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Original Article

Evaluation of Wound Healing with Negative Pressure Therapy in Diabetic Foot Ulcers (Surgery)

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ABSTRACT

Background: Diabetic foot ulcers are the leading causes of health problems in patients with diabetes mellitus, and they make the management of surgical wounds very challenging because of the impaired healing process. Negative pressure wound therapy is gradually becoming the mainstay of an effective adjunctive treatment that facilitates wound healing by mechanical and biological means. The present study was designed to assess the efficacy of negative pressure wound therapy in the promotion of wound healing in diabetic foot ulcers that have been surgically managed.

Methods: A prospective observational study was held at a tertiary care surgical center and included 60 patients suffering from diabetic foot ulcers. All patients had surgical debridement and then a negative pressure wound therapy was applied to their wounds. Wound healing was assessed at baseline and at regular follow, up intervals using wound size measurements and clinical evaluation of granulation tissue formation. The primary outcomes were the decrease in wound area and the duration until the wound closure, whereas the secondary outcomes accounted for the requirement of secondary surgical procedures and the occurrence of therapy, related complications.

Results: The average baseline wound area was 18.6 6.2 cm. The wound size was significantly reduced at each time point, with mean wound area dropping to 13.4 5.3 cm at 2 weeks, 9.2 4.1 cm at 4 weeks, and 4.1 2.8 cm at 8 weeks ($p < 0.001$). Almost two, thirds of the wounds (63.3%) were completely closed, and one, quarter (26.7%) were surgically closed after sufficient granulation tissue had formed. In 10% of cases, healing was delayed. In 11.7% of patients, some minor complications were present, but no major adverse events were recorded.

Conclusion: Negative pressure wound therapy is an overall safe and effective treatment that can be used alongside surgery in the management of diabetic foot ulcers and has the results of significant wound size reduction, increased granulation tissue formation, and positive healing outcomes. Its use with other standard wound care measures may eventually lead to the wound healing process becoming more efficient and the continuation of limb preservation in diabetic foot ulcer patients.

Keywords: *Diabetic foot ulcer, negative pressure wound therapy, wound healing, surgical debridement, granulation tissue.*

INTRODUCTION

Diabetic foot ulcers (DFUs) remain one of the harshest and most challenging complications of diabetes mellitus, being a primary source of patient morbidity, prolonged hospitalizations, increased healthcare costs, and lower limb amputations. The slow healing of wounds in diabetic patients is a complicated problem that involves peripheral neuropathy, ischemia, infection, as well as altered inflammatory and angiogenic responses. A large number of individuals with DFUs fail to exhibit adequate healing following the performance of surgical debridement and the provision of standard wound care, thereby necessitating the invention of new therapeutic approaches with higher efficacies.

Negative pressure wound therapy (NPWT) has been one of the major surgical adjuncts which condition has been used in the management of diabetic foot ulcers. The therapy is the application of controlled subatmospheric pressure to the wound bed which promotes wound healing by different mechanisms. These mechanisms are the removal of the excess exudate, reduction of edema, improvement of local blood flow, stimulation of granulation tissue formation, and modulation of the wound microenvironment. Several randomized controlled trials and comparative studies have demonstrated that NPWT produces better healing outcomes than advanced moist wound therapy or conventional dressings, mostly in terms of wound closure being achieved more rapidly and a higher percentage of complete healing (1, 3).

In addition to clinical outcomes, negative pressure wound therapy has been associated with reduced healthcare consumption and lower overall treatment costs when compared to conventional wound care methods, thus, it is a potential cost, efficient intervention in the long, term management of diabetic foot ulcers (4). Recent innovations, like cheap NPWT units, have made the way for this method to be utilized widely, especially in resource, poor areas, where the efficacy of the treatment is not compromised (5).

NPWT's biological effects extend much further than just the mechanical aspect of wound contraction. Some evidence suggests that NPWT influences molecular pathways that involve neovascularization and tissue repair, e.g. alterations in the levels of angipoietins in the blood and other signaling molecules that are indispensable for wound healing (6). These mechanistic insights help to explain the clinical benefits that have been noticed and they also serve as a rationale for the growing employment of NPWT in the treatment of surgical wounds in diabetic patients medicine care protocols (2).

