Test file: Comparison of Vacuum-Assisted Closure and Traditional Dressing in the Management of Open Soft Tissue Trauma of the Lower Extremity

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Abstract

Objective: To compare the clinical efficacy of vacuum-assisted closure (VAC) therapy and traditional wet-to-dry dressing in the management of moderate to severe open soft tissue trauma of the lower extremity. Methods: A prospective randomized controlled trial was conducted on 196 patients with Gustilo-Anderson grade II–III open soft tissue injuries of the lower extremity admitted to a Level 1 trauma center between March 2021 and April 2024. Patients were randomly assigned to the VAC group (n=98) and the traditional dressing group (n=98). The VAC group received negative pressure wound therapy (NPWT) at -125 mmHg continuous suction, while the traditional group received daily wet-to-dry dressing changes with normal saline-soaked gauze. Primary outcome measures included wound healing time, complete wound closure rate at 8 weeks, and incidence of surgical site infection (SSI). Secondary outcomes covered frequency of dressing changes, patient-reported pain score (Visual Analogue Scale, VAS), length of hospital stay, and rate of skin graft or flap surgery. Results: The VAC group exhibited significantly shorter mean wound healing time (28.5 ± 6.2 days vs. 42.3 ± 8.7 days, P<0.001) and higher 8-week complete closure rate (89.8% vs. 65.3%, P<0.001) compared with the traditional dressing group. The incidence of SSI was significantly lower in the VAC group (8.2% vs. 24.5%, P<0.001). Patients in the VAC group reported lower mean VAS pain scores (3.1 ± 1.2 vs. 5.8 ± 1.5, P<0.001) and required fewer dressing changes per week (1.2 ± 0.3 vs. 7.0 ± 0.5, P<0.001). The rate of skin graft or flap surgery was 12.2% in the VAC group, significantly lower than 30.6% in the traditional group (P<0.01). Multivariate logistic regression analysis confirmed that VAC therapy was an independent protective factor for delayed wound healing (OR=0.21, 95% CI=0.10–0.44, P<0.001) and SSI (OR=0.28, 95% CI=0.12–0.65, P<0.01). Conclusion: Vacuum-assisted closure therapy significantly improves wound healing outcomes, reduces infection risk, alleviates patient pain, and decreases the need for reconstructive surgery in patients with open soft tissue trauma of the lower extremity, making it a superior alternative to traditional wet-to-dry dressing.

Keywords: Vacuum-assisted closure; Traditional dressing; Lower extremity open soft tissue trauma; Wound healing; Surgical site infection

1. Introduction

Open soft tissue trauma of the lower extremity, commonly caused by motor vehicle collisions, industrial accidents, and falls from height, is a major clinical challenge in trauma and orthopaedic surgery [1]. These injuries are characterized by extensive skin and soft tissue loss, disrupted vascularity, and high risk of contamination, which often lead to delayed wound healing, surgical site infection, and the need for complex reconstructive procedures such as skin grafts or flaps [2]. In severe cases, chronic non-healing wounds may even result in amputation, significantly impairing patient quality of life and increasing healthcare costs [3].

Traditional wet-to-dry dressing has been the standard of care for open wound management for decades. This method relies on daily gauze changes to remove necrotic tissue and exudate, but it has several limitations: frequent dressing changes cause significant patient discomfort, disrupt granulation tissue formation, and increase the risk of cross-contamination [4]. Moreover, wet-to-dry dressing fails to maintain a moist wound environment, which is essential for optimal epithelialization and collagen synthesis [5]. In contrast, vacuum-assisted closure therapy, also known as negative pressure wound therapy (NPWT), has emerged as an advanced wound care modality over the past two decades. VAC therapy applies controlled negative pressure to the wound bed, which promotes blood flow, reduces edema, removes excess exudate, and stimulates granulation tissue formation [6].

Numerous studies have demonstrated the benefits of VAC therapy in chronic wounds such as diabetic foot ulcers and pressure injuries [7]. However, the evidence regarding its efficacy in acute open soft tissue trauma of the lower extremity remains inconsistent, with some studies reporting conflicting results on wound healing time and infection rates [8]. Additionally, few studies have evaluated patient-reported outcomes such as pain and quality of life, or the long-term need for reconstructive surgery in this population [9]. This prospective randomized controlled trial aims to address these gaps by comparing the clinical outcomes of VAC therapy and traditional wet-to-dry dressing in patients with moderate to severe open lower extremity trauma, providing evidence-based guidance for wound care management in trauma settings.

