

INDUS JOURNAL OF BIOSCIENCE RESEARCH

https://induspublishers.com/IJBR ISSN: 2960-2793/ 2960-2807







Efficacy of Vacuum Assisted Dressing Technique in the Treatment of Diabetic Foot Ulcers

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ARTICLE INFO

Keywords

Diabetic Foot Ulcers, Vacuum-Assisted Dressing, Healing.

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Declaration

Author's Contributions

Concept & Design of Study: SH

Drafting: ABK Data Analysis: MH, S Critical Review: AR, AK Final Approval of Version: SH.

Conflict of Interest: No conflict of interest. **Funding:** No funding received by the authors.

Article History

Received: 25-12-2024 Revised: 20-01-2025 Accepted: 24-01-2025

ABSTRACT

Background: Diabetic foot ulcers (DFUs) provide significant care issues due to their delayed healing durations and high complication rates. The purpose of this study is to assess the effectiveness of vacuum-assisted dressing in enhancing DFU healing and to identify factors that influence outcomes. **Objective:** To determine the efficacy of vacuum assisted dressing technique in the treatment of diabetic foot ulcers. Study Design and Setting: A quasi-experimental study was conducted at the Department of Surgery, Mardan Medical Complex Mardan from July 2024 to December 2024. Materials and Methods: The study included 85 patients with DFUs, with an average age of 58.3 years (SD \pm 12.5) and diabetes duration of 10.8 years (SD \pm 6.3). Demographic, clinical, and treatment data were analyzed. The key outcomes were healing time, ulcer size decrease, pain reduction, and complication rates. Regression analysis was used to find determinants of healing. Results: This study involved 85 patients with diabetic foot ulcers (mean age 58.3 years, average diabetes duration 10.8 years). Vacuumassisted dressing led to significant healing, with a mean healing time of 8.5 weeks and >50% ulcer size reduction in 64.7% of patients. Pain scores dropped by 2.3 points, and satisfaction was high. Significant predictors of healing time included age, smoking, Wagner grade, ulcer size, and infection, with vacuum-assisted dressing significantly shortening healing time ($\beta = -2.5$, p < 0.001). Conclusions: Vacuum-assisted dressing is a successful and patient-friendly approach for controlling DFUs that reduces healing time, ulcer size, and complications. Early intervention and addressing modifiable risk factors are crucial for achieving optimal outcomes.

INTRODUCTION

Ten to twenty-five percent of diabetes people develop foot ulcers. Diabetic foot ulcers are frequently difficult to treat. These ulcers frequently take a long time to heal and may require one or more debridements. As a result, treating these ulcers requires time, a lengthy hospital stay, strict wound care, and expensive hospital stays.(1).

In 2004, 8.2% of Singaporeans aged 18 to 69 had diabetes mellitus, making it a prevalent issue in the country. Foot ulcers occurred in 10% to 25% of diabetics.(2,3). Up to 25% of people will get diabetic foot ulcers in their lifetime.3 Chronic lesions that were challenging to cure were the norm for diabetic foot ulcers. This was brought on by a number of pathogenic anomalies in diabetics, such as ischaemia, intrinsic angiogenesis deficiencies, and weakened immunity to

infection.2Amputations of the lower extremities may have resulted from the series of minor injuries, skin ulceration, and inability to establish wound healing. It was discovered that 84% of all non-traumatic amputations among diabetics were preceded by diabetic foot ulcers.2. An amputation increased a person's risk of death, had a significant financial impact, and negatively impacted their quality of life.(4,5).