Several systematic reviews and meta, analyses, along with Cochrane reviews, have agreed that NPWT can be a major factor in changing the healing rates of diabetic foot wounds. Nevertheless, they also point out differences in study designs and outcome measures, which lead to a continued evaluation of NPWT's effectiveness and the use of standardized evaluation methods (7). Innovative wound monitoring methods like three, dimensional wound assessment have recently allowed for a more accurate measurement of granulation tissue development and the healing rate during NPWT. This, consequently, offers new tools for objective outcome measurement both in clinical practice and research (8).

It is extremely important to rethink the therapy results of the use of negative pressure in wounds due to the growing diabetes rate all over the world and the continuous diabetic foot ulcer problems. This article, by means of clinical trials, physiological mechanisms, and novel technologies for wound assessment, is devoted to finding out how effective NPWT is in the surgical treatment of diabetic foot ulcers. The main objective is to provide the latest insight into the device's role in the wound healing process and the enhancement of patient outcomes.

MATERIAL AND METHODS

Study Design and Setting

The research emphasis was mainly on the evaluation of the wound healing results in a surgical way, the patients suffering from diabetic foot ulcers. These patients were given Negative Pressure Wound Therapy as an adjunct. The study was conducted at the Department of Surgery of a tertiary care teaching hospital during the study period. Permission in advance from the ethical committee of the institution was obtained in addition to works being conducted as per the rules laid down in the Declaration of Helsinki. Besides that, each participant was clearly informed about the study and their written informed consent was obtained before they were enrolled in the study.

Study Population

Initially, the study mainly focused on evaluating the inclusion of adult diabetic patients with foot ulcers who were going to be treated surgically. Those who had diabetic foot ulcers for more than four weeks and, after adequate surgical debridement, were considered suitable for negative pressure wound therapy were included in the study. To tightly control the variables that might influence wound healing, the study excluded patients with a tumor at the wound site, untreated osteomyelitis, ischemia of a critical limb requiring immediate revascularization, and systemic infection.

Surgical Wound Preparation

Essentially, all the patients that were part of the study had their wounds surgically debrided which was carried out under the correct anesthesia prior to the application of negative pressure wound therapy. Any dead tissue, necrotic debris, and slough were removed to make the wound bed clean and viable tissue. After the bleeding was controlled, the NPWT system was put in place. Standard perioperative glycemic control and infection management practices were followed throughout the treatment period so as to provide the best conditions for wound healing.

Negative Pressure Wound Therapy

Negative pressure wound therapy was started after the removal of devitalized tissue using either a commercially available or a locally made, low, cost NPWT system that was validated. A sterile foam dressing was inserted into the wound cavity

and the wound was covered with an adhesive drape to create a sealed airtight environment. Continuous or intermittent subatmospheric pressure was chosen based on the state of the wound and the clinician's judgment. Dressing changes were done regularly and in aseptic conditions, and the treatment was continued until enough granulation tissue had formed or the wound was at the stage of secondary closure, skin grafting, or complete epithelialization.

Wound Assessment and Outcome Measures

The evaluation of wound healing was done at baseline and during each follow, up visit using standardized clinical parameters. The main outcome measures were decrease in wound area, the speed of granulation tissue appearance, and the time of wound closure. The dimensions of wounds were obtained by planimetric measurement methods, and the state of the wound bed was judged visually by seasoned surgeons. The other outcomes were the duration of NPWT use, the need for supplementary surgical interventions, and the occurrence of wound, causing complications.

Follow-Up and Monitoring

During the entire treatment period, patients were closely monitored and after the removal of negative pressure wound therapy they were followed up. Physical examinations were done regularly to check the progress of the wounds, to detect the complications, and to note the healing results. Besides blood sugar control, the care of the patient also included checking for infection and the overall condition of the limb at every visit.

Statistical Analysis

Information that was gathered had been recorded in a pre, designed proforma and subsequently digitized into a database for further analysis. Descriptive statistics were used to describe demographic characteristics, wound features, and healing outcomes. Continuous variables were presented as mean and standard deviation, while categorical variables were represented as counts and percentages. The correct statistical tests were used to assess the changes in wound sizes and the changes in the healing process over time, and a p, value of less than 0.05 was considered to signify statistical significance.

