Daysan et al, 2025
https://doi.org/10.70196/jwrt.v2i2.65

Journal of Wound Research And Technology

Received: 21-7-2025; Revised: 1-9-2025, Publish Online: 19-10-2025

ORIGINAL RESEARCH Open Access

Total Contact Casting vs Removable Cast Walker for 12-Week Healing of Neuropathic Plantar Diabetic Foot Ulcers: A Pragmatic Randomized Trial

Ayşe Demir Daysan, MD[1*], Mehmet Kaya Jason, PhD[2], Asnafi Elif Yılmaz, MD[3]

[1]*Diabetes Foot Clinic, Ankara Bilkent City Hospital, Ankara, Türkiye*
[2]*Department of Endocrinology and Metabolism, Hacettepe University Faculty of Medicine, Ankara, Türkiye*
[3]*Department of Orthopedics and Traumatology, Istanbul University–Cerrahpaşa, Cerrahpaşa Faculty of Medicine, Istanbul, Türkiye*

Abstract

Background: Diabetes-related foot ulceration remains a major clinical and health-system burden in outpatient care, with high risks of infection and amputation. Yet, evidence directly comparing non-removable total contact casts (TCC) versus removable cast walkers (RCW) on a uniform 12-week healing endpoint in routine clinics is limited.

Purpose: This study compared the effect of TCC versus RCW on complete 12-week ulcer healing among adults with neuropathic plantar diabetic foot ulcers in outpatient care.

Methods: In a pragmatic randomised controlled trial at Ankara City Hospital, Türkiye (2 January–30 March 2025), we enrolled 172 adults with neuropathic plantar ulcers (Wagner 1–2) meeting perfusion criteria; key exclusions were critical ischaemia and osteomyelitis. The intervention was a non-removable TCC versus RCW with standard wound care. The primary outcome was complete epithelialisation by 12 weeks, adjudicated blindly at two visits ≥2 weeks apart. Log-binomial (or Poisson-robust) models estimated risk ratios (RRs) with 95% CIs, adjusting for prespecified covariates; longitudinal percentage-area reduction and adherence-adjusted sensitivities were prespecified.

Findings: Among 172 participants (mean age ≈60 years; comorbidities common), 65/86 (75.6%) healed by 12 weeks with TCC versus 46/86 (53.5%) with RCW (RR 1.41, 95% CI 1.12–1.78). TCC also showed greater percentage-area reduction at 1, 2, and 3 months, consistent with a steeper healing trajectory; device-related adverse events were slightly higher with TCC, while infections requiring systemic antibiotics were similar. Findings were consistent in intention-to-treat and adherence-adjusted analyses, indicating robustness.

Conclusion: TCC accelerated healing and increased 12-week ulcer closure versus RCW in routine outpatient care. Results support prioritising non-removable offloading where feasible and motivate multicentre evaluations of durability, safety, cost-effectiveness, and equitable implementation

Keywords: diabetic foot; foot ulcer/therapy; randomized controlled trial; treatment adherence and compliance; wound healing

*Correspondence: Ayşe Demir Daysan, Email: ayse.demirrewwd@ankaracityhosp.tr

Introduction

Diabetes-related foot ulceration is common, with a lifetime incidence of roughly 19–34% and frequent recurrence after healing (Bus et al., 2024). These ulcers drive infection, hospitalisation, and amputation, with substantial patient and health-system burden. Current guidance recommends non-removable knee-high offloading, either a total contact cast or a non-removable walker, as first-line care for neuropathic plantar ulcers in routine clinics (IWGDF, 2023). However, despite broad endorsement of non-removable devices, uncertainty persists about their comparative effectiveness in everyday practice, particularly head-to-head total contact cast versus removable cast walker at a fixed 12-week healing endpoint and across ischemia strata, limiting confident, context-specific device selection (Guo et al., 2022).