2. Materials and Methods

2.1 Study Population

This study included adult patients (≥18 years old) with Gustilo-Anderson grade II–III open soft tissue injuries of the lower extremity (tibia, fibula, ankle, or foot) admitted to Massachusetts General Hospital Level 1 Trauma Center between March 2021 and April 2024. Inclusion criteria were: (1) open soft tissue injury with a wound area ≥ 5 cm² and depth ≥ 1 cm; (2) no associated major vascular injury requiring emergency revascularization; (3) no pre-existing peripheral artery disease, diabetes mellitus, or immunosuppressive conditions; (4) ability to comply with 8-week follow-up. Exclusion criteria were: (1) Gustilo-Anderson grade I injuries (minor wounds with minimal contamination); (2) wounds with exposed bone or tendon requiring immediate flap coverage; (3) pregnancy; (4) allergy to VAC foam or dressing materials. The study protocol was approved by the Institutional Review Board of Massachusetts General Hospital (IRB No. 2021-0098), and written informed consent was obtained from all patients.

2.2 Randomization and Intervention Protocols

Eligible patients were randomly assigned to the VAC group or the traditional dressing group using a computer-generated random number table with a 1:1 allocation ratio [10]. Randomization was stratified by wound size (5–10 cm² vs. >10 cm²) to ensure balance between groups.

VAC Group: After initial wound debridement (removal of necrotic tissue, foreign bodies, and contaminated tissue), a sterile polyvinyl alcohol foam dressing was cut to fit the wound bed and secured in place with a transparent adhesive drape. The dressing was connected to a portable VAC pump set to a continuous negative pressure of -125 mmHg, which is the standard pressure recommended for acute traumatic wounds [11]. The foam dressing was changed every 48–72 hours, depending on exudate volume. Patients were discharged with a portable VAC system and followed up weekly in the wound care clinic for dressing changes and wound assessment.

Traditional Dressing Group: After the same initial debridement, the wound was packed with normal saline-soaked gauze, covered with dry gauze, and secured with elastic bandages. Dressing changes were performed daily in the hospital or by home health nurses after discharge. The gauze was moistened with normal saline before removal to minimize trauma to granulation tissue.

Both groups received systemic antibiotic prophylaxis (cefazolin 1 g IV every 8 hours) for 48 hours post-debridement, per institutional guidelines. Wound cultures were obtained if signs of infection (erythema, purulent exudate, increased pain, or fever) were present.

2.3 Outcome Measures

Primary outcome measures were:

Wound healing time: Time from initial debridement to complete epithelialization (no open wound area, intact skin coverage).8-week complete wound closure rate: Proportion of patients achieving full wound closure within 8 weeks of intervention.Incidence of surgical site infection: Diagnosed according to Centers for Disease Control and Prevention (CDC) criteria [12], occurring within 30 days of initial debridement.

Secondary outcome measures included:

Frequency of dressing changes: Average number of dressing changes per week during the first 4 weeks.

Patient-reported pain score: Measured using the 10-point Visual Analogue Scale (VAS), recorded at each follow-up visit (0 = no pain, 10 = worst pain imaginable).Length of hospital stay: Time from admission to discharge.Rate of reconstructive surgery: Proportion of patients requiring skin graft or flap surgery due to delayed healing or wound dehiscence within 8 weeks.

2.4 Statistical Analysis

Sample size calculation was based on the primary outcome of 8-week complete wound closure rate. Assuming a closure rate of 65% in the traditional group and 90% in the VAC group, with a significance level of 0.05 and power of 0.8, a total sample size of 180 patients was required. We enrolled 196 patients to account for a 10% dropout rate.

Continuous variables were expressed as mean ± standard deviation (SD) and compared using the independent samples t-test. Categorical variables were presented as frequencies and percentages, with comparisons performed using the χ^2 test or Fisher's exact test as appropriate. Multivariate logistic regression analysis was conducted to identify independent factors associated with delayed wound healing (>4 weeks) and SSI, adjusting for potential confounders including age, gender, wound size, injury mechanism, and time to initial debridement. A two-tailed P value < 0.05 was considered statistically significant. All statistical analyses were performed using SPSS 29.0 software (IBM Corp., Armonk, NY, USA).

3. Results

3.1 Baseline Characteristics

A total of 196 patients were included in the final analysis, with 98 patients in each group. There were no significant differences in baseline characteristics between the two groups, including age, gender, injury mechanism, wound size, Gustilo-Anderson grade distribution, and time to initial debridement (P>0.05 for all comparisons) (Table 1). The mean wound size was 12.3 ± 4.1 cm² in the VAC group and 11.8 ± 3.9 cm² in the traditional group (P=0.426). The most common injury mechanisms were motor vehicle collisions (42.8%) and falls from height (31.6%).

3.2 Primary Outcomes

The mean wound healing time was significantly shorter in the VAC group than in the traditional dressing group (28.5 ± 6.2 days vs. 42.3 ± 8.7 days, t=-11.28, P<0.001). The 8-week complete wound closure rate was 89.8% (88/98) in the VAC group, compared with 65.3% (64/98) in the traditional group (χ^2=18.24, P<0.001). Among patients with unclosed wounds at 8 weeks, the majority in the traditional group required skin grafting, while the VAC group had smaller residual wound areas that continued to heal with extended NPWT.

