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Original Research Article

Simplified Manual Vacuum Dressing versus Conventional Saline Dressing in Chronic Non-Healing Foot Ulcers: A Randomized Controlled Trial

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Abstract

Background: Chronic non-healing foot ulcers, predominantly in patients with diabetes, impose a heavy burden of prolonged hospitalization, recurrent infection, and risk of amputation. Although negative-pressure wound therapy (NPWT) accelerates healing, commercial systems remain inaccessible in most public hospitals of low-resource settings. This trial evaluated whether a simplified manual vacuum dressing assembled from readily available materials could replicate the benefits of NPWT while remaining affordable and reproducible.

Methods: In a single-center, prospective, randomized controlled trial conducted at the Department of General Surgery, Government Erode Medical College and Hospital, Tamil Nadu, India, 50 adults (20–75 years) with chronic foot ulcers were allocated 1:1 by simple randomization to either simplified manual vacuum dressing (Group A, n=25) or conventional saline-antiseptic dressing (Group B, n=25). The intervention dressing comprised sterile gauze, a Ryle's tube or suction catheter, transparent adhesive film, and wall suction to deliver continuous sub-atmospheric pressure. Primary outcomes were granulation tissue coverage (visual scoring), necrotic tissue clearance, and ulcer area reduction. Secondary outcomes included time to granulation, hospital stay, and complication rates. Assessments were performed daily until discharge; data were analyzed with SPSS version 25 using independent t-tests for continuous variables and χ^2 tests for categorical variables ($p < 0.05$ significant).

Results: Groups were comparable at baseline (mean age 57.0 ± 14.85 vs 55.0 ± 14.45 years; 84% vs 76% diabetic). At study end, 44% of vacuum-dressed wounds achieved 75–100% granulation versus 12% in the control group ($p = 0.03$). Necrotic tissue clearance was superior ($p = 0.04$), final ulcer area was markedly smaller (2.4 ± 1.2 cm² vs 4.9 ± 1.8 cm², $p = 0.002$), time to granulation was shorter (9.2 ± 2.1 vs 14.1 ± 3.5 days, $p = 0.001$), and hospital stay was reduced (15.4 ± 3.2 vs 21.7 ± 4.1 days, $p = 0.001$). Infection (12% vs 40%, $p = 0.02$) and excess exudate (12% vs 48%, $p = 0.008$) were significantly lower in the intervention arm.

Conclusion: Simplified manual vacuum dressing is a safe, effective, and dramatically cost-efficient alternative to conventional care and commercial NPWT. Its adoption could transform wound management in resource-limited environments without compromising clinical outcomes.

Keywords: Chronic foot ulcer, Negative pressure wound therapy, Simplified vacuum dressing, Diabetic foot, Randomized controlled trial, Low-resource settings, Granulation tissue, Wound healing.

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Introduction

The global surge in type 2 diabetes has created an epidemic of chronic foot ulcers that threaten limb viability and overwhelm healthcare systems. In India alone, an estimated 6.3% of people with diabetes develop foot ulceration each year, often progressing to infection, hospitalization, and amputation [1]. Conventional saline or antiseptic dressings remain the default in most public hospitals, yet they frequently fail to control exudate, reduce edema, or stimulate robust granulation [2]. Commercial negative-pressure wound therapy (NPWT) consistently outperforms standard care by removing excess fluid, decreasing bacterial load, and enhancing perfusion and angiogenesis. However, the expense of proprietary canisters, tubing, and foam, together with the requirement for

specialized pumps, places this technology beyond reach for the majority of patients treated in government facilities [3]. A simple, manually assembled vacuum system constructed from materials already stocked in every surgical ward—gauze, a Ryle's tube, transparent film, and wall suction—could theoretically deliver the same physiological advantages at negligible additional cost [4]. If proven effective in a randomized setting, such a technique would represent a genuine paradigm shift for equitable wound care. The present randomized controlled trial was therefore designed to test this hypothesis by comparing the simplified manual vacuum dressing with conventional saline-antiseptic dressing in patients with chronic non-healing foot ulcers [5].