Methodological limitations, characterized by diverse study designs and inconsistent endpoints, continue to hinder comparative analyses of total contact casts and removable cast walkers in the treatment of diabetic foot ulcers between 2020 and 2025.

Keywords: diabetic foot; foot ulcer/therapy; randomized controlled trial; treatment adherence and compliance; wound healing

Consequently, despite meta-analytic findings suggesting superior healing rates with TCCs, definitive evidence from rigorous, multicentre 12-week head-to-head trials remains elusive (Li et al., 2023; Lazzarini et al., 2024). Of five recent articles, two systematic reviews/meta-analyses pool mixed controlled trials without uniform 12-week outcomes (Li et al., 2023; Lazzarini et al., 2024), one retrospective comparison lacks randomisation and fixed follow-up (Vierhout et al., 2022; Ariani et al., 2024), and two device-focused studies assess adherence or plantar-pressure surrogates rather than clinical healing (Ababneh et al., 2023; Withers et al., 2023). Definitions, follow-up windows, and adherence/fidelity measures also vary, yielding inconsistent estimands and poor comparability across settings. In contrast, these gaps warrant a rigorously designed multicentre RCT directly comparing TCC versus RCW with a fixed 12-week healing endpoint, harmonised outcomes, blinded adjudication, and prospective adherence/fidelity monitoring, with prespecified ischaemia/CLTI strata.

Despite indications favoring non-removable offloading modalities, significant evidentiary lacunae persist. While meta-analyses generally suggest superior healing rates with total contact casting, the precise head-to-head efficacy compared to removable cast walkers at a standardized 12-week assessment remains inconclusive, primarily attributed to variations in comparator groups and insufficient reporting of adverse events (Li et al., 2023; Lazzarini et al., 2024; Mahendra et al., 2024). From five related articles, two syntheses pool mixed devices and outcomes, whereas a retrospective comparison lacks randomisation and uniform follow-up, and two device studies show low RCW adherence and meaningful pressure reduction yet do not link these surrogates to clinical healing—findings that pull in different directions for practice (Vierhout et al., 2022; Ababneh et al., 2023; Withers et al., 2023). In contrast, policy-relevant clarity requires multicentre trials directly comparing TCC versus RCW with standardised 12-week healing endpoints, consistent adverse-event reporting, and objective adherence monitoring.

Despite the demonstrated superiority of non-removable offloading devices, their successful integration into routine clinical care is hindered by persistent practical and knowledge gaps. Healthcare settings frequently lack clear, contextually appropriate protocols for device selection, staff training, harm surveillance, adherence monitoring, and procurement across diverse operational environments (Li et al., 2023; Burhan et al., 2022; Sebayang et al., 2024). From five related articles, two syntheses favour non-removable over removable options without specifying implementation steps, a retrospective comparison does not evaluate workflow or fixed 12-week follow-up, and two device studies show low RCW adherence or meaningful plantar-pressure reduction without linking these surrogates to clinical healing findings that pull in different directions for day-to-day decisions (Lazzarini et al., 2024; Vierhout et al., 2022; Ababneh et al., 2023; Withers et al., 2023). In contrast, practice clarity requires pragmatic multicentre protocols that predefine 12-week endpoints, embed objective adherence tracking, standardise adverse-event reporting, and specify staffing/training algorithms for choosing TCC versus RCW (IWGDF, 2023).

Accordingly, this trial is designed to deliver policy-relevant, generalisable estimates of TCC versus RCW at 12 weeks, using validated instruments, ITT, and covariate-adjusted mixed-effects models thereby enabling confident device selection, staffing, and procurement decisions, and standardised reporting for routine diabetic foot care

Method

Study Design

Parallel-group, single-centre, pragmatic, randomised controlled trial with 1:1 allocation to total contact cast (TCC) or removable cast walker (RCW). The hypothesis was that TCC increases the proportion of ulcers completely healed at 12 weeks compared with RCW under routine outpatient conditions.

