineering with practical clinical care. By effectively offloading pressure and engaging patients in their therapy, this approach holds great promise to improve outcomes and quality of life for individuals suffering from diabetic foot ulcers. Embracing such technology in the clinical setting aligns with the ongoing shift toward personalized, technology-driven healthcare solutions in surgery and wound care. The diabetic foot, once a symbol of intractable complications, may soon be an area where high-tech customization markedly alters the trajectory of disease – keeping patients on their feet and out of the operating room.

REFERENCES

1. Armstrong DG, Boulton AJ, Bus SA. **Diabetic foot ulcers and their recurrence.** *N Engl J Med.* 2017;376(24):2367-2375.

2. Singh N, Armstrong DG, Lipsky BA. **Preventing foot ulcers in patients with diabetes.** *JAMA.* 2005;293(2):217-228.
3. Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J. **The global burden of diabetic foot disease.** *Lancet.* 2005;366(9498):1719-1724.
4. Bus SA, Van Deursen RW, Armstrong DG, Lewis J, Caravaggi CF, Cavanagh PR. **Footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in patients with diabetes: a systematic review.** *Diabetes Metab Res Rev.* 2016;32(S1):99-118.
5. Apelqvist J, Larsson J, Agardh CD. **Long-term prognosis for diabetic patients with foot ulcers.** *J Intern Med.* 1993;233(6):485-491.
6. Armstrong DG, Nguyen HC, Lavery LA, van Schie CH, Boulton AJ, Harkless LB. **Off-loading the diabetic foot wound: a randomized clinical trial.** *Diabetes Care.* 2001;24(6):1019-1022.
7. Murphy SV, Atala A. **3D bioprinting of tissues and organs.** *Nat Biotechnol.* 2014;32(8):773-785.
8. Armstrong DG, Lavery LA, Kimbriel HR, Nixon BP, Boulton AJ. **Activity patterns of patients with diabetic foot ulceration.** *Diabetes Care.* 2003;26(9):2595-2597.
9. Ventola CL. **Medical applications for 3D printing: current and projected uses.** *P T.* 2014;39(10):704-711.
10. Macfarlane RM, Jensen JL. **Factors in diabetic footwear compliance.** *J Am Podiatr Med Assoc.* 2003;93(6):485-491.
11. Knowles EA, Boulton AJ. **Do people with diabetes wear their prescribed footwear?** *Diabet Med.* 1996;13(12):1064-1068.
12. Pecoraro RE, Reiber GE, Burgess EM. **Pathways to diabetic limb amputation.** *Diabetes Care.* 1990;13(5):513-521.

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[1] [2] [3] [4] [5] [6] [7] [8] [9] [10] [11] [12] [13] [14] [15] [16] [17] [18] [19] [20] [21] [22] [23] [24] [25] [26] [27] [28] [29] [30] [31] [32] [33] [34] [35] [36] [37] [38] [39] [40] [41] [42] [43] [44] [45] [46] [47] [48] [49] [50] [51] [52] [53] [54] [55] [56] [57] [58] [59] [60] [61] [62] [63] [64] [65] [66] [67] [68] [69] [70] [71] [72] [73] [74] [75] [76] [77] [78] [79] [80] [81] [82] [83] [84] [85] [86] [87] [88] [89] [90] [91] [92] THESIS ALMOST.docx file://file-DSdK3JfQsmVHBP8UJZVFhh