

## Evaluation of Modified Vacuum Dressing in Treatment of Refractory Diabetic Foot Ulcers

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### Abstract:

Diabetic foot ulcer (DFU); is a common, complex and costly sequelae of diabetes mellitus. DFU is a serious global health issue that lead to amputation of lower extremity, causing significant morbidity and increased financial burden. Management of diabetic foot ulcers remains a significant challenge that requires a thorough knowledge of the available dressing techniques in addition to the frequent routine evaluation. Negative pressure wound therapy (NPWT) or vacuum assisted closure (VAC) is a recently introduced technology that has been widely practiced in the treatment of such ulcers. However, the consumables for VAC are very expensive and not economically feasible in the developing countries. Therefore, this study aims to assess the effects of modified vacuum dressing compared with standard care wound therapy (Wet saline dressing) and compare healing rates. A prospective study of convenient 50 patients divided into two groups (25 each) has been carried out. Group A consisted of patients with modified vacuum dressing and group B with wet saline dressing. Both groups were compared for healing rates. There was a 44.75% decrease in area of the ulcer in group A compared to 25.15% in group B after 4 weeks. Decrease in wound depth was 55.41 % and 26.94% in group A and B respectively. The mean hospital stay was 33.18 days in group A compared to 45.58 days in group B. The average cost incurred for patients in group A was Egyptian pounds 18,756 compared to 19,662 Egyptian pounds in group B. The vacuum dressing methods reduces the average time to complete healing, as well as the hospital stay. Thus, we recommended modified vacuum dressings might be considered as a promising method of treating diabetic foot ulcers.

**Keywords:** Diabetic foot, Negative pressure dressing, Modified vacuum dressing, Wound healing

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### I. Introduction

The prevalence of diabetes is steadily increasing worldwide<sup>(1-4)</sup>. Over the past few decades, diabetes and its complications cause substantial economic loss to the diabetic patients, health systems as well as to the national economies; most markedly in the world's middle-income countries<sup>(5-8)</sup>. People with diabetes are prone to develop foot ulcers, which if not heal, can cause serious health issue leading to increase cost, reduce productivity and implied high rates of morbidity and mortality. The lifetime risk of developing foot complications is 25%<sup>(9-12)</sup>. The standard-of-care therapeutic modalities are not sufficient for some refractory and complex diabetic foot ulcers (DFU). Wet saline dressing has been the standard topical therapy for DFU for years. However, it is difficult to optimize the amount of moisture and promote an ideal wound environment with these dressings. Negative pressure wound therapy (NPWT) is a relatively newer noninvasive adjunctive therapy that involves the application of a wound dressing attached to a vacuum assisted closure device (VAC) under controlled negative pressure<sup>(13-18)</sup>. This study has been carried out at Alexandria Vascular Center to assess the effectiveness of modified VAC compared with the conventional saline dressings in healing of diabetic foot ulcers.

## II. Methods

The present study used a prospective comparative quasi experimental designed. 50 patients were recruited at Alexandria Vascular Center/ Egypt from November 2020 to June 2021. The study was cleared by institution ethics committee. All patients who fall within the inclusion criteria were randomly divided into two groups- study group and control group. Odd numbers were in Group A and even numbers in Group B.

Study group (A): Received modified vacuum dressing therapy.

Control group (B): Received daily dressing with wet saline gauze.

Patients who aged >40 years; have diabetic foot ulcers with Wagner grade II, III; dorsal or plantar foot ulcer >2 cm<sup>2</sup> after debridement; and those whom dorsalis pedis pulse were palpable; were included in the study.

Patients who aged > 75 years, who had obvious septicemia, osteomyelitis, venous insufficiency, serious pre-existing cardiovascular disease in the last 6 months, have chronic kidney disease on dialysis; using enzymatic debridement; ulcers resulting from electrical, chemical, collagen vascular diseases, malignancy, and inadequate perfusion; pregnant/ lactating ladies; patients on being treated with corticosteroids, immunosuppressive drugs or chemotherapy and those who are not willing to consent were excluded from the study.

**Study procedure:** After initial sharp surgical debridement and taking pus for culture and sensitivity, all patients were started on amoxicillin and clavulanic acid empirically and then changed based on culture. In Group A patients, a sterilized gauze-based dressing was applied over the wounds under aseptic conditions. An evacuation tube embedded in the gauze was connected to a vacuum generator machine and sub atmospheric (negative) pressure of 125 mmHg on an intermittent basis (half hour VAC applied every 1 hour interval) for 72 hours was applied. The group B received once daily saline-moisted gauze dressing. After every 3 days, microbial cultures were taken from the base of the ulcer to assess the bacterial flora. Ulcers were treated until 100% wound closure with re-epithelialization or scab with no wound drainage present and no dressing required. Blood glucose levels were monitored strictly and appropriate doses of insulin given. The study aimed to compare healing. The observations were noted and all results were tabulated and analyzed using SPSS statistical package. The percentage change in wound size and the appearance of granulation tissue and the primary study endpoint were tested for significance and the necessary statistical tables were constructed.

