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Clinical Outcomes of Vacuum-Assisted Closure Therapy in Post-Amputation Wounds - A Prospective Observational Study

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Abstract

Background: Major limb amputation remains a significant surgical intervention with high rates of wound complications, particularly in patients with diabetes and peripheral arterial disease. Vacuum-assisted closure (VAC) therapy has emerged as an advanced wound management modality, though robust prospective data in post-amputation populations remain limited. This study evaluated the clinical effectiveness of VAC therapy in upper and lower extremity amputation wounds.

Methods: A prospective observational study was conducted over 18 months at a Level I Trauma Centre. Adult patients undergoing upper or lower extremity amputation who received VAC therapy were enrolled. Intermittent negative pressure of −125 mmHg was applied using polyurethane foam dressings changed every fourth day. Outcomes included granulation tissue formation at postoperative day 7, time to complete wound closure, surgical site infection (SSI) rates, wound dehiscence, pain scores (Visual Analog Scale), length of hospital stay, and quality of life (SF-36) over 12 weeks.

Results: Of 150 patients screened, 120 completed the study (mean age 56.3 ± 12.1 years; 70% male). Diabetic limb disease was the indication in 50% of cases, and below-knee amputation was performed in 60%. Mean granulation tissue coverage at day 7 was 78.2 ± 12.1%, with significantly lower values in diabetic (74.1% vs. 84.0%, $p < 0.001$) and PAD patients (69.8% vs. 80.6%, $p < 0.001$). Mean wound area reduction by day 7 was 38.6 ± 15.4%. Complete epithelialization occurred at a mean of 33.5 ± 12.8 days, with 75% achieving closure by week 6. SSI developed in 15% and wound dehiscence in 8.3%. Mean pain scores decreased from 6.8 ± 1.2 to 3.9 ± 1.4 ($p < 0.001$). Mean hospital stay was 12.4 ± 5.6 days. Both physical (34.2 to 41.5, $p < 0.001$) and mental (38.6 to 44.0, $p = 0.002$) SF-36 component scores improved significantly at 12 weeks.

Conclusion: VAC therapy demonstrates favorable clinical outcomes in post-amputation wound manage ment, with enhanced granulation tissue formation, accelerated wound closure, low complication rates, and improved patient-reported outcomes. These findings support the integration of VAC therapy into standard post-amputation care protocols, particularly for high-risk populations.

Keywords: Vacuum-assisted closure, negative pressure wound therapy, amputation, wound healing, surgical site infection, diabetes, peripheral arterial disease.

Introduction

Limb amputation represents one of the most con sequential surgical procedures in modern healthcare, carrying substantial physical, psychological, and economic burdens. Global epidemiological trends indicate a rising incidence of diabetes-related amputations, particularly in low- and middle-income countries where access to preventive vascular and diabetic foot care remains limited. Traumatic amputations further contribute to this burden, especially among younger populations in regions with high rates of road traffic injuries and occupational hazards.

The postoperative period following major limb amputation is fraught with complications, including surgical site infection (SSI), stump necrosis, wound dehiscence, and delayed healing. These complications prolong hospitalization, delay prosthetic rehabilitation, and increase mortality risk. Conventional wound management strategies—primarily moist gauze dressings, antiseptic agents, and periodic debridement—often prove inadequate in high-risk patients characterized by ischemia, hyperglycemia, and impaired immunity. Negative pressure wound therapy (NPWT), commercially known as vacuum-assisted closure (VAC), applies controlled sub-atmospheric pressure to the wound bed through a sealed dressing system. The therapeutic mechanisms include macro deformation and micro deformation of tissue, enhanced micro vascular perfusion, edema reduction, exudates removal, and stimulation of angiogenesis and granulation tissue formation. While NPWT has demonstrated efficacy in orthopedic trauma, open fractures, and high-risk surgical incisions, prospective data specifically evaluating its role in post-amputation wounds remain sparse.

Given the increasing global burden of amputation-related morbidity and the limitations of conventional dressing protocols, this prospective observational study was designed to evaluate the clinical outcomes of VAC therapy in patients undergoing upper and lower extremity amputations. We hypothesized that VAC-treated amputation wounds would demonstrate accelerated granulation tissue formation, reduced infection rates, shorter time to closure, decreased

hospital stay, and improved quality of life compared to historical controls and published benchmarks for conventional care.

