# ORIGINAL RESEARCH

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Vacuum-assisted Closure Vs Conventional Open Treatment in Diabetic Foot Ulcer - A Comparative Study

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### ABSTRACT

Background: Vacuum-assisted closure (VAC) therapy also called negative pressure wound therapy (NPWT) is an emerging therapeutic option for diabetic foot ulcers. So, the current study intends to compare vacuum-assisted closure therapy and conventional open therapy in diabetic foot ulcers.

18 Methods: A prospective case-control study was conducted and 54 patients were randomly allotted into 2 groups during the study period. The cases group includes patients undergone VAC therapy and the control group includes patients undergone conventional open therapy.

**Results:** Patients in Group A had fewer positive wound cultures and secondary amputations as compared to Group B. VAC therapy was found to considerably improve the meantime to complete wound healing (24.22 days vs. 32.66 days). Secondary amputations were performed on 0% of patients in group A and 11.11 percent of patients in group B. The average hospital stay for group A was 20.33 days

22 performed on 0% of patients in g and 26.77 days for group B.

Conclusion: When compared to standard dressing, VAC treatment considerably lowers the time to complete wound healing, accelerates granulation tissue production, and reduces ulcer area. The VAC treatment group had no significant increase in bleeding or infection, according to the research.

7 Keywords: Diabetic Foot Ulcer, Infections, Conventional Dressings, Vacuum-Assisted Closure, Wound Closure

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### 1 INIT

**INTRODUCTION** 

Wound healing is a natural innate immune response of the body. It occurs automatically without the interference of any external stimulus. However, the presence of diabetes, a metabolic disorder, slows down or prevents this process by creating a pro-inflammatory state also favorable for the growth of various bacteria and fungi leading to secondary infections. Diabetes foot ulcers are a serious consequence of the disease. An open sore or wound develops in around 15% of diabetics and is commonly located on the bottom of the foot. Six percent of people who get a foot ulcer are hospitalized because of infection or another ulcer-related disease.<sup>1</sup> Amputation is then performed up to 85 percent of the time.<sup>2</sup> The conventional treatment for diabetic foot ulcers is wound closure with debridement of all necrotic, callus, and fibrous tissue and the use of saline-soaked gauze.

This approach was rendered ineffective due to its inability to maintain a continuous wet atmosphere for extended periods. Many alternative therapies, such as hyperbaric oxygen therapy, growth factors, enzymatic debridement chemicals, cultured skin substitutes hydrocolloid wound gels, and other wound treatments, have been promoted as a result. All of these therapies come at a high cost, and they are used in some cases despite a lack of scientific evidence supporting their usefulness.<sup>3</sup>

Negative pressure wound therapy (NPWT) also referred to as V.A.C. therapy, involves placing an open-cell foam dressing inside the wound cavity and application of controlled sub-atmospheric pressure to the wound. This procedure helps to speed up the healing process by draining fluid from open wounds, preparing the wound bed for closure, lowering edema, and encouraging the growth and

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perfusion of granulation tissue. So, we aimed to compare the
vacuum-assisted closure and conventional open treatment in
diabetic foot ulcers.

# 7 METHODOLOGY

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9 The research was carried out in a tertiary care teaching 10 hospital in Pune's general surgery department. Randomized case-control research was carried out to compare the efficacy 11 12 of VAC against conventional dressings in the treatment of DFU. Patients with type 2 diabetes, aged 33-71 years, and 13 14 DFU stage 3 or above as defined by Wagner's classification,<sup>4</sup> were randomly allocated to Group A (VAC patients) or 15 Group B (open conventional therapy patients), with an equal 16 number of patients in each group (n=27). Patients under the 17 age of 18 or above the age of 90, pregnant or nursing mothers, 18 non-diabetic foot ulcers, and comorbidities involving the 19 respiratory, cardiovascular, or other bodily systems were all 20 excluded. 21

22 People taking corticosteroids, immunosuppressive drugs, 23 or chemotherapy were also excluded from the study. All 24 patients underwent a thorough medical history, physical 25 examination, and necessary diagnostics. The study was 26 approved by an institutional ethics subcommittee. Patients 27 were made to comprehend the treatment and the study in 28 their own language before it began. Informed consent was 29 obtained before they were randomly assigned to one of two 30 groups using statistical software. Sharp surgical debridement was used to remove necrotic tissue and slough from all of the 31 patients' wounds at the beginning of the research and during 32 subsequent dressing changes. After debridement in the 33 minor operation theatre, a foam-based dressing was applied 34 to the wounds of the Study Group A patients under all aseptic 35 conditions. The dressing was wrapped with an adhesive 36 drape to establish an airtight seal. A vacuum was connected 37 to an evacuation tube implanted in the foam, and continuous 38 sub-atmospheric (negative) pressure in the 80-125 mmHg 39 range was applied for 72 hours. 40

41 Study Group B was administered a saline-soaked gauze 42 bandage every day, which necessitates frequent dressing 43 changes (two to three times a day) depending on the wound 44 severity. Dressings should be moistened before removal 45 to minimise any possibility of bleeding. All of the patients 46 were given oral analgesics at the time of dressing changes. 47 All patients were given conventional antibiotic regimens, which began with broad-spectrum antibiotics and were 48 later modified based on culture sensitivity data. Patients in 49 groups A and B received subcutaneous insulin for diabetes 50 management. The data was entered and analysed using 51 EXCEL and SPSS 24. 52

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#### RESULTS

Following eligibility screening, 54 patients satisfied the inclusion criteria and were randomly allocated to one of two groups of nine patients each. VAC treatment was given to Study Group A, whereas conventional dressing was given to Control Group B. At the trial's conclusion, 27 patients from each group were assessed.