## III. Results

In this study on 50 patients, we found that wound healing was much faster in cases in which modified VAC was applied.

The mean age was 54.13 in Group A and 52.15 in Group B. The study had 24 (48%) females and 26 (52%) males. The mean area of the ulcers in Group A prior to treatment was 28.20 cm<sup>2</sup> and in Group B 25.15 cm<sup>2</sup>. After 2 weeks of treatment mean area of Group A was 24.65 cm<sup>2</sup> and in Group B 23.52 cm<sup>2</sup>. After 4 weeks mean area of Group A was 15.30 cm<sup>2</sup> and Group B was 20.23 cm<sup>2</sup>. There was a 44.75% decrease in area of the ulcer compared to 25.15% in group B after four weeks. The patients in group A had a 55.41% decrease in wound depth compared to 26.94%. The average duration of hospital stay was 33.18 days in group A compared to 45.58 days in group B. The mean cost incurred for patients in group A was 13756 compared to 19662 EGP.

**Table 1: Glycemic control – HbA1C.**

HbA1c		GROUP A	GROUP B	Total
		No (%)	No (%)	No (%)
	7.5-8.5	5 (20)	7 (28)	12 (24)
	8.5-9.5	14 (56)	10 (40)	24 (48)
	>9.5	6 (24)	8 (32)	14 (28)
	Total	25 (100)	25 (100)	50 (100)

**Table 2: Grade of ulcer among groups.**

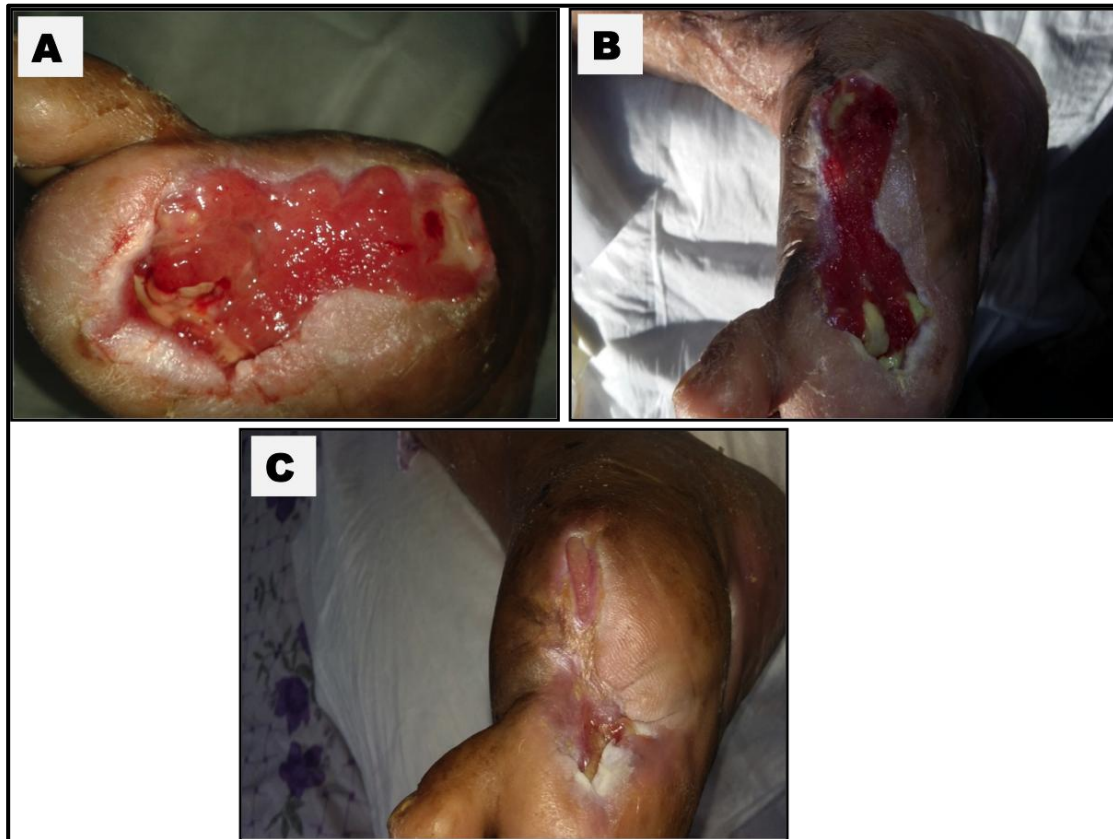
Wagner grad	GROUP A No (%)	GROUP B No (%)	Total No (%)
Grad II	12 (48)	7 (28)	19 (38)
Grad III	13 (52)	18 (72)	31 (62)

**Table 3: Reduction in depth of wound.**

Depth mm	GROUP A	GROUP B
Week 1	18.36	16.07

Week 2	15.82	1552
Week 4	7.89	3.41
% Change in depth	55	26

Our study also reveals that the non-healing diabetic foot ulcers with larger surface area and a higher Wagner score have better results with a modified VAC group. Modified VAC dressing results are complementary to the conventional VAC dressing technique in achieving complete healing in selective patients, reducing wound surface area, depth, volume, and pain, and increasing comfort in subjects with a chronic non-healing diabetic foot ulcer.