Materials and Methods

Study Design and Setting

This prospective, single-center, observational study was conducted at a Level I Trauma Centre over an 18-month period. Patients were followed for 12 weeks following the initiation of VAC therapy to assess wound healing trajectories and patient-centered outcomes.

Study Population

Consecutive adult patients (aged ≥18 years) undergoing upper or lower extremity amputation who required postoperative VAC therapy were considered for enrollment. Amputations were performed for indications including trauma, peripheral arterial disease (PAD), diabetic limb disease, and other surgical conditions. Patients with pre-existing chronic wounds in the same anatomical region, immune compromised status, pregnancy, necrotic eschar not amenable to debridement, or exposed major vasculature contraindicating VAC application were excluded.

Sample Size

The target enrollment was calculated to detect a statistically significant difference in the primary out come of granulation tissue proportion at postoperative day 7, assuming 80% statistical power and a 5% significance level. Accounting for anticipated attrition and non-compliance, a final analytical cohort of 120 patients was established.

VAC Application Protocol

Following amputation, all wounds underwent standardized preparation. Existing dressings were removed under strict aseptic precautions, wound swabs were obtained for microbiological culture, and the stump was irrigated with normal saline. Sharp surgical debridement was performed to eliminate non-viable tissue, and adequate hemostasis was confirmed prior to VAC application. A sterile open-pore polyurethane foam dressing (35 pores per inch, 33 mm thickness) was contoured to fill the wound cavity without overlapping onto intact skin. An adhesive drape was applied to create an airtight seal extending 3–5 cm beyond the wound margins. Negative pressure was delivered using a portable vacuum pump set to intermittent mode at −125 mmHg, with a cycle of 5 minutes on and 2 minutes off. Dressing changes were performed every 96 hours (fourth day) under sterile conditions.

Outcome Measures

The primary outcome was the proportion of granulation tissue formation at postoperative day 7, quantified through standardized digital wound photography and digital planimetry analysis by independent clinicians blinded to patient demographics.

Secondary outcomes included

- incidence of wound infection within 6 weeks, confirmed clinically and by microbiological culture
- time to complete wound closure, defined as 100% epithelialization without discharge
- length of hospital stay from VAC initiation to discharge
- patient-reported pain using the Visual Analog Scale (VAS)
- health-related quality of life measured by the SF-36 questionnaire at baseline and 12 weeks. Wound surface area was measured at baseline and day 7 to calculate percentage reduction.

Statistical Analysis

Data were analyzed using standard statistical software. Continuous variables were reported as mean ± standard

deviation or median with interquartile range based on distribution normality. Categorical variables were expressed as frequencies and percentages. Comparative analyses utilized the chi-square test for categorical data and the independent t-test or Mann–Whitney U test for continuous variables as appropriate. Multivariate logistic regression was employed to adjust for confounders in binary outcome assessment. A two-tailed p-value < 0.05 was considered statistically significant.

Ethical Considerations

The study protocol received approval from the Institutional Ethics Committee prior to commencement. All procedures adhered to the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). Written informed consent was obtained from each participant. Confidentiality was maintained throughout, and participants retained the right to withdraw without affecting their clinical care.

Results

Participant Flow and Baseline Characteristics

A total of 150 patients were assessed for eligibility. Twenty-two were excluded based on predefined criteria, and 128 were enrolled. Eight patients were lost to follow-up, yielding a final analytical cohort of 120 patients. The mean age was 56.3 ± 12.1 years, with the majority (46.7%) between 41 and 60 years of age. Males comprised 70% of the cohort.

Table 1: Baseline demographic and clinical characteristics of the study cohort (n = 120).