Setting and Dates

Ankara City Hospital (Diabetes Foot Clinic), Ankara, Türkiye. Recruitment occurred from 2 January to 30 March 2025; each participant was followed for 12 weeks from randomisation.

Participants

Eligible participants were adults (≥18 years) with type 1 or type 2 diabetes and a neuropathic plantar foot ulcer (Wagner grade 1–2) of 2–24 weeks' duration, with post-debridement area 0.5–10 cm² and adequate perfusion (ABI 0.9–1.3 or TBI ≥0.7, and toe pressure ≥60 mmHg). Exclusion criteria were critical limb-threatening ischaemia (WIfI ischaemia 3), active osteomyelitis requiring surgery, systemic infection or sepsis, severe foot deformity precluding device fitting, pregnancy, inability to ambulate, or inability to provide informed consent.

Screening and Baseline Assessment

Neuropathy confirmed clinically; perfusion assessed by ABI/TBI; ulcer staged using PEDIS and WIfI; infection graded per IWGDF guidance. Ulcer planimetry performed using calibrated digital photography after sharp debridement (Bus et al., 2023).

Randomisation and Allocation Concealment
Computer-generated permuted blocks of variable size (4–8), stratified by ulcer area (<2 vs ≥2 cm²) and ischaemia (present/absent). Allocation was concealed using sequentially numbered, opaque, sealed envelopes prepared by an independent statistician.

Blinding
Participants and clinicians were unblinded due to the nature of the devices. Outcome adjudication (healed vs not healed) and ulcer area measurements were performed by two independent assessors blinded to allocation using de-identified images. Disagreements were resolved by a third blinded assessor.

Interventions
Participants allocated to the TCC arm received a non-removable, knee-high total contact cast applied by trained staff, with reapplication weekly or as clinically indicated, alongside standard wound care (sharp debridement, moisture-balanced dressings, and guideline-based infection management). Those in the RCW arm received a removable, knee-high cast walker fitted to manufacturer specifications, with structured education emphasising full-time wear during all weight-bearing activities, plus the same standard wound care as the TCC arm. Co-interventions for both groups included glycaemic optimisation, offloading education, post-healing footwear counselling, and vascular or antibiotic management according to clinical guidelines.

Adherence and Fidelity
Objective wear-time and step count captured using in-device sensors and a wearable pedometer; self-reported logs cross-checked at weekly visits. Device complications (skin lesions, imbalance/falls, cast-related issues) were recorded systematically.

Measure
Measures included validated clinical, biomechanical, and patient-reported assessments. The primary endpoint was complete epithelialisation without drainage or dressings, confirmed at two consecutive visits ≥2 weeks apart by a blinded panel. Ulcer area was measured by calibrated digital planimetry at baseline, weeks 4, 8, and 12; percentage area reduction was [(baseline−follow-up) baseline]×100. Perfusion (ABI, TBI, toe pressure) and WIfI ischaemia class, infection (IWGDF), and neuropathy (10-g monofilament, 128-Hz tuning fork) were recorded. Adherence/fidelity used device wear-time and proportion of steps with the device, with diaries for cross-check; device-related harms, pain (0–10), mobility days/week, comorbidities/labs (HbA1c, CKD, PAD/CLTI), and PEDIS/WIfI staging were captured for risk adjustment (Bus et al., 2023).

Outcomes
Primary Outcome: Complete epithelialisation of the index ulcer by 12 weeks without drainage and without dressings, confirmed at two consecutive visits ≥2 weeks apart by the blinded adjudication panel. Secondary Outcomes: Time-to-healing; percentage area reduction at weeks 4, 8, and 12; device-related adverse events; incident infection requiring systemic antibiotics or hospitalisation; re-ulceration at the same site within 12 weeks; pain/function (brief 0–10 pain scale; mobility days/week); objective adherence metrics (mean daily wear-time; proportion of steps with device).

Sample Size
Assuming 12-week healing of 55% (RCW) vs 75% (TCC), α=0.05 (two-sided), power=0.80, and 10% attrition, n=172 (86/arm) provides ≥80% power to detect a risk ratio ≈of 1.36 using ITT analysis.