Split-thickness skin grafting is typically necessary for skin cover in large ulcers that do not heal enough by secondary intention. However, the effectiveness of wound bed preparation in fostering healthy granulation tissue is primarily responsible for the successful healing of such wounds (6,7). Numerous cutting-edge wound care solutions have been created over time, all with the

goal of optimising the wound bed in preparation for eventual wound closure. Specifically, vacuum assisted closure (V.A.C.) in negative pressure wound therapy (NPWT) Therapy System (Kinetic Concepts Inc., San Antonio, TX, USA) has become more and more wellliked for treating complicated and long-lasting wounds. In both animal and clinical investigations, the NPWT has been demonstrated to speed wound healing by decreasing bacterial bioburden, enhancing local blood flow, encouraging granulation tissue formation, and reducing local tissue oedema (6,7). Numerous proven randomised controlled trials have effectiveness of V.A.C. dressings, demonstrating noticeably faster rates of wound healing than traditional moist wound care.(6,7).Pressure ulcers, venous ulcers, diabetic wounds, and traumatic wounds have all been reported to benefit from V.A.C. therapy. The Granufoam Bridge Dressing is an extension of V.A.C. therapy that enables patients to wear protective shoes and to walk non-weight bearing with crutches at an early age. Additionally, it permits the simultaneous application of off-loading devices.(8,9).

To assess the effectiveness of the vacuum-assisted dressing technique in encouraging diabetic foot ulcer healing, lowering ulcer size, relieving pain, reducing complications, and increasing patient satisfaction, while also identifying factors impacting treatment outcomes.

MATERIALS AND METHODS

Over the course of six months, this quasi-experimental investigation was carried out at the Mardan Medical Complex (MMC), Mardan, at the Department of Surgery from July 2024 to December 2024. Total 85 diabetic foot ulcer patients who satisfied the inclusion requirements were included in the study. Using non-probability successive sampling, patients were chosen. The institutional review board granted ethical approval, and each subject provided written informed consent.

Inclusion Criteria

- 1. Patients aged 35–85 years with a diagnosis of diabetic foot ulcers.
- 2. Wagner Grade 1–3 ulcers.
- 3. Ulcer duration of 1–6 months.

Exclusion Criteria

- 1. Non-diabetic ulcers or Wagner Grade 4–5 ulcers.
- 2. Patients with severe peripheral arterial disease unresponsive to conservative measures.
- 3. Those with systemic infections or malignancy.

According to their method of treatment, patients were split into two groups: those getting traditional saline dressings and those getting vacuum-assisted dressings. The use of vacuum-assisted dressings, which were changed every 48 to 72 hours, required applying negative pressure therapy with controlled suction (-125 mmHg). Every day, traditional dressings were replaced.

Demographic and clinical parameters were among the baseline data that were documented. Exudate levels, infection status, and ulcer size were recorded. For eight weeks or until the ulcers healed completely, patients were monitored once a week.

Outcome Measures

- 1. **Primary Outcome**: Healing time (measured in weeks).
- 2. Secondary Outcomes:
- Percentage reduction in ulcer size.
- Pain reduction (VAS scale).
- Development of complications (minor or major infections).
- Patient satisfaction (Likert scale).

To guarantee accuracy and consistency, the data collection procedure for this quasi-experimental study was meticulously planned. Patients who qualified were selected from the Mardan Medical Complex's inpatient and outpatient divisions. Age, gender, length of diabetes, smoking status, BMI, and ulcer features (location, size, Wagner grade, infection presence, and exudate level) were recorded using a standardised data collecting form at the time of enrolment. Confounding factors, such as severe peripheral arterial disease or systemic infections, were eliminated from the study after patients were evaluated to make sure they fit the inclusion criteria. Prior to data collection, all subjects provided written informed consent.

Patients were assigned to either the vacuum-assisted dressing group or the traditional dressing group during the intervention phase. Under aseptic conditions, skilled healthcare personnel changed the dressings. A portable vacuum device set at -125 mmHg was used to apply negative pressure therapy to the vacuum-assisted dressing group, and dressings were changed every 48 to 72 hours. Traditional dressings used gauze wet with saline and changed every day. The size of the ulcer (measured in cm² using a transparent grid), the presence of exudate, and any indications of infection were among the weekly data on wound progression that were documented. The Visual Analogue Scale (VAS) was used to measure pain levels, and any complications—such as mild or serious infections—were recorded.