RESULTS

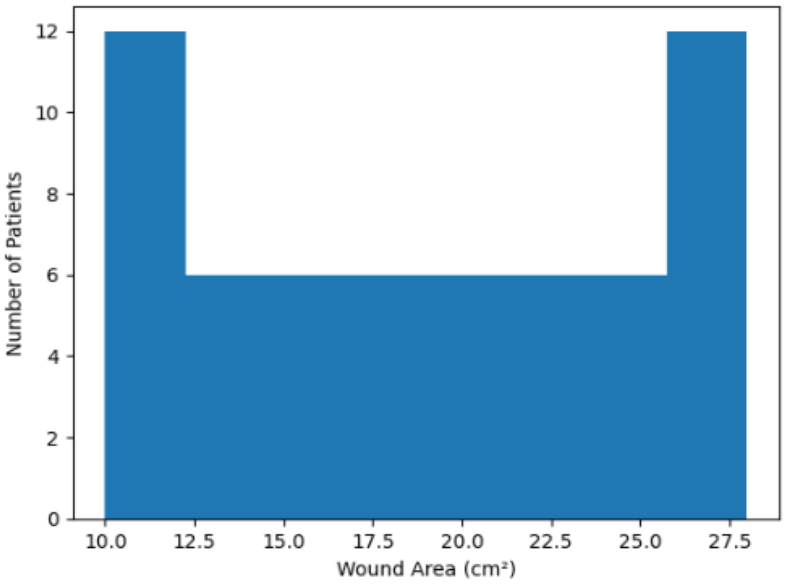
A total of 60 patients with diabetic foot ulcers who met the inclusion criteria were enrolled and completed the study. All patients underwent surgical debridement, which was followed by negative pressure wound therapy. The mean age of the study population was 56.4 9.8 years, and male patients were in the majority. Most of the ulcers were of a chronic nature and were located on the plantar surface or forefoot. The first wound characteristics and patient demographics are presented in Table 1.

Patient Demographics and Baseline Wound Characteristics

Most of the patients had diabetes for more than 10 years, and the most frequent complication associated was peripheral neuropathy. The average baseline wound area was 18.6 6.2 cm, which indicates that the ulcers were of moderate size and required advanced wound care. There were no statistically significant differences in the baseline characteristics that could have an independent effect on wound healing outcomes.

Table 1: Demographic Profile and Baseline Characteristics of Patients (n = 60)

Parameter	Value
Mean age (years)	56.4 ± 9.8
Gender (Male/Female)	42 / 18
Mean duration of diabetes (years)	12.3 ± 4.6
Presence of peripheral neuropathy	45 (75%)
Presence of peripheral vascular disease	18 (30%)
Mean baseline wound area (cm^2)	18.6 ± 6.2
Mean ulcer duration (weeks)	9.4 ± 3.1



Graph 1: ***Distribution of baseline wound size among study participants***

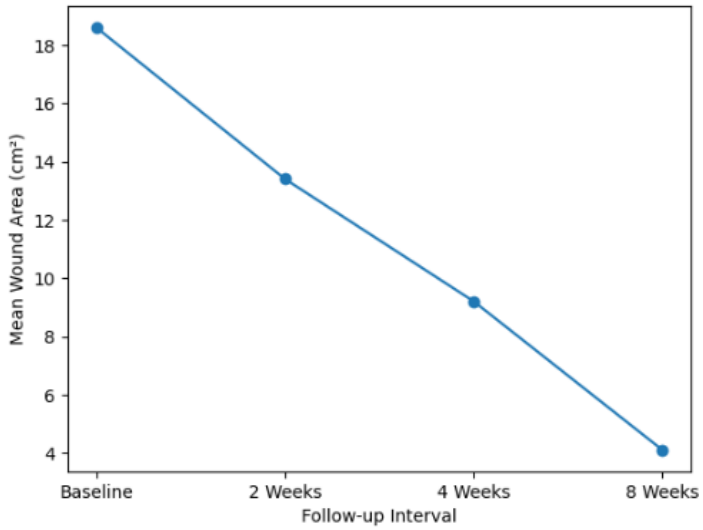
Wound Healing Outcomes Following NPWT

Negative pressure wound therapy led to an overall major improvement of the various wound healing parameters. The wound area was progressively reduced at every follow, up visit. Four weeks later, the average wound area had been reduced to 9.2 4.1 cm, which is equivalent to a 50.5% average reduction. At 8 weeks, full wound closure was attained in a large number of patients, and the rest of the wounds showed good granulation tissue for secondary surgical closure.