**Figure 1:** Showing the Ulcer: (A) Before applying modified VAC. (B) After 2 weeks of applying modified VAC. (C) After 4 weeks of applying modified VAC.

In Group A patients wound bed healed twice as fast. Neuropathy and decreased distal vascularity were identified to have a direct effect on the wound healing pattern in both the groups, as it was seen that was the effect of distal vascularity was directly proportional to the wound healing, while the presence of neuropathy dampened the healing in both the groups. There were a better patient compliance and satisfaction within the modified-VAC group.



Figure 2: Gradual reduction in wound area

#### IV. Discussion

Modified VAC was effective in reducing wound area. This technique significantly improves the quality of life. There is a marked reduction in the number of inpatient days which indirectly cuts the treatment cost. The total cost for treatment was lesser than when compared with the conventional saline group and moreover it was much lower when compared with the standard VAC therapy.

Patient compliance was better with modified VAC group, as it was less painful. There was a marked reduction in wound infection particularly nosocomial and the need for therapeutic antibiotic also less in the modified VAC group.

Among topical wound management, NPWT therapy is the most discussed and described form of treatment modality. There are numerous trials done so far based on various variables all of which are aiming for a better faster healing, with an acceptable risk during treatment<sup>(19)</sup>. The mechanisms of action that can be attributed to NPWT therapy are an increase in blood flow- perfusion (human and animal studies), Promotion of angiogenesis (animal studies only), granulation tissue formation, Reduction in the wound surface area of several types of wounds (chronic) but not all wounds (acute), A positive modulation of the inhibitory contents in the wound fluid, there is an induction of cell proliferation (in vitro and animal studies only), reduction of oedema and bacterial clearance, removal of exudates<sup>(20)</sup> In short it is a fact that VAC therapy, is a faster more effective and clinically proven wound healing. One of the major problem facing of people low socio-economic subset of the population is the cost for dressing. So we introduce a technique of topical dressing with slight modification without losing the basic concepts of negative pressure wound therapy. In our study, we consider objectives like healing rate and economic cost<sup>(21)</sup>. In our study satisfactory healing was attained in 33.18 and 45.58 days as compared to 22.8 day and 42.8 days in a study done by Mc Callon et al. The percentage decrease in surface area of wounds in our study were 43.75% and 25.15% in the modified VAC group to control group compared to 28.4% and 9.5% by Mc callon et al.<sup>(22)</sup> The patients in group A had a 55.41% decrease in wound depth compared to 26.94% in group B vs 59% and 8% in a study by Ramanujam et al.<sup>(23)</sup> In our study VAC therapy group had better healing, had significantly lower 'In-Patient' days. VAC therapy is a cost-effective and relatively safe non-invasive procedure with better outcome in terms of meeting the endpoints as incomplete closure of wounds or till skin graft ability of wound is achieved. In our study the mean duration of hospital stay in cases is 33.18 days and for the control group is 45.58 days. The mean costs of treatment for case and control groups are 13756 EGP and 19662 EGP respectively. This is mainly because of the fact that there is a marked decrease in hospital stay, number of surgical debridement/ amputations, and decreased use of therapeutic antibiotic during treatment in cases or modified-VAC group.

#### V. Conclusion

Our study compared the effectiveness of modified vacuum dressing versus conventional wet normal saline dressings in the healing of chronic diabetic foot ulcerations in terms of healing, economic cost, and patient stay in hospital. We found that the healing was much faster in cases in which modified VAC was applied by reducing wound surface area, depth, and the volume of the ulcer. VAC significantly improves quality of life. There is a marked reduction in the number of "inpatient" days and there is an early achievement of endpoints, which indirectly cuts the treatment cost. There is a rapid filling of granulation tissue and the disappearance of discharge from the ulcer bed. Prepare wound bed over twice as fast. Number of surgical intervention is also less and a better patient compliance. Our study also reveals that the non-healing diabetic foot ulcers with larger

surface area and a higher Wagner score III have better results with a modified VAC group. Modified VAC dressing results are complementary to the conventional VAC dressing technique in achieving complete healing in selective patients. Our study like other previous studies has established that NPWT technique has a better outcome when compared to the conventional modalities. With adequate resource and follow up problems of chronic diabetic foot ulcer could be managed in an effective economical way.

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