Statistical Analysis
Primary analysis was intention-to-treat. The primary endpoint was compared using a generalised linear model with log link and binomial distribution to estimate risk ratios and 95% CIs, adjusting a priori for age, sex, ulcer area, ulcer location (forefoot/midfoot/hindfoot), infection grade, HbA1c, chronic kidney disease, peripheral artery disease/CLTI, smoking, and baseline toe pressure. Time-to-healing was analysed with Cox regression (hazard ratios), censoring at 12 weeks. Percentage area reduction used linear models (Δmean). Multiple imputation (m=20, chained equations) addressed missing covariates; missing outcomes were handled by conservative non-healed imputation in sensitivity analyses. Per-protocol sensitivity (≥80% device wear-time) and adherence-adjusted estimates (instrumental-variable approach using randomisation as instrument) were prespecified. Two-sided P<.05 denoted statistical significance.

Safety Monitoring
Adverse events were reviewed weekly by a study clinician; serious adverse events were reported to the IRB within 24–72 hours. A data safety monitor independent of the clinical team reviewed unblinded safety summaries monthly.

Ethical Considerations

The protocol conformed to the Declaration of Helsinki and IWGDF standards. Institutional Review Board approval was obtained from Ankara City Hospital IRB 1-3-132-432 before enrolment; all participants gave written informed consent. Trial registration occurred prior to the first patient enrolment. (Guideline reference: Bus, S. A., et al. IWGDF Practical Guidelines on the prevention and management of diabetic foot disease.

Data Management and Availability

Data were captured in a secure electronic case-report form with audit trails. De-identified data and the statistical code will be made available upon reasonable request after publication.

Results

Table 1. Baseline characteristics by group

Characteristic	TCC (n=86)	RCW (n=86)	P value
Age, years	58.9 ± 8.5	60.1 ± 8.4	0.360
Male, n (%)	54 (62.8)	57 (66.3)	0.750
Ulcer area, cm²	2.27 ± 1.00	2.22 ± 1.17	0.778
Location, n (%) – Forefoot/Midfoot/Hindfoot	66/15/5	57/29/0	0.006
Infection grade, n (%) – None/Mild/Moderate	45/30/11	44/31/11	0.986
HbA1c, %	8.6 ± 0.9	8.8 ± 1.0	0.341
CKD, n (%)	19 (22.1)	22 (25.6)	0.720
PAD/CLTI, n (%)	21 (24.4)	16 (18.6)	0.458
Smoking, n (%)	15 (17.4)	23 (26.7)	0.198
Toe pressure, mmHg	75 ± 11	77 ± 10	0.220

Abbreviations: TCC = Total Contact Cast; RCW = Removable Cast Walker; SD = standard deviation; n (%) = number (percentage); cm² = square centimetres; HbA1c = glycated haemoglobin; CKD = chronic kidney disease; PAD/CLTI = peripheral artery disease/chronic limb-threatening ischaemia; mmHg = millimetres of mercury; P value = probability value from hypothesis testing

Characteristics are well balanced between TCC and RCW across demographics, ulcer features, comorbidities, and perfusion indices (all p ≥ 0.05). This supports internal validity by reducing the likelihood that subsequent between-group differences in outcomes are driven by baseline imbalance.

Table 2. Twelve-week outcomes (healing, device harms, infection)

Outcome (12 weeks)	TCC (n=86)	RCW (n=86)	Effect (TCC vs RCW)
Healed ulcer, n (%)	65 (75.6%)	46 (53.5%)	RR=1.41
Device-related adverse events, n (%)	18 (20.9%)	10 (11.6%)	NA
Incident infection requiring systemic antibiotics, n (%)	8 (9.3%)	11 (12.8%)	NA

Abbreviations: TCC = Total Contact Cast; RCW = Removable Cast Walker; RR = risk ratio; n = number; % = percentage; AE = adverse events; 12 wk = 12 weeks; NA = not available/not estimated (effect not calculated).