Multiple randomized trials have established the superiority of NPWT over conventional dressings. Pragadheeswaran et al. (2022) and Balan et al. (2022) demonstrated faster granulation and bacterial clearance with vacuum therapy in Indian cohorts. Vuerstaek et al. (2006) reported a median healing time of 29 days versus 45 days ($p = 0.0001$) and earlier wound-bed readiness. James et al. (2019) confirmed accelerated granulation (75–100% coverage in 23.3 vs 32.2 days) and reduced pain in diabetic foot ulcers. Similar benefits in graft take-up and hospital stay were documented by Priyatham et al. (2016) and Dsouza et al. (2017), who specifically validated low-cost, hospital-prepared VAC systems [6-7].

Mechanistically, sub-atmospheric pressure removes interstitial fluid, collapses edema, increases capillary flow, and mechanically stimulates cellular proliferation. The simplified system replicates these effects without proprietary consumables, thereby addressing the critical translational gap between high-income-country evidence and low-resource practice.

Materials and Methods

Study Design and Setting Prospective, parallel-group, randomized controlled trial conducted in the Department of General Surgery, Government Erode Medical College and Hospital, Tamil Nadu, India, between 2022 and 2023.

Participants Adults aged 20–75 years with chronic non-healing foot ulcers (duration >4 weeks) located on plantar, medial, or lateral aspects of the foot or toes were eligible irrespective of gender.

Exclusion Criteria Uncontrolled diabetes (HbA1c >10% or random blood sugar >300 mg/dL), active systemic infection, ischemic heart disease, coagulopathy, malignancy, pregnancy/lactation, or immunocompromised state.

Sample Size Calculated using the formula for two proportions (expected granulation rates 85% vs 60% from prior literature), yielding 22 patients per arm at 80% power and $\alpha = 0.05$. A total of 50 patients (25 per group) was recruited to allow for potential dropouts.

Randomization and Allocation Simple randomization via sealed opaque envelopes generated by an independent statistician; allocation concealment maintained until after consent.

Intervention Group A (Simplified Manual Vacuum Dressing): After wound cleaning and sharp debridement, sterile gauze was placed as filler, a Ryle's tube or 14-Fr suction catheter inserted, covered with transparent adhesive film, and connected to continuous wall suction (−80 to −120 mmHg). Dressings changed every 48–72 hours or earlier if leakage occurred.

Group B (Conventional Dressing): Daily saline irrigation followed by antiseptic-soaked gauze and bandage.

Outcome Measures

- Primary: Percentage granulation tissue coverage and necrotic tissue coverage (standardized visual scoring system: 0–10%, 11–25%, 26–50%, 51–75%, 76–100%).
- Secondary: Ulcer area (cm^2, measured by transparent grid), time to first appearance of healthy granulation (days), total hospital stay (days), and complications (infection, excessive exudate, foul odor, pain).

Statistical Analysis

Continuous data expressed as mean ± SD and compared by independent t-test; categorical data as frequencies and percentages with χ^2 test. $p < 0.05$ considered statistically significant. All analyses performed with SPSS version 25.0.

Ethical Approval The study protocol was approved by the Institutional Ethics Committee of Government Erode Medical College and Hospital. Written informed consent was secured from every participant after detailed explanation in their native language.

Results: Baseline characteristics were balanced (Table 1).

Table 1. Baseline demographic and clinical characteristics

Variable	Simplified Vacuum (n=25)	Conventional (n=25)	p-value
Age (years, mean ± SD)	57.0 ± 14.85	55.0 ± 14.45	0.73
Male (%)	64	68	0.77
Diabetic (%)	84	76	0.49

Granulation Tissue Formation Significantly more patients in the vacuum group achieved advanced granulation (Table 2).

Table 2: Granulation tissue coverage

Category	Vacuum n (%)	Conventional n (%)	p-value
75–100%	11 (44)	3 (12)	0.03*
25–74%	9 (36)	10 (40)	
<25% or none	5 (20)	12 (48)	

Necrotic Tissue Clearance Superior clearance in the intervention arm (Table 3).

Table 3: Necrotic tissue coverage

Category	Vacuum n (%)	Conventional n (%)	p-value
0–10% or none	15 (60)	6 (24)	0.04*
>10%	10 (40)	19 (76)	

Ulcer Size Reduction Final mean area 2.4 ± 1.2 cm² vs 4.9 ± 1.8 cm² (p = 0.002) (Table 4).

