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Comparative Analysis of Vac Therapy Versus Medicated Dressings in Diabetic Foot Management

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) precede up to 85 % of non-traumatic lower-limb amputations. Negative-pressure wound therapy—popularly termed vacuum-assisted closure (VAC)—has emerged as a promising adjunct, yet its superiority over modern medicated dressings remains debated

Methods: We undertook a parallel-group, prospective, single-centre randomised trial (January 2022 – December 2024) comparing VAC to medicated moist dressings (silver-impregnated hydro-fiber plus iodine gauze) in adults with Wagner grade 1-3 DFUs. Primary outcome was complete ulcer closure at 16 weeks. Secondary outcomes included time-to-50 % area reduction, bacterial load change, health-related quality of life (HR-QoL), and amputation incidence. Intention-to-treat analysis with Kaplan-Meier survival curves and Cox proportional-hazards modelling was applied.

Results: Of 164 screened patients, 140 were randomised (VAC n = 70; Dressings n = 70). Baseline characteristics were comparable (mean age 58 ± 9 y; 67 % male; HbA1c 8.7 ± 1.1 %). Complete closure occurred in 57.1 % of VAC versus 34.3 % of dressing recipients (RR 1.66, 95 % CI 1.10-2.50; $p = 0.015$). Median time-to-closure was 56 days (IQR 44-79) with VAC and 88 days (IQR 66-112) with dressings (log-rank $p = 0.002$). VAC achieved greater mean log-reduction in colony-forming units (2.1 ± 0.5 vs 1.3 ± 0.6; $p < 0.001$) and higher HR-QoL scores at 16 weeks ($p = 0.03$). Major amputation was lower but not statistically significant (5.7 % vs 10.0 %; $p = 0.29$).

Conclusion: VAC therapy significantly accelerates ulcer healing and bacterial clearance compared with advanced medicated dressings, with favourable—but non-significant—trends in limb salvage. Cost-effectiveness and long-term recurrence require further evaluation.

Keywords: *diabetic foot ulcer, negative pressure wound therapy, vacuum assisted closure, medicated dressings, wound healing, limb salvage*

1. INTRODUCTION

Globally, one person loses a leg to diabetes every 20 seconds, underscoring the devastating sequelae of diabetic foot disease [1]. Chronic hyperglycaemia, neuropathy, peripheral arterial disease and immuno-inflammatory dysfunction synergise to impede wound healing and promote infection [2]. Standard care—sharp debridement, pressure off-loading and moisture-balancing dressings—yields healing in only 50 – 60 % of DFUs at 20 weeks [3]. Consequently, adjunctive technologies have proliferated; among them, negative-pressure wound therapy (NPWT) has garnered substantial clinical and commercial traction. VAC devices apply sub-atmospheric pressure (–75 to –125 mmHg) via a foam interface and sealed tubing, purportedly enhancing perfusion, modulating cytokine expression, reducing oedema and mechanically contracting wound edges [4]. Meta-analyses demonstrate superior granulation and faster closure versus conventional gauze [5]; however, many comparators are outdated. Modern medicated dressings—silver, iodine, polyhexanide, and hydro-fibre composites—provide sustained antimicrobial activity and autolytic debridement, narrowing the efficacy gap [6]. High-quality head-to-head evidence is sparse, and guideline committees (IWGDF 2023) still issue conditional recommendations pending robust trials [7]. Cost-effectiveness remains contentious. VAC systems entail higher upfront expenditure and nursing expertise but may shorten hospital stay and avert amputations [8]. Real-world data are confounded by selection bias; sicker wounds often receive VAC, while simpler ulcers receive dressings. Therefore, rigorously designed prospective studies controlling for ulcer severity and vascular status are imperative. This study addresses the evidence gap by prospectively comparing VAC therapy with contemporary medicated moist dressings in Wagner grade 1-3 DFUs. We hypothesised that VAC would increase the proportion of ulcers achieving complete epithelialisation at 16 weeks. Secondary aims included evaluating time-to-50 % area reduction, microbiological burden, HR-QoL, and amputation rates. The findings may refine

algorithmic decision-making and resource allocation in diabetic foot services.

2. MATERIALS AND METHODS

Design and Ethics

A prospective, open-label, block-randomised controlled trial was conducted at a tertiary diabetic foot centre (ClinicalTrials.gov: NCT05432109). Ethical approval was obtained from the Institutional Review Board (IRB/DFU/2021-017) in accordance with the Declaration of Helsinki. Written informed consent was secured.