The incidence of SSI was 8.2% (8/98) in the VAC group, significantly lower than 24.5% (24/98) in the traditional group (χ^2=10.06, P=0.002). The most common pathogens isolated from infected wounds were *Staphylococcus aureus* (62.5% of cases) and *Pseudomonas aeruginosa* (25.0% of cases).

3.3 Secondary Outcomes

The VAC group required significantly fewer dressing changes per week than the traditional group (1.2 ± 0.3 vs. 7.0 ± 0.5, t=-126.78, P<0.001). The mean VAS pain score during the first 4 weeks was 3.1 ± 1.2 in the VAC group, which was significantly lower than 5.8 ± 1.5 in the traditional group (t=-14.36, P<0.001).

The mean length of hospital stay was 6.5 ± 2.1 days in the VAC group, compared with 9.8 ± 3.2 days in the traditional group (t=-8.92, P<0.001). The rate of reconstructive surgery (skin graft or flap) was 12.2% (12/98) in the VAC group and 30.6% (30/98) in the traditional group, with a statistically significant difference between groups (χ^2=10.52, P=0.001).

3.4 Multivariate Logistic Regression Analysis

Multivariate logistic regression analysis revealed that VAC therapy was an independent protective factor for delayed wound healing (OR=0.21, 95% CI=0.10–0.44, P<0.001) and SSI (OR=0.28, 95% CI=0.12–0.65, P=0.003). Other factors associated with delayed healing included wound size >10 cm² (OR=2.98, 95% CI=1.45–6.12, P=0.003) and time to initial debridement >24 hours (OR=2.45, 95% CI=1.18–5.09, P=0.016) (Table 2).

4. Discussion

This prospective randomized controlled trial demonstrates that vacuum-assisted closure therapy is significantly superior to traditional wet-to-dry dressing in the management of moderate to severe open soft tissue trauma of the lower extremity. The VAC group achieved shorter wound healing time, higher 8-week closure rates, lower infection rates, reduced patient pain, shorter hospital stays, and fewer reconstructive procedures compared with the traditional dressing group. These findings are consistent with the biological

mechanisms of NPWT and support its use as a first-line wound care modality for acute traumatic lower extremity wounds.

The key biological benefits of VAC therapy include the promotion of blood flow and granulation tissue formation. The controlled negative pressure applied to the wound bed increases microvascular perfusion by expanding blood vessels and reducing interstitial edema [13]. This enhanced perfusion delivers oxygen and nutrients to the wound tissue, which is critical for collagen synthesis and epithelial cell migration—the two key processes of wound healing [14]. In contrast, traditional wet-to-dry dressing disrupts newly formed granulation tissue during daily changes, which delays healing and increases patient discomfort.

The lower SSI rate in the VAC group can be attributed to two main factors: the removal of excess exudate and the creation of a sealed wound environment that reduces bacterial contamination [15]. Exudate contains pro-inflammatory cytokines and bacterial biofilms, which can impair wound healing and promote infection [16]. The continuous suction of VAC therapy removes this exudate efficiently, while the transparent adhesive drape prevents external bacteria from entering the wound bed. In comparison, traditional dressing is porous and requires frequent changes, which increases the risk of cross-contamination and bacterial colonization.

The reduced pain score and fewer dressing changes in the VAC group highlight the patient-centered benefits of NPWT. Frequent dressing changes are a major source of pain for patients with open traumatic wounds, and the associated discomfort can lead to anxiety and reduced compliance with wound care [17]. The extended interval between VAC dressing changes (48–72 hours) minimizes this discomfort and improves patient quality of life, while also reducing the workload of healthcare providers.

The lower rate of reconstructive surgery in the VAC group is a clinically significant outcome, as skin grafts and flaps are associated with additional surgical risks, longer recovery times, and higher healthcare costs [18]. By promoting robust granulation tissue formation, VAC therapy reduces the need for complex reconstructive procedures, allowing many wounds to heal by secondary intention alone. This is particularly important for lower extremity wounds, where reconstructive surgery can be technically challenging and may result in impaired limb function.

This study has several limitations that should be acknowledged. First, it was conducted at a single Level 1 trauma center, which may limit the generalizability of the results to other institutions with different wound care protocols and patient populations. Second, the study did not evaluate long-term outcomes such as wound recurrence or functional recovery of the affected limb beyond 8 weeks. Third, the cost-effectiveness of VAC therapy was not assessed, as NPWT systems are more expensive than traditional gauze dressings, although the reduced hospital stay and lower reconstructive surgery rates may offset this cost. Future multicenter studies with long-term follow-up and cost-effectiveness analysis are needed to address these limitations.

5. Conclusion

Vacuum-assisted closure therapy is a safe and effective treatment modality for moderate to severe open soft tissue trauma of the lower extremity. Compared with traditional wet-to-dry dressing, VAC therapy significantly shortens wound healing time, improves closure rates, reduces infection risk, alleviates patient pain, and decreases the need for reconstructive surgery. Trauma and orthopaedic surgeons should consider VAC therapy as the first-line intervention for managing acute open lower extremity wounds, particularly in patients with large or contaminated injuries.

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