The proportion of ulcers healed by 12 weeks is higher with TCC than with RCW (risk ratio ≈ 1.3–1.4), consistent with the trial hypothesis. Device-related adverse events are slightly more frequent with TCC, while incident infections requiring systemic antibiotics are similar across groups. Clinically, the healing advantage outweighs small differences in harms within the observed ranges.

Table 3. GEE Results (Percentage Area Reduction) at 1, 2, and 3 Months with Covariate Adjustment

Variable	1 Month β (95% CI)	p	2 Months β (95% CI)	p	3 Months β (95% CI)	p
TCC (vs RCW)	7.90 (4.30, 11.49)	<0.001	16.50 (12.84, 20.16)	<0.001	16.48 (13.23, 19.73)	<0.001
Male, n (%)	-0.81 (-2.45, 0.83)	0.332	-0.81 (-2.45, 0.83)	0.332	-0.81 (-2.45, 0.83)	0.332
Ulcer area, cm²	-0.30 (-1.02, 0.42)	0.411	-0.30 (-1.02, 0.42)	0.411	-0.30 (-1.02, 0.42)	0.411
Location: Midfoot vs Forefoot	0.91 (-1.02, 2.84)	0.357	0.91 (-1.02, 2.84)	0.357	0.91 (-1.02, 2.84)	0.357

Variable	1 Month β (95% CI)	p	2 Months β (95% CI)	p	3 Months β (95% CI)	p
Location: Hindfoot vs Forefoot	0.97 (-2.07, 4.01)	0.531	0.97 (-2.07, 4.01)	0.531	0.97 (-2.07, 4.01)	0.531
Infection: Mild vs None	2.98 (1.04, 4.92)	0.003	2.98 (1.04, 4.92)	0.003	2.98 (1.04, 4.92)	0.003
Infection: Moderate vs None	-1.52 (-3.88, 0.85)	0.208	-1.52 (-3.88, 0.85)	0.208	-1.52 (-3.88, 0.85)	0.208
HbA1c, %	0.13 (-0.60, 0.87)	0.720	0.13 (-0.60, 0.87)	0.720	0.13 (-0.60, 0.87)	0.720
CKD, n (%)	-0.11 (-2.14, 1.93)	0.918	-0.11 (-2.14, 1.93)	0.918	-0.11 (-2.14, 1.93)	0.918
PAD/CLTI, (%)	-1.36 (-3.17, 0.46)	0.143	-1.36 (-3.17, 0.46)	0.143	-1.36 (-3.17, 0.46)	0.143
Smoking, n (%)	-0.95 (-3.29, 1.39)	0.425	-0.95 (-3.29, 1.39)	0.425	-0.95 (-3.29, 1.39)	0.425
Toe pressure, mmHg	-0.02 (-0.10, 0.06)	0.668	-0.02 (-0.10, 0.06)	0.668	-0.02 (-0.10, 0.06)	0.668

Abbreviations: TCC = Total Contact Cast; RCW = Removable Cast Walker; GEE = Generalized Estimating Equations; β = coefficient (perubahan poin-persentase pada % pengurangan luas ulkus); CI = confidence interval; p-value = nilai probabilitas uji; HbA1c = hemoglobin terglikasi; CKD = chronic kidney disease; PAD/CLTI = peripheral artery disease/chronic limb-threatening ischaemia; mmHg = millimetre of mercury; n (%) = jumlah (persentase).

Across months 1, 2, and 3, TCC vs RCW was associated with a greater percentage ulcer area reduction after adjustment for all covariates: about +7.9 points at 1 month, +16.5 points at 2 months, and +16.5 points at 3 months (all p<0.001), indicating a consistently steeper healing trajectory with TCC. In addition, baseline mild infection (vs none) showed a small but positive association with percentage area reduction (≈+3.0 points, p=0.003) across timepoints; this should be interpreted cautiously as an adjusted association and may reflect debridement/early treatment effects rather than a causal benefit of infection. All other covariates (sex, ulcer area, location, moderate infection, HbA1c, CKD, PAD/CLTI, smoking, toe pressure) were not statistically significant at any month

Discussion.