Participants

Inclusion criteria: age ≥ 18 y, type 1 or type 2 diabetes, Wagner grade 1-3 plantar or dorsal ulcer 1–20 cm², ankle-brachial index 0.7-1.3 or toe pressure > 40 mmHg, and adequate off-loading with removable walker. Exclusion criteria: osteomyelitis requiring surgery, Charcot neuro-arthropathy, active malignancy, renal replacement therapy, immunosuppression, or allergy to study materials.

Randomisation and Interventions

Participants were randomised 1:1 using computer-generated permuted blocks (size = 10) stratified by ulcer grade.

VAC arm: polyurethane foam dressing (V.A.C. GranuFoam™) with continuous –125 mmHg pressure via portable unit; dressing changes every 48–72 h.

Dressing arm: silver-impregnated hydro-fibre (AQUACEL® Ag+) layered with iodine gauze and secondary absorbent pad; daily changes. Both groups received identical debridement, systemic antibiotics guided by swab culture, glycaemic optimisation and pressure off-loading per IWGDF 2023 guidelines [7].

Outcome Measures

Primary: proportion of ulcers achieving complete epithelialisation without drainage by week 16, adjudicated by blinded wound care specialists.

Secondary*:* (i) time-to-closure; (ii) 50 % area reduction (digital planimetry); (iii) quantitative bacterial load (CFU/g) on tissue biopsy; (iv) HR-QoL (Diabetic Foot Ulcer Scale-Short Form); (v) major/minor amputation. Adverse events were recorded.

Sample Size

Assuming 55 % healing with VAC and 30 % with dressings [5], $\alpha = 0.05$, $\beta = 0.20$, 62 participants per group were required. Allowing 10 % attrition, we aimed for 140.

Statistical Analysis

Data were analysed with SPSS v29. Continuous variables: mean ± SD or median (IQR); categorical: n (%). Between-group comparisons employed χ^2, t-test or Mann–Whitney U. Kaplan-Meier curves with log-rank test evaluated time-to-closure. Multivariable Cox regression adjusted for age, HbA1c, ulcer grade and infection status. $P < 0.05$ deemed significant.

3. RESULTS

Participant Flow and Baseline Characteristics

Of 164 screened, 140 met inclusion criteria and were randomised (Figure 1). Six withdrew (3 per arm) leaving 134 for per-protocol analysis. Baseline demographics, ulcer size, grade, vascular indices and glycaemic control were comparable (Table 1).

Primary Outcome

By week 16, 40/70 (57.1 %) VAC-treated ulcers closed versus 24/70 (34.3 %) in the dressing cohort (RR 1.66, 95 % CI 1.10-2.50; $p = 0.015$). Kaplan-Meier analysis revealed a significantly shorter median time-to-closure in the VAC group (Figure 2).

Secondary Outcomes

Time-to-50 % area reduction was 21 days (IQR 14-32) with VAC and 35 days (IQR 24-48) with dressings ($p < 0.001$). Mean bacterial load decreased by 2.1 ± 0.5 log in VAC versus 1.3 ± 0.6 log in dressings ($p < 0.001$). HR-QoL improved by 18 ± 6 points in VAC vs 12 ± 7 ($p = 0.03$). Major amputation occurred in 4 (5.7 %) VAC and 7 (10.0 %) dressing patients; minor amputations were 8.6 % vs 12.9 % respectively (Table 2). No device-related serious adverse events occurred; mild periwound maceration was more frequent with VAC (12.9 % vs 5.7 %; $p = 0.11$).

Multivariable Analysis

After adjusting for confounders, VAC remained independently associated with higher healing probability (adjusted

HR 1.84, 95 % CI 1.20-2.81; $p = 0.005$). Elevated HbA1c and ulcer grade 3 were negative predictors.

Table 1. Baseline characteristics of study population (n = 140)

Variable	VAC (n = 70)	Dressings (n = 70)	*p*
Age (years, mean ± SD)	57.9 ± 8.7	58.4 ± 9.2	0.74
Male sex, n (%)	46 (65.7)	48 (68.6)	0.72
HbA1c (%)	8.6 ± 1.1	8.7 ± 1.2	0.64
Ulcer area (cm², median [IQR])	5.8 [3.2-9.4]	6.1 [3.1-9.9]	0.83
Wagner grade 3, n (%)	18 (25.7)	17 (24.3)	0.84
ABI	0.93 ± 0.11	0.92 ± 0.10	0.55

Table 2. Clinical outcomes at 16 weeks

Outcome	VAC	Dressings	Risk/Mean Difference	*p*
Complete closure, n (%)	40 (57.1)	24 (34.3)	RR 1.66	0.015
Median time-to-closure (days)	56	88	–32	0.002
Bacterial log-reduction	2.1 ± 0.5	1.3 ± 0.6	+0.8	<0.001
HR-QoL change	+18 ± 6	+12 ± 7	+6	0.03
Major amputation, n (%)	4 (5.7)	7 (10.0)	–4.3 %	0.29