Patients in Group A ranged in age from 33 to 70 years, with a mean age of 51.8 years. In contrast, patients in Group B ranged in age from 42 to 71 years, with a mean age of 54.33 years. Men made up 77.77 percent of each category, while women made up roughly 22.22 percent. All of the patients required insulin to control their diabetes and were initially treated with a series of subcutaneous insulin injections. Secondary amputations were performed on 0% of patients in group A and 11.11 percent of patients in group B. VAC therapy was found to significantly reduce the time to complete wound healing (24.22 days vs. 32.66 days). The average hospital stay for group A was 20.33 days. This was followed by 26.77 days for group B. Staphylococcus aureus was the most common bacteria cultured from wounds in group B patients. E Coli and Staphylococcus aureus were identified at comparable levels in group A patients.

Table 1. Safety and efficacy of VAC over conventional dressings in the treatment of diabetic foot ulcers				
	Group A (Case)	Group B (Control)		
Age (in years)	$51.8\pm9.58$	$54.33\pm9.39$		
Secondary amputation required (number of patients)	0	3 (11.11%)	-	
Mean hospital stay (Days)	$20.33 \pm 1.58$	$26.77\pm4.35$		
Meantime for wound healing (Days) (Time for granulation tissue develop- ment)	$24.22\pm4.96$	$32.66\pm7.33$		
Split skin graft required (number of patients)	12 (44.44%)	9 (33.33%)		
Spontaneous wound closure (number of patients)	15 (55.55%)	15 (55.55%)	-	
Average ulcer area (cm <sup>2</sup> )	$19.88 \pm 13.4$	$21.55\pm16.7$		

### DISCUSSION

A newly granulating wound surface denotes good wound healing because granulation tissue development is a component of the wound healing proliferative stage. The interval from the beginning of VAC treatment to the achievement of a fresh & continuous bed of granulation in the wound was used to quantify the amount of time needed

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2 for wound bed preparation prior to surgical intervention. 3 Prior to secondary closure or split-skin grafting, this was 4 accomplished in all 54 of the cases in our study. According 5 to Armstrong et al., NPWT delivered through a VAC device 6 was a safe and effective treatment for difficult diabetic 7 foot wounds, potentially leading to a higher proportion 8 of healed wounds, faster healing rates, and maybe fewer 9 re-amputations than standard care.5 10

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11 Negative pressure applied to the wound bed dilates the 12 arterioles, enhancing the efficacy of local circulation and 13 encouraging angiogenesis, which aids in the proliferation 14 of granulation tissue.<sup>6</sup> Moreover, wound volume and depth 15 were dramatically reduced with VAC dressings compared 16 to wet gauze dressings., according to Mark et al.<sup>7</sup> While 17 evaluating the safety of the treatment, we found that those who received VAC had fewer future amputations than those 18 who received gauze dressings.8 In Group A vs Group B, 19 we discovered that VAC was safer than saline-moistened 20 gauze dressings in terms of fewer future amputations, which 21 was consistent with what Blume et al reported. Wounds in 22 Group A were treated with a split-thickness skin transplant 23 in 44.44 percent of cases, whereas wounds in Group B were 24 treated with a split-thickness skin graft in 33.33 percent of 25 cases. The patient's other wounds healed on their own. Our 26 findings contrast those of Ali M. Lone et al., who reported 27 split-thickness skin transplantation as the most common 28 wound closure procedure.<sup>9</sup> Group A had a greater success rate 29 in terms of complete granulation and readiness for closure 30 with split-thickness skin grafting or secondary intention, but 31 Group B required amputation more frequently. In our study, 32 the length of time taken to complete VAC therapy ranged 33 from 18 to 30 days, with an average of 24.22 days. This was 34 much shorter than the average time taken by Armstrong et al 35 of 32.9 days.<sup>5</sup> Another advantage noticed was the propensity 36 of VAC treatment to reduce bacterial infection in a wound 37 according to Morykwas et al.<sup>6</sup> All the wounds tested positive 38 for bacteria at the start of the study, but by the end of the trial, 39 all wounds undergoing VAC treatment showed clearance 40 of bacterial infection, which confirms the findings of Aziz Nather et al.<sup>10</sup> 41 42

Analyzing the cost efficiency of the VAC over conventional 43 techniques will be made easier with further study. But until 44 then, the facts from the scientific literature point that VAC 45 is a cost-effective therapy that produces comparable or 46 occasionally superior wound healing with few major side 47 effects. 48

#### CONCLUSION 50

51 According to the current randomized case-control study, 52 VAC treatment is efficacious and safe in DFUs. When 53 compared to standard dressing, it greatly accelerates the time 54

taken to complete wound healing. It hastens the production of granulation tissue without increasing the incidence of complications such as infections and bleeding. It also reduces the ulcer area and the VAC treatment group had no significant increase in bleeding or infection

#### **END NOTE**

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Conflict of Interest: None declared

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#### Author Queries???

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