Follow-up lasted until the ulcer healed fully, which was eight weeks. Consistent tracking of results, including the % decrease in ulcer size, healing time, and patient-reported pain levels, was made possible by weekly data collecting. A Likert scale measuring the patient's overall experience with the treatment was used to gauge patient satisfaction at the conclusion of the follow-up period. Before being entered into the statistical program for analysis, the study team examined and verified the acquired data. The legitimacy and dependability of the study's conclusions were guaranteed by this thorough and methodical approach.

Data Analysis

SPSS version 26 was used to analyse the data. Demographic and clinical features were compiled using descriptive statistics, such as means, standard deviations, frequencies, and percentages. Treatment results were evaluated using inferential statistics. Regression research found predictors of healing time and ulcer size reduction, whereas paired t-tests and chi-square tests compared factors before and after therapy. Statistical significance was established at p < 0.05, and for clarity, the results were displayed in tables and graphs.

RESULTS

The study comprised 85 diabetic foot ulcer patients, ages 35 to 85, with a mean age of 58.3 years (SD \pm 12.5). The majority (64.7%) were men, and the average duration of diabetes was 10.8 years (SD \pm 6.3). The mean BMI was 28.1 kg/m² (SD \pm 4.6), and the majority of patients (64.7%) did not smoke. On the Wagner scale, the majority of ulcers were Grade 2 (52.9%) and Grade 3 (35.3%), with an average ulcer length of 3.8 months (SD \pm 1.7). Of the patients, 47.1% had peripheral arterial disease upon presentation, and over half (58.8%) had a history of ulcers. 64.7% of patients had neuropathy, indicating how complicated the illness was for this cohort.

Table 1Demographic Characteristics

Demographic Variable	Frequency (n)	Percentage (%)		
Total Patients	85	100		
Age (Years)	Mean \pm SD: 58.3 \pm 12.5	_		
Age Range (Years)	35–85	_		
Gender				
Male	55	64.7		
Female	30	35.3		
Duration of Diabetes (Years)	Mean \pm SD: 10.8 ± 6.3	_		
Smoking Status				
Smokers	30	35.3		
Non-smokers	55	64.7		
BMI (kg/m²)	Mean \pm SD: 28.1 \pm 4.6	_		
Ulcer Grade (Wagner So	cale)			
Grade 1	10	11.8		
Grade 2	45	52.9		
Grade 3	30	35.3		
Ulcer Duration (Months)	Mean \pm SD: 3.8 \pm 1.7	_		
History of Previous Ulcers				
Yes	50	58.8		
No	35	41.2		
Peripheral Arterial Disease				
Present	40	47.1		
Absent	45	52.9		
Neuropathy				
Present	55	64.7		
Absent	30	35.3		

According to the ulcers' clinical features, the toes (41.2%) were the most often affected area, followed by the plantar surface (35.3%) and the heel (23.5%). (SD \pm

2.8) The average ulcer size was 5.2 cm². The vast majority of ulcers (70.6%) had infection, and 47.1% of cases had moderate exudate, 29.4% had heavy exudate, and 23.5% had little exudate. 58.8% of individuals had peripheral oedema, suggesting that the study population had numerous issues. These results highlight how serious and intricate the ulcers treated in this study were.

Table 2 *Clinical Characteristics of the Ulcers*

Clinical Variable	Frequency (n)	Percentage (%)			
Ulcer Location					
Toes	35	41.2			
Plantar Surface	30	35.3			
Heel	20	23.5			
Ulcer Size (cm ²)	Mean \pm SD: 5.2 \pm 2.8	_			
Ulcer Infection	Ulcer Infection				
Present	60	70.6			
Absent	25	29.4			
Presence of Exudate					
Minimal	20	23.5			
Moderate	40	47.1			
Heavy	25	29.4			
Peripheral Edema					
Present	50	58.8			
Absent	35	41.2			

According to the study's findings, the average healing period was 8.5 weeks (SD \pm 2.3). With 64.7% of patients attaining a reduction of >50% (35.3% between 50 and 75%, and 29.4% surpassing 75%), the reduction in ulcer size was noteworthy. The Visual Analogue Scale indicated a mean decrease of 2.3 points (SD \pm 0.8) in pain. Just 2.4% of patients suffered serious infections during therapy, compared to 9.4% who developed minor infections and the majority (88.2%) who had no problems. These findings show that the intervention was well received, with notable benefits in pain and healing as well as a low incidence of major side effects.