Table 2: Changes in Wound Area Over Time Following NPWT

Time Point	Mean Wound Area (cm²)	Percentage Reduction
Baseline	18.6 ± 6.2	—
2 weeks	13.4 ± 5.3	27.9%
4 weeks	9.2 ± 4.1	50.5%
8 weeks	4.1 ± 2.8	77.9%

Statistical analysis demonstrated a significant reduction in wound size over time ($p < 0.001$), indicating effective wound contraction and granulation with NPWT.



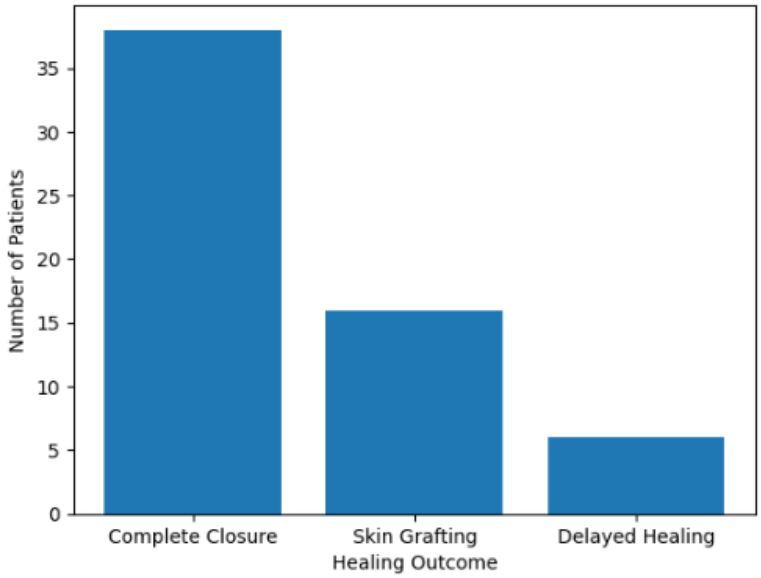
Graph 2: Mean wound area reduction over time during negative pressure wound therapy Clinical Outcomes and Complications

Wound healing was complete in 38 patients (63.3%) at the end of the treatment period, whereas 16 patients (26.7%) were made ready for split, thickness skin grafting after sufficient granulation. Six patients (10%) had delayed healing and thus required prolonged therapy. A few patients only were reported to have minor complications such as periwound

maceration and mild pain during dressing changes, however, these symptoms did not cause discontinuation of the therapy. There were no major complications like bleeding or worsening infection.

Table 3: Clinical Outcomes Following NPWT

Outcome Parameter	Number of Patients (%)
Complete wound closure	38 (63.3%)
Secondary closure / skin grafting	16 (26.7%)
Delayed healing	6 (10.0%)
Minor complications	7 (11.7%)
Major complications	0 (0%)



***Graph 3**: Distribution of final wound healing outcomes in the study population*

DISCUSSION

Diabetic foot ulcers represent a complex clinical problem resulting from the impaired healing of wounds due to metabolic dysfunction, neuropathy, ischemia, and infection. The present investigation demonstrates that negative pressure wound therapy employed along with surgical debridement brings about a significant change in the wound healing process which is evidenced by the gradual reduction of wound area, the impressive formation of granulation tissue, and the favorable final healing results. Such information resonates with an increasing number of publications that consider NPWT a proper and effective method for the treatment of diabetic foot ulcers.

The reduction in wound size from one follow, up to another in this study reflects what has been reported in both clinical routine and randomized trials. In the DiaFu RCT from Germany, wound healing was faster and closure rates were higher with NPWT than with standard moist wound care in patients with diabetic foot ulcers, thereby confirming the effectiveness of NPWT even outside controlled trial settings (9).Similarly, the gradual wound contraction here corresponds to the results of prospective randomized studies that have been dedicated to showing faster healing and more granulation with the use of NPWT (10).