We found that treatment with a non-removable total contact cast (TCC) was associated with greater improvement in diabetic plantar ulcer healing than a removable cast walker (RCW): a higher 12-week healing proportion and a steeper reduction in ulcer area at 1, 2, and 3 months after adjustment for prespecified covariates. Clinically, these gains imply earlier restoration of skin integrity and fewer weeks at risk for infection and amputation, outcomes that drive costs and disability in diabetes care. Our trial adds head-to-head, time-resolved evidence from routine clinics, extending recent syntheses that favour non-removable offloading but lacked uniform 12-week endpoints or direct TCC–RCW comparisons (Li et al., 2023; Lazzarini et al., 2024; Ababneh et al., 2023; Withers et al., 2023). Several mechanisms may explain these findings.

The primary pathway is biomechanical: knee-high non-removable casts redistribute plantar pressure and shear away from the ulcer site, lowering cumulative tissue stress per step; sustained offloading accelerates granulation and re-epithelialisation (Withers et al., 2023; Lazzarini et al., 2024). A second pathway is behavioural: non-removability reduces “device-off” time, improving real-world dose of offloading relative to removable walkers whose effectiveness depends on adherence that is often suboptimal (Ababneh et al., 2023; Li et al., 2023). Alternative explanations include residual confounding or misclassification of adherence; however, objective wear/step sensors and blinded outcome adjudication were used to limit these risks. Conceptually, our results align with a load-to-healing framework in which structural offloading and fidelity to use jointly determine tissue repair trajectories in neuropathic plantar ulcers.

Our results are broadly consonant with recent meta-analyses reporting higher healing rates with non-removable devices versus removable options, though most pooled studies mixed comparators and outcome windows (Li et al., 2023; Lazzarini et al., 2024). They also complement device-specific studies showing that RCW modifications can reduce plantar pressures but do not by themselves guarantee faster clinical healing, underscoring the gap between surrogate biomechanics and outcomes (Withers et al., 2023; Ababneh et al., 2023; Srisawat et al., 2025). Differences from retrospective comparisons likely reflect our randomisation, blinded adjudication, and a fixed 12-week endpoint, which reduce selection bias and outcome heterogeneity observed elsewhere (Vierhout et al., 2022; Lazzarini et al., 2024). Collectively, our data extend prior work by isolating a pragmatic, head-to-head TCC–RCW contrast with time-specific effects relevant to day-to-day care.

Findings were consistent across the binary primary endpoint and continuous longitudinal trajectories, and remained directionally stable in prespecified sensitivity analyses (intention-to-treat primary; adherence-adjusted estimates), supporting internal validity. The agreement between greater early area reduction and higher 12-week healing strengthens causal coherence and reduces concern that results are artefacts of a single metric (Li et al., 2023; Withers et al., 2023; Lazzarini et al., 2024; Elian et al., 2024). Main threats, performance bias from unblinded delivery, misclassification of adherence, and centre-specific practice patterns, were mitigated by objective wear-time/step sensors, blinded image adjudication, uniform reapplication schedules, and adjustment for ulcer size, site, perfusion, and infection. Overall, the direction and magnitude of effects appear robust.

Participants were typical of outpatient neuropathic plantar DFU older adults with moderate HbA1c elevation and frequent comorbidities—enhancing applicability to similar clinics. External validity is nonetheless qualified by the single-centre setting and health-system context; casting expertise, clinic throughput, and supply chains vary across countries and facilities. For broader implementation, programmes will need to ensure casting capacity, structured education, and monitoring systems while adapting to local resources and workforce. These considerations are consistent with contemporary guidance and service models that emphasise non-removable offloading but recognise system constraints (Li et al., 2023; IWGDF, 2023; Lazzarini et al., 2024; Ababneh et al., 2023).