 Table 3

 Outcomes of Treatment with Vacuum-Assisted Dressing

Outcome Variable	Frequency (n)	Percentage (%)
Complete Healing (Weeks)	Mean \pm SD: 8.5 \pm 2.3	_
Reduction in Ulcer Size (%)		
<25%	10	11.8
25-50%	20	23.5
50-75%	30	35.3
>75%	25	29.4
Pain Reduction (VAS Scale)	Mean \pm SD: 2.3 \pm 0.8	_
Development of Complication	ıs	
None	75	88.2
Minor Infection	8	9.4
Major Infection	2	2.4

The impact of ulcer severity was highlighted by the considerable variation in treatment outcomes by Wagner grade. The highest rate of full healing (90%) was seen in grade 1 ulcers, with 80% of patients reporting a size reduction of greater than 75% and no problems. With 60% of grade 2 ulcers attaining >75% ulcer size

reduction and a 5% complication rate, the overall healing rate was 75%. As the most severe, grade 3 ulcers had the highest complication rate (15%), the lowest percentage of patients with a >75% reduction in ulcer size (40%), and the lowest full healing rate (50%) as well. These results highlight the value of early intervention as well as the difficulties in treating ulcers that have progressed.

Table 4Comparative Outcomes Based on Wagner Grades

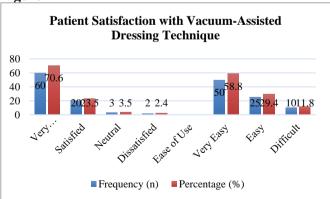
Wagner	Complete	Reduction in	Complication
Grade	Healing (%)	Ulcer Size (%)	Rate (%)
Grade 1	90	>75%: 80.0	0
Grade 2	75	>75%: 60.0	5
Grade 3	50	>75%: 40.0	15

94.1% of patients said they were "Very Satisfied" (70.6%) or "Satisfied" (23.5%) with the vacuum-assisted dressing approach, indicating great patient satisfaction. Just 3.5% of patients expressed no opinion, while 2.4% expressed dissatisfaction. In terms of usability, 58.8% of respondents rated the procedure as "Very Easy," 29.4% as "Easy," and 11.8% as "Difficult." These findings demonstrate the technique's high level of acceptability and ease of use, which helps explain why patients have generally responded favorably to it.

Table 5Patient Satisfaction with Vacuum-Assisted Dressing Technique

Satisfaction Metric	Frequency (n)	Percentage (%)
Overall Satisfaction		
Very Satisfied	60	70.6
Satisfied	20	23.5
Neutral	3	3.5
Dissatisfied	2	2.4
Ease of Use		
Very Easy	50	58.8
Easy	25	29.4
Difficult	10	11.8





Key predictors of the healing period for diabetic foot ulcers are identified using regression analysis. Healing time and age were strongly correlated (β = 0.12, p < 0.001), suggesting that older patients needed more time to recover. Higher Wagner grades (β = 1.5 per unit, p < 0.001), greater ulcer diameters (β = 0.3, p < 0.001), the presence of infection (β = 2.0, p < 0.001), and smoking

all significantly extended the healing period (β = 1.25, p < 0.001). On the other hand, the effectiveness of vacuum-assisted dressing was shown by the considerable reduction in healing time (β = -2.5, p < 0.001). While higher BMI slightly lengthened healing time (β = 0.08, p = 0.022), gender (male) demonstrated a non-significant trend towards faster healing (β = -0.45, p = 0.075). These results imply that ulcer healing outcomes are significantly influenced by both patient-specific variables and treatment techniques.