In a doctors arsenal, negative, pressure wound therapy (NPWT) is thus an extremely effective tool, as it was the main factor in this study, where a large number patients were able to achieve complete wound closure or make secondary surgical operations like split, thickness skin grafting feasible. Numerous systematic reviews and meta, analyses have consistently reported that NPWT results in increased healing rates and reduced times to closure compared to standard dressings, in particular, in complex and long, standing diabetic foot ulcers (11). On the other hand, some meta, analytical studies have been challenged due to their methodological flaws. Nevertheless, the general trend of the literature is that NPWT is a wound healing facilitator.

On a biological level, Negative Pressure Wound Therapy (NPWT) is reputed to alter the local wound environment by the production of new blood vessels, reduction of inflammatory load, and stimulation of cellular proliferation. Recent molecular level study revealed that NPWT might affect gene expression related to wound healing by lowering the level of proinflammatory microRNAs such as miR, 155, thus allowing granulation tissue development and tissue remodeling (12). These physiological changes provide plausible reasons for the clinical outcomes that have been consistently enhanced in this research.

The minimally complicated rate of NPWT in this study corresponds to what has been disclosed through several clinical trials. Minor issues such as periwound maceration or pain during dressing changes were of a kind that they subsided on their own and thus, no therapy discontinuation was necessary. Studies comparing standard NPWT to modified systems with the use of irrigation have also indicated very good safety profiles even for patients with complicated foot infections. Therefore, it is possible to conclude that NPWT can be a safe method in various clinical environments provided that appropriate patient selection and wound preparation are ensured (13).

Although negative pressure wound therapy (NPWT) has been largely studied in the situation of open wounds, it is less acknowledged that different studies show NPTW as a successful method even in the treatment of surgical wounds by primary closure, mainly in the decrease of wound complications and the enhancement of results in high, risk patients (14). Such a move to different wounds types, therefore, positions NPWT as an instrument that can manage a variety of incisions and surgical situations, hence, another put forward point for its being incorporated into diabetic foot treatment regimens.

Even though the outcomes are quite encouraging, the authors are still compelled to admit some limitations. Variations in wound features, the occurrence of other diseases in patients, and the duration of diabetes may influence wound healing and thereby complicate the comparison of this study's results with those of other studies. In addition, a control group treated with only standard wound care is not available; thus, it is not possible to make definite statements about the comparative effectiveness of the treatment. However, the current results' consistency with the evidence from rigorously conducted randomized controlled trials, systematic reviews, and real, world studies, thus, confirming the present findings' confidence (9-11, 15).

The research outcomes basically give the green light to the use of negative pressure wound therapy as a safe and efficient method that can be additionally employed in the surgical treatment of diabetic foot ulcers. Along with surgical debridement, control of blood sugar and good follow, up, NPWT is definitely capable of making a very significant change in wound healing, it can shrink the wound load and it can serve as a device for limb rescue. Besides, more large, scale randomized trials with standard outcome measures are required to clarify the treatment regimens more and to determine which patients will benefit most clinically to the greatest extent.

CONCLUSION

One cannot question the positive and reliable manner, in which negative pressure wound therapy (NPWT) is, often, the surgical treatment instrument for diabetic foot ulcers, the case. The result of the study to a great extent demonstrates that the healing of the wound is significantly influenced by the use of NPWT as this is evidenced by the steady reduction of the wound size, marked intensification of granulation tissue, and a big number of wounds getting either completely closed or in a condition suitable for the second surgical intervention. Therefore, a patient has an excellent recovery possibility with a low number of complications if, after adequately cleansing the wound surgically, NPWT is applied together with good glycemic control and infection management. The patient agreed with the treatment, and it consisted only of a low rate of minor, self, resolving side effects, which confirms its safety in regular clinical practice. To begin with, the findings of this study substantially align with the evidence from randomized controlled trials, real, world studies, and mechanistic studies, thus, indicating that the role of NPWT was that which ultimately led to the improvement of the healing process in the cases of chronic diabetic foot ulcers. In patients with diabetic foot ulcers, the implementation negative pressure wound therapy in the regimen of standard surgical wound care may be instrumental in the reduction of the healing time, the reduction of the wound, related morbidity, and the increase of the limb salvage rates. It is necessary to conduct further research with larger sample sizes and comparative designs in order to clarify treatment strategies and facilitate the development of standard guidelines for the use of NPWT in the group of patients at high risk.

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