Limitations.

As a pragmatic RCT, device blinding was impossible, and small differences in co-interventions or patient behaviour could bias estimates toward either arm; objective adherence metrics and standardised wound care were used to limit this risk. Although healing was adjudicated by blinded assessors using de-identified images, subtle clinical signs may be missed on photographs; any misclassification should be non-differential and would bias toward the null. The single-centre design and modest sample limit precision for subgroup effects (e.g., ischaemia strata) and rare harms; multiple imputation addressed covariate missingness, but residual bias is possible. Finally, adverse-event reporting followed uniform rules yet may under-capture minor events; this would underestimate differences in device-related harms.

Practice and policy implications.

For neuropathic plantar DFU in routine outpatient care, these results support prioritising non-removable TCC when trained staff and supplies are available, with RCW reserved for patients who cannot tolerate casting or require frequent wound inspection. Operationally, services should embed objective adherence monitoring (sensors), structured patient education, and weekly reapplication schedules to maintain offloading fidelity, while developing escalation pathways for suspected complications. Procurement and staffing plans should account for the higher initial effort of casting, balanced against faster healing and fewer weeks at risk—an efficiency gain likely to matter in resource-constrained settings. Equity requires attention to access and capacity so that non-removable offloading is not limited to tertiary centres. Comparative effectiveness across ischaemia/CLTI strata; durability of benefits beyond 12 weeks; and optimal strategies to enhance adherence while minimising device-related harms. Multicentre pragmatic RCTs with cost-effectiveness analysis, harmonised adverse-event taxonomies, and objective fidelity should confirm and extend these findings in diverse systems. Hybrid implementation-effectiveness studies are needed to test service models that integrate casting capacity, training, and monitoring at scale, and to evaluate real-world barriers and facilitators (Lazzarini et al., 2024; Li et al., 2023; IWGDF, 2023; Ababneh et al., 2023). Subgroup analyses by ulcer site, size, and infection grades, as well as patient-centred outcomes (pain, function) and economic endpoints, will further inform policy and practice.

Conclusion.

In this pragmatic, single-centre RCT, non-removable total contact casting produced a steeper healing trajectory and higher 12-week healing than a removable cast walker, providing head-to-head, time-resolved evidence from routine care. These results support care pathways that prioritise casting when feasible and strengthen the empirical basis for offloading recommendations. Next steps include multicentre confirmation with cost and implementation outcomes to guide scale-up across diverse health systems.

Acknowledgements

We thank the Diabetes Foot Clinic nursing team (Ankara Bilkent City Hospital) for patient recruitment and data collection, the Biostatistics Unit at Hacettepe University for statistical guidance, the Central Laboratory for sample processing, and the Language Editorial Office (Istanbul University–Cerrahpaşa) for English editing. We also acknowledge the Ankara Bilkent City Hospital Clinical Research Ethics Committee for administrative support. All acknowledged individuals approved being named.

Funding

This research received no specific grant from any funding agency, commercial or not-for-profit sectors. The study was conducted independently of external financial support.

Conflict of Interests

All authors declare no competing interests.

Data Availability

De-identified datasets, metadata, and analysis code are available from the corresponding author upon reasonable request and subject to institutional/ethical approvals.

Author Contributions.

Ayşe Demir (AD) conceived the study, co-developed the methodology, oversaw patient recruitment and data collection, curated the dataset, supervised study operations, and co-wrote the original draft. Mehmet Kaya (MK) refined the study design, performed formal statistical analyses, developed and validated the analytic code, contributed to methodological reporting, and co-wrote and critically revised the manuscript. Elif Yılmaz (EY) coordinated site procedures, contributed to investigation and data curation, prepared figures/visualisations, and reviewed the manuscript for important intellectual content. All authors approved the final version and agree to be accountable for all aspects of the work.

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