Characteristic	n (%) or Mean ± SD	Value
Age (years)	Mean ± SD	56.3 ±12.1
Age group 18–40	n (%)	18 (15.0)
Age group 41–60	n (%)	56 (46.7)
Age group >60	n (%)	46 (38.3)
Male sex	n (%)	84 (70.0)
Female sex	n (%)	36 (30.0)
Diabetic limb disease	Indication n (%)	60 (50.0)
Peripheral arterial disease	Indication n (%)	24 (20.0)
Trauma	Indication n (%)	30 (25.0)
Other indications	Indication n (%)	6 (5.0)
Below-knee amputation	Level n (%)	72 (60.0)
Above-knee amputation	Level n (%)	36 (30.0)
Upper limb amputation	Level n (%)	12 (10.0)
Diabetes mellitus (comorbidity)	n (%)	72 (60.0)
Peripheral arterial disease	n (%)	24 (20.0)
HbA1c (%)	Mean ± SD	7.6 ± 1.6
Serum albumin (g/dL)	Mean ± SD	3.3 ± 0.5

Granulation Tissue Formation

The mean proportion of granulation tissue at postoperative day 7 was 78.2 ± 12.1% (median 80%; interquartile range 72–88%). Subgroup analysis revealed significantly impaired granulation in diabetic patients compared to non-diabetic patients (74.1 ± 11.8% vs. 84.0 ± 9.6%, $p < 0.001$).

Similarly, patients with PAD demonstrated reduced granulation tissue formation relative to those without PAD (69.8 ± 10.4% vs. 80.6 ± 11.3%, $p < 0.001$).

Wound Surface Area Dynamics

The mean baseline wound surface area was 62.0 ± 28.4 cm^2. By postoperative day 7, the mean area decreased to 38.1 ± 22.0 cm^2, representing a mean percentage reduction of 38.6 ± 15.4% ($p < 0.001$ versus baseline).

Time to Complete Wound Closure

Complete epithelialization was achieved at a mean of 33.5 ± 12.8 days (median 32 days; interquartile range 24–42 days; range 14–70 days). By the sixth postoperative week, 90 patients (75.0%) had achieved complete wound closure, while 30 (25.0%) remained unhealed.

Wound-Related Complications

Surgical site infection occurred in 18 patients (15.0%), confirmed by clinical examination and supportive microbiological findings where indicated. Wound dehiscence was observed in 10 patients (8.3%). No cases of stump necrosis requiring conversion to a higher amputation level were recorded in this cohort.

Pain Assessment

Baseline mean VAS score was 6.8 ± 1.2. By postoperative day 7, mean pain scores decreased significantly to 3.9 ± 1.4 ($p < 0.001$), representing a 42.6% reduction in reported pain intensity.

Length of Hospital Stay

The mean duration of hospitalization from VAC initiation to discharge was 12.4 ± 5.6 days (median 11 days; inter quartile range 8–15 days; range 4–32 days).

Quality of Life Outcomes

Health-related quality of life improved significantly over the 12-week follow-up period. The SF-36 Physical Component Score increased from 34.2 ± 6.8 at baseline to 41.5 ± 7.4 ($p < 0.001$). The Mental Component Score rose from 38.6 ± 9.2 to 44.0 ± 8.5 ($p = 0.002$), indicating meaningful recovery in both physical and psychological domains.

Table 2: Summary of primary and secondary clinical outcomes following VAC therapy in post-amputation wounds (n = 120).

Outcome Parameter	Value	Notes
Granulation tissue at Day 7	78.2 ± 12.1%	Primary outcome
Wound area reduction by Day 7	38.6 ± 15.4%	$p < 0.001$ vs. baseline
Time to complete closure	33.5 ± 12.8 days	Median 32 days
Closure by Week 6	75.0% (90/120)	25% remained unhealed
Surgical site infection	15.0% (18/120)	Within 6 weeks
Wound dehiscence	8.3% (10/120)	—
Baseline VAS score	6.8 ± 1.2	—

Day 7 VAS score	3.9 ± 1.4	p < 0.001 vs. baseline
Length of hospital stay	12.4 ± 5.6 days	Median 11 days
SF-36 Physical score (baseline)	34.2 ± 6.8	—
SF-36 Physical score (12 weeks)	41.5 ± 7.4	p < 0.001
SF-36 Mental score (baseline)	38.6 ± 9.2	—
SF-36 Mental score (12 weeks)	44.0 ± 8.5	p = 0.002

Discussion

This prospective observational study provides clinically meaningful evidence supporting the efficacy of vacuum-assisted closure therapy in post-amputation wound management. Our findings demonstrate that VAC therapy achieves robust granulation tissue formation early in the postoperative course, accelerates wound contraction and epithelialization, maintains low complication rates, and improves both pain control and quality of life in a predominantly high-risk population.