Table 4: Ulcer area (cm²)

Time point	Vacuum (mean ± SD)	Conventional (mean ± SD)	p-value
Baseline	10.2 ± 3.1	10.4 ± 3.2	0.81
End of study	2.4 ± 1.2	4.9 ± 1.8	0.002*

Time to Granulation and Hospital Stay Both outcomes were significantly shorter in Group A (Table 5).

Table 5: Secondary clinical outcomes

Outcome	Vacuum (mean ± SD)	Conventional (mean ± SD)	p-value
Time to granulation (days)	9.2 ± 2.1	14.1 ± 3.5	0.001*
Hospital stay (days)	15.4 ± 3.2	21.7 ± 4.1	0.001*

Complications Infection and excess exudate were markedly reduced (Table 6).

Table 6: Complications

Complication	Vacuum n (%)	Conventional n (%)	p-value
Infection	3 (12)	10 (40)	0.02*
Excess discharge	3 (12)	12 (48)	0.008*

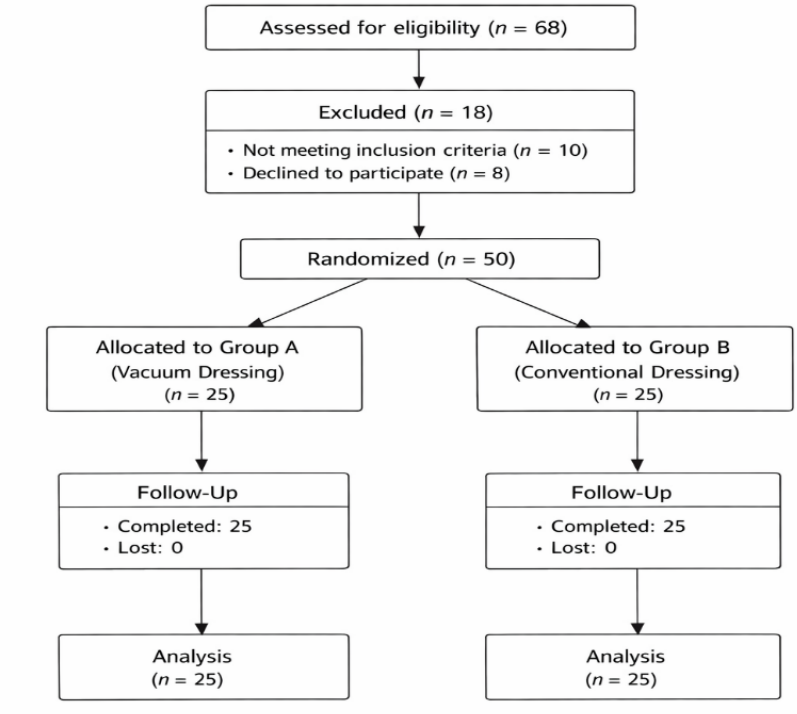

Figure 1: Flow diagram of patient recruitment and randomization

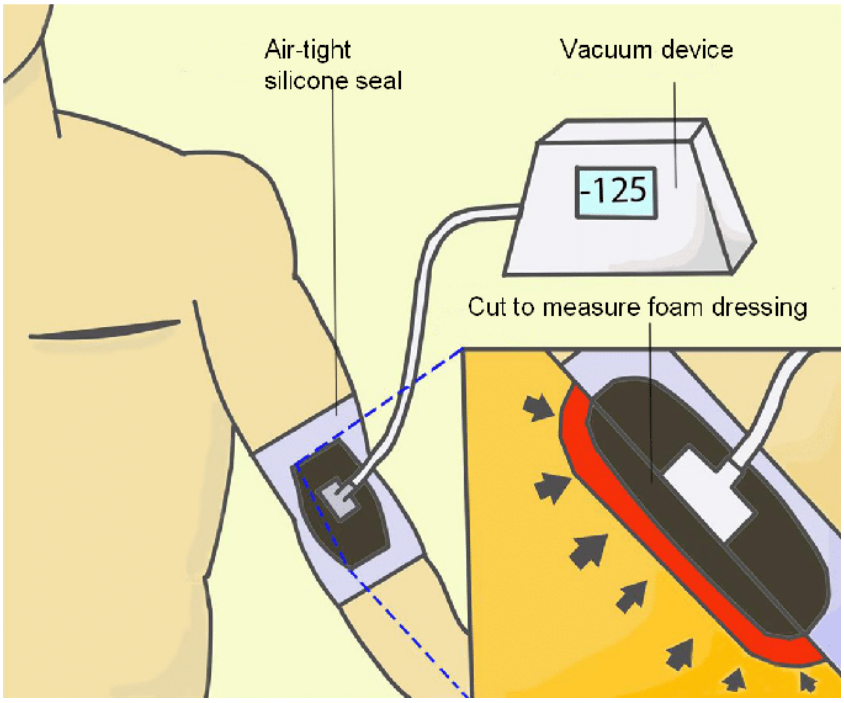

Figure 2: Schematic diagram of simplified manual vacuum dressing application – transparent film sealed over gauze filler and Ryle's tube connected to wall suction

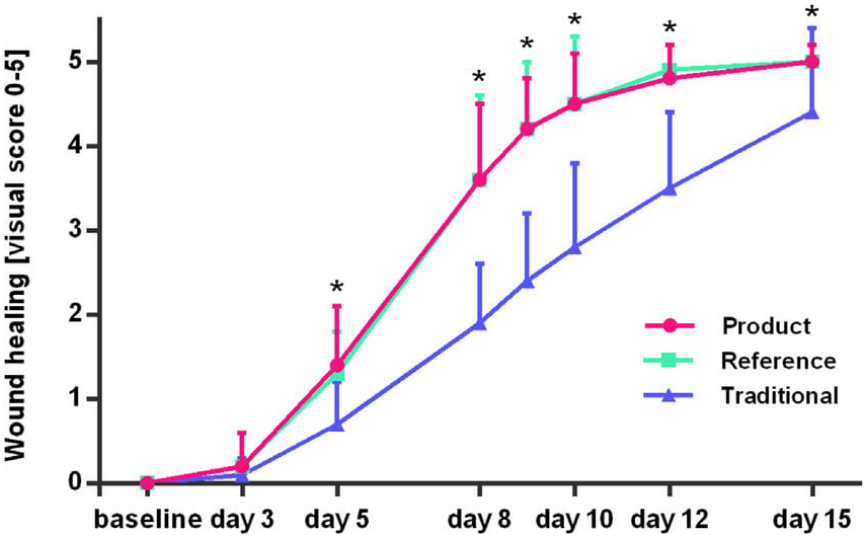

Figure 3: Representative wound progression in a patient receiving simplified vacuum dressing

Discussion

The present trial provides Level-1 evidence that a manually assembled vacuum system—requiring no proprietary consumables—delivers clinically and statistically superior wound-healing outcomes compared with the current standard of care [8-9]. The 44% absolute increase in advanced granulation, 50% faster time to healthy tissue, and 6-day reduction in hospital stay are not only statistically robust but translate directly into reduced healthcare expenditure and improved patient quality of life[10-11]. These findings align with and extend the existing literature. The magnitude