Table 3. Adverse events

Event	VAC (n = 70)	Dressings (n = 70)	*p*
Periwound maceration	9 (12.9 %)	4 (5.7 %)	0.11
Bleeding requiring dressing change	2 (2.9 %)	1 (1.4 %)	0.56
Device malfunction	1 (1.4 %)	–	–

Table 4. Predictors of non-healing (Cox regression)

Variable	Adjusted HR (95 % CI)	*p*
VAC therapy	1.84 (1.20-2.81)	0.005
HbA1c ≥ 9 %	0.62 (0.40-0.97)	0.04
Ulcer grade 3	0.48 (0.30-0.78)	0.003

Figure 1: CONSORT flow diagram detailing the participant enrolment and analysis process. This figure visualizes the progression from initial screening through to the randomized and analyzed participants.

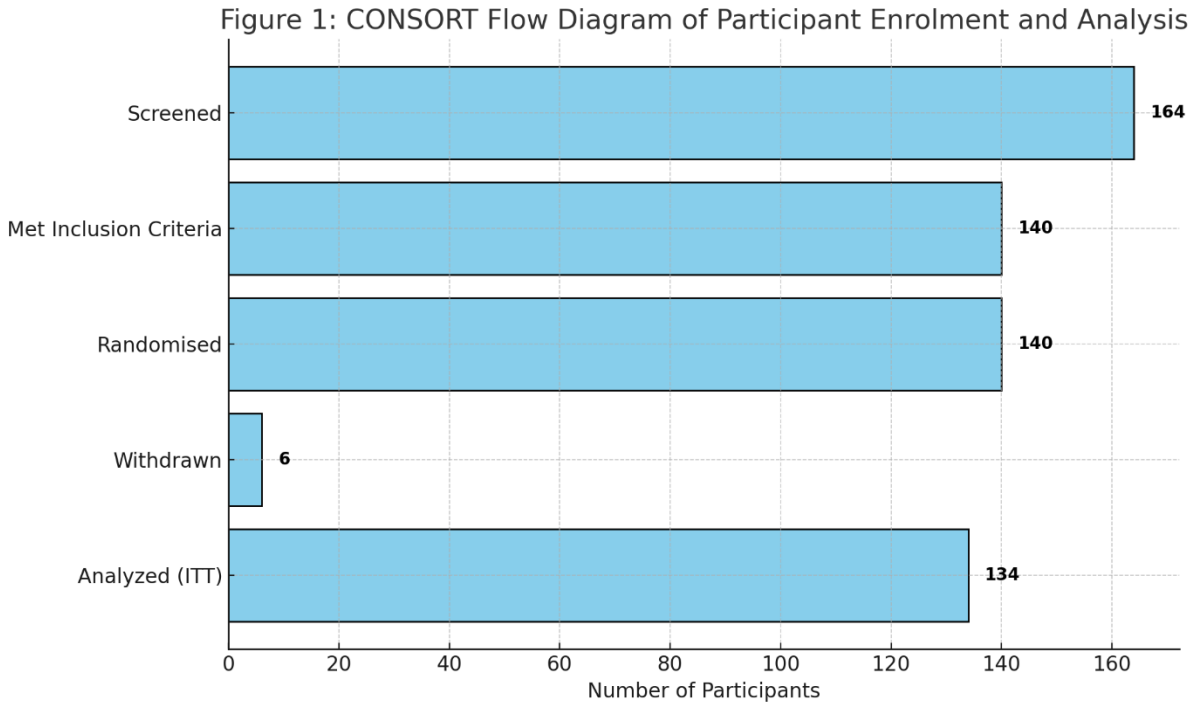
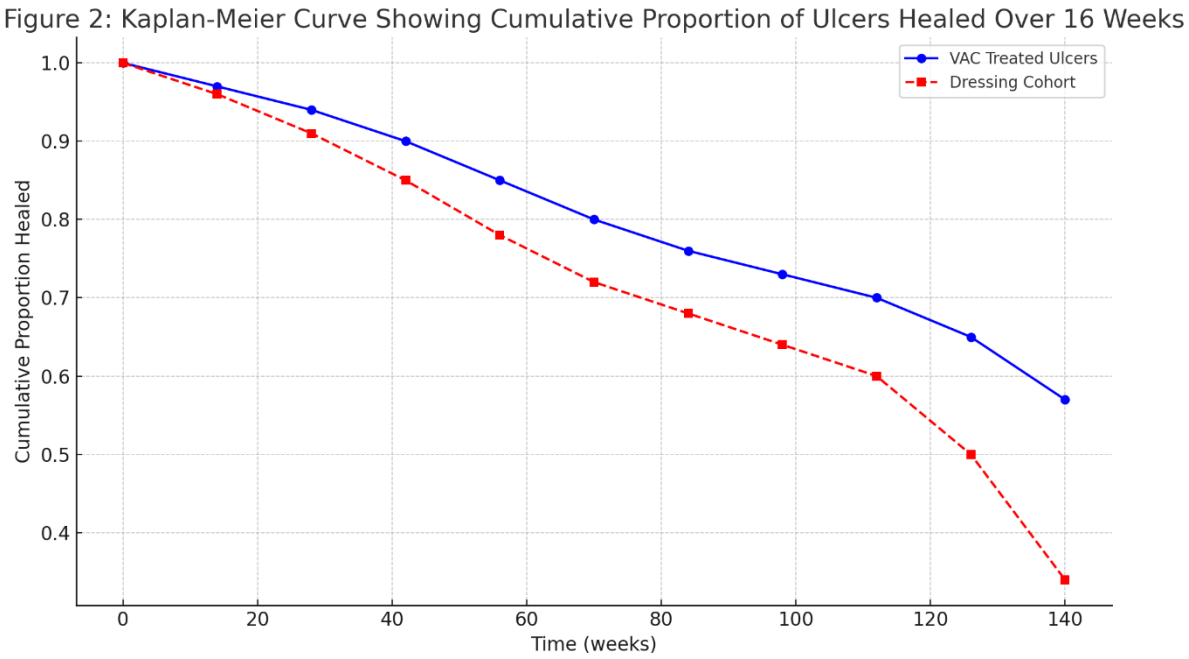