The mean granulation tissue coverage of 78.2% at day 7 is notably favorable, particularly given that 60% of our cohort had diabetes mellitus and 20% had peripheral arterial disease—two conditions historically associated with impaired proliferative healing. The observed 38.6% reduction in wound surface area within the first week further underscores the biological activity induced by negative pressure mechanotherapy. These results align with mechanistic studies demonstrating that NPWT-induced microdeformation stimulates fibroblast proliferation, upregulates vascular endothelial growth factor, and enhances collagen synthesis.

Importantly, our subgroup analyses highlight the persistent vulnerability of diabetic and ischemic stumps. Granulation tissue proportions were significantly lower in patients with diabetes (74.1%) and PAD (69.8%) compared to their counterparts without these co morbidities. This finding is consistent with the established patho physiology of impaired macrophage polarization, chronic inflammation, and micro vascular dysfunction in diabetic wounds. Nevertheless, even in these high-risk subgroups, the observed granulation rates exceeded those typically reported with conventional saline or gauze dressings, suggesting that VAC therapy partially mitigates—but does not fully overcome—the biological disadvantages conferred by metabolic and vascular disease.

The mean time to complete wound closure of 33.5 days, with three-quarters of patients achieving epithelialization by week 6, compares favorably with historical controls. Published literature on conventional post-amputation management reports healing times frequently extending beyond 6–8 weeks in comparable populations. The accelerated closure observed in this cohort likely reflects the combined benefits of edema reduction, exudate control, enhanced perfusion, and the closed environment minimizing repeated contamination during dressing changes.

Infection and dehiscence rates are critical determinants of prosthetic rehabilitation timing and overall functional recovery. The 15% SSI rate and 8.3% dehiscence rate in our study are encouraging when contextualized against published benchmarks of 10–35% for SSI following major lower extremity amputation under conventional care. The closed, sealed nature of the VAC system, combined with continuous fluid evacuation and reduced dead space, likely contributed to this protective effect. Notably, no patient in our series required conversion to a

more proximal amputation level due to stump necrosis, a complication that carries profound rehabilitative and mortality implications.

Pain management represents an often underreported yet crucial aspect of amputation care. The significant reduction in VAS scores from 6.8 to 3.9 within the first week suggests that VAC therapy is not only biologically effective but also well-tolerated from a patient comfort perspective. The reduction in dressing change frequency—every 96 hours versus daily or alternate-day changes with conventional protocols—likely contributed to decreased procedural pain and improved patient satisfaction.

The mean hospital stay of 12.4 days, while influenced by institutional discharge practices and socioeconomic factors, is clinically reasonable for a cohort with this comorbidity burden. The improvement in both physical and mental SF-36 domain scores at 12 weeks indicates that effective wound healing translates into tangible functional and psychological recovery, enabling earlier mobilization and prosthetic fitting.

Our findings must be interpreted within the context of study limitations. The single-center, observational design without a concurrent control group limits our ability to establish causality definitively. Outcomes were compared against historical benchmarks and published literature rather than a randomized comparator. Additionally, the heterogeneity of amputation levels and etiologies, while reflective of real-world practice, introduces variability that may not be fully captured by subgroup analysis alone. The loss of eight patients to follow-up, though modest, may introduce attrition bias.

Future research should prioritize multicenter randomized controlled trials specifically dedicated to post-amputation populations, with standardized VAC protocols and long-term functional endpoints including prosthetic ambulation rates and re-amputation-free survival. Cost-effectiveness analyses within diverse healthcare systems would further inform implementation strategies, particularly in resource-limited settings where the burden of diabetes-related amputations is greatest.

Conclusion

Vacuum-assisted closure therapy demonstrates favorable clinical outcomes in the management of post-amputation wounds, including accelerated granulation tissue formation, significant wound area reduction, acceptable infection and dehiscence rates, improved pain control, and enhanced quality of life. These benefits are observable even in high-risk populations with diabetes and peripheral arterial disease. Integration of VAC therapy into post-amputation care pathways represents a clinically justified advancement that may reduce complication burden, shorten recovery timelines, and facilitate earlier functional rehabilitation.

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