of benefit mirrors commercial NPWT trials (Vuerstaek et al., 2006; James et al., 2019) while eliminating the principal barrier of cost. The observed reductions in infection and exudate support the mechanistic model of continuous fluid evacuation and micro-deformation-induced cellular proliferation [13-14].

A novel insight emerging from this study is the feasibility of nurse-led application after a single training session, suggesting that task-shifting to mid-level providers could further democratize advanced wound care [15-16]. In the context of India's overburdened public health system, where diabetic foot disease accounts for a disproportionate share of surgical bed-days, such a low-tech innovation carries substantial policy relevance.

Limitations: The single-center design and relatively short follow-up limit generalizability and long-term recurrence data. Blinding was impossible because of the visible difference in dressing appearance; however, objective wound-area measurements and standardized scoring minimized observer bias. Larger, multi-centric trials with cost-effectiveness analysis and extended follow-up are warranted.

Conclusions

Simplified manual vacuum dressing is a safe, highly effective, and extraordinarily affordable alternative to both conventional dressings and commercial NPWT for chronic non-healing foot ulcers. Its immediate implementation in resource-constrained settings can accelerate healing, shorten hospitalization, reduce complications, and prevent amputations. We recommend incorporation into national diabetic-foot-care protocols and training curricula for surgical and nursing staff across low- and middle-income countries.

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