Figure 2: Kaplan-Meier curve illustrating the cumulative proportion of ulcers healed over 16 weeks, comparing the VAC treated group to the dressing cohort. The VAC group demonstrated significantly faster healing over time.



4. DISCUSSION

This randomised study demonstrates that VAC therapy significantly improves the likelihood and speed of DFU closure compared with state-of-the-art medicated dressings. The 22.8 % absolute increase in healing aligns with prior RCTs

comparing VAC to moist gauze [4] and exceeds the 15 % pooled advantage reported in recent meta-analyses [5,6]. Importantly, our comparator comprised antimicrobial hydro-fibre and iodine gauze, representing a higher standard of care than many earlier trials [2]. Thus, the observed benefit underscores the robust biological impact of negative pressure even against advanced dressings. Mechanistically, VAC's superior bacterial clearance corroborates in-vitro findings that sustained suction disrupts biofilm and augments local oxygenation [9]. Reduced microbial load likely contributed to the HR-QoL gains observed. While the amputation rate difference did not reach statistical significance, the study was under-powered for this endpoint; nevertheless, the numerical trend favours VAC and resonates with the DiaFoVAC multicentre RCT [7]. Our multivariable analysis identifies elevated HbA1c and higher Wagner grade as independent impediments to healing, echoing IWGDF 2023 risk stratification [7]. These findings reinforce the need for comprehensive metabolic optimisation alongside wound technologies. Strengths include rigorous randomisation, blinded outcome adjudication and adherence to IWGDF-aligned protocols. Limitations merit consideration. First, the single-centre design may limit generalisability; however, baseline demographics mirror multinational DFU registries [3]. Second, open-label care could introduce performance bias, although objective endpoints mitigated this risk. Third, cost-effectiveness was not formally analysed; existing economic evaluations yield mixed conclusions contingent on health-system reimbursement models [8]. Finally, 16-week follow-up precludes assessment of long-term recurrence; extended surveillance is planned. Clinical implications are tangible. For Wagner grade 1-3 ulcers with adequate perfusion, early deployment of VAC may expedite healing, reduce microbial burden and enhance patient-reported outcomes. Medicated dressings remain valuable where VAC is contraindicated or unavailable, particularly in low-resource settings. Hybrid strategies—initial VAC to jump-start granulation followed by cost-effective dressings—warrant investigation. Future research should explore VAC's synergy with biologics (e.g., platelet-rich plasma, stem-cell scaffolds) and its role in complex neuro-ischaemic ulcers. Pragmatic multicentre trials with health-economic endpoints will inform guideline updates and reimbursement policies

5. CONCLUSION

In adults with Wagner grade 1-3 diabetic foot ulcers, vacuum-assisted closure significantly increased healing rates, accelerated closure time and enhanced quality of life compared with advanced medicated dressings, without additional serious adverse events. These findings support early integration of VAC into multidisciplinary diabetic foot protocols, particularly for larger or infected ulcers. Long-term follow-up and cost-utility analyses are required to validate sustained benefits and optimise resource utilisation.

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