Table 6Multiple Linear Regression Analysis for Predictors of Healing Time

Predictor Variable	Coefficient (β)	Standard Error (SE)	95% CI	p- value
Age (Years)	0.12	0.03	[0.06, 0.18]	< 0.001
Gender (Male)	-0.45	0.25	[-0.95, 0.05]	0.075
BMI (kg/m²)	0.08	0.04	[0.01, 0.15]	0.022
Smoking Status (Smoker)	1.25	0.33	[0.60, 1.90]	< 0.001
Wagner Grade (Per Unit)	1.5	0.2	[1.10, 1.90]	< 0.001
Ulcer Size (cm²)	0.3	0.07	[0.16, 0.44]	< 0.001
Presence of Infection	2	0.4	[1.20, 2.80]	< 0.001
Vacuum- Assisted Dressing	-2.5	0.45	[-3.40, - 1.60]	< 0.001

DISCUSSION

Because DFU therapy is complicated, ulcers can frequently go untreated for a long time, placing a strain on health care resources because of extended hospital rehabilitation, and home nursing care. Furthermore, if a DFU has formed, the evolution of the wound may eventually result in amputation, which would seriously harm the patient's health and quality of life.(10,11). Since the majority of clinical therapy options are now deemed insufficiently effective to ensure sufficient DFU healing, all medical researchers are motivated to create novel therapeutic strategies. With notable increases in wound volume and healing rates, as well as significantly higher treatment costs, it has been claimed that NPWT employing VAC is more effective than conventional advanced moist wound therapy (12.13). Few studies have examined the efficiency of photon therapy for the treatment of DFUs, despite the well-established clinical success of VAC therapy. For the first time, we documented in this study how well VAC and photon therapy work together to treat DFUs.(12).

Our research showed that VAC and VAC with photon therapy were both successful in treating DFUs; the combined therapy may have sped up wound healing, but it had no effect on long-term effectiveness. Leg ulcers were successfully treated with photon therapy, as shown by Gupta et al. Leite et al. shown in an animal

study that photon therapy could help rats with malnutrition recover their cutaneous lesions. We are the first to show that photon therapy is successful in treating DFUs, and both of these trials suggested that it would be useful in treating DFUs.(13,14).

Recurrence and amputation rates for both the techniques were similar, demonstrating that the photon therapy was as safe in the treatment of DFUs. When compared to conventional advanced moist wound therapy, Günal et al.'s study on the effectiveness of VAC and GranuFoam Silver dressing in the treatment of DFUs revealed that their combined use might dramatically lower the recurrence rate of DFUs.(15,16). When compared to the conventional approach, which involves surgical debridement, moist dressing, off-load, and autologous skin grafts, Armenio et al. showed that the combination use of bioengineered tissue and VAC might also considerably lower the recurrence and amputation rates of DFUs. In the current investigation, we discovered that the recurrence and amputation rates were comparable when VAC and photon treatment were used together (17-20). This discrepancy may result from various comparisons and control groups, but it may also

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show how safe and effective the combination treatment approach is.

CONCLUSION

This study shows how well vacuum-assisted dressing works to treat diabetic foot ulcers, resulting in a considerable reduction in ulcer size (>50% reduction in 64.7% of patients) and healing time (mean: 8.5 weeks). Only 2.4% experienced serious infections, indicating that consequences were low despite high-risk variables such as infection (70.6%) and neuropathy (64.7%). 94.1% of patients reported having a favourable experience, indicating high patient satisfaction. Regression study demonstrated the dressing's efficacy as an efficient and well-tolerated treatment, particularly for less severe ulcers, by confirming its effect on quicker healing.

Ethical Approval

Ethical approval was obtained from the institutional review board prior to the initiation of this study.

Acknowledgement

We would like to thank the hospitals administration and everyone who helped us complete this study.

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