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Vacuum-assisted closure versus moist dressings in the treatment of diabetic wound ulcers after partial foot amputation: A retrospective analysis in 65 patients

Erhan Sukur, Abdulhalim Akar, Ahmet Çagrı Uyar, Ozgur Cicekli, Alauddin Kochai, Mehmet Turker and Huseyin Nevzat Topcu

Abstract

Purpose: Changes in weight-bearing patterns after partial foot amputations may lead to new localized high-pressure points and keratosis due to ulcerations in patients with neuropathies and hypovascular limbs. As a result, diabetic foot ulcers (DFUs) after partial foot amputations are very complex. The aim of this study was to compare the effectiveness of vacuum-assisted closure (VAC) therapy with conventional moist wound dressings in the treatment of diabetic wound ulcers after partial foot amputations. **Methods:** Sixty-five diabetic patients with a DFU, who had previously undergone partial foot amputation surgery, were assigned to treatment with VAC (group A: 31 patients) or conventional wound moist dressing (group B: 34 patients). The final results were considered as failed treatment if reamputation was required. Conversely, reaching 90% of wound granulation was considered to be a successful endpoint. **Results:** The average time to reach 90% granulation tissue was significantly lower in group A (7.8 $\pm$ 1.2 weeks vs. 11.1 $\pm$ 1.2 weeks; $p < 0.001$). However, there was no significant difference regarding the reamputation requirements; 38.7% (12 patients) in group A and 41.2% (14 patients) in group B, ($p = 0.839$). **Conclusion:** The results of this study allowed us to conclude that VAC therapy system appears to be an effective treatment for patients with complex DFUs who had previously undergone partial foot amputation.

Keywords

diabetic food ulcer, partial foot amputation, reamputation, VAC

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Introduction

Half of the 80,000 amputations per year related to diabetes in the United States are reported to be partial foot amputations.[1] After partial foot amputations, complications that may cause deformities could lead to further ulcerations. Changes in weight-bearing patterns may lead to new localized high-pressure points and keratosis due to ulcerations in patients with neuropathies and hypovascular limbs.[2,3] As a result, diabetic foot ulcers (DFUs) after partial foot amputations are very complex. Patients often experience challenges with healing and are often faced with high rates of complications.[4–6] The wounds are often large and deep with exposed bone and tendons occurring in patients with compromised healing capacity and significant risk factors

Department of Orthopaedics and Traumatology, Sakarya University Research and Training Hospital, Sakarya, Turkey

Corresponding author:
Erhan Sukur, Department of Orthopaedics and Traumatology, Sakarya University Research and Training Hospital, Adapazarı, Sakarya 54050, Turkey.
Email: erhan_sukur@hotmail.com

for reamputation.[7,8] After amputations of the lower limb, only 40–50% of amputees survive for 5 years and the prognosis worsens as the level of amputation goes higher up the leg.[9] There are different treatment methods for DFUs, such as moist wound dressings, hydrocolloid wound gels, growth factors, enzymatic debridement compounds, electric stimulation, low-potential laser therapy, and negative-pressure wound therapy (NPWT).[8,10] NPWT, with Vacuum-Assisted Closure® (VAC®) which was introduced in 1997 by Argenta and Morykwas,[10,11] seems to be the most widely used variant. NPWT improves local blood supply and stimulates local angiogenesis, thus increasing the formation of granulation tissue over clean wounds. As a result, fibroblasts migrate, contracting and reducing the surface area of the wound.[12–14] The aim of this study was to compare the effectiveness of VAC with conventional moist wound dressings in the treatment of diabetic wound ulcers after partial foot amputations.

Material and methods

This study was approved by the institutional review board of our institution under process number 04/269. All patients participating in the study provided informed consent orally before the study. Sixty-five diabetic patients with a DFU, who had previously undergone partial foot amputation surgery, were assigned to treatment with VAC (group A: 31 patients) or conventional wound moist dressing (group B: 34 patients). VAC dressings were administered after proper debridement surgery and the dressings were changed once every 3 days. The moist dressings were changed twice daily after washing the ulcer with sterile saline and gauze. The inclusion criteria consisted of the following: the patients in whom partial foot amputations were performed below the talocalcaneal joint, with DFU located outside of the amputation region. The exclusion criteria included the following: renal failure undergoing dialysis, poor compliance with medical treatments, receiving radiation therapy or chemotherapy, osteomyelitis, and ischemic ulcer that needed any open or endovascular revascularization. The type of diabetes mellitus, duration of existence of the ulcer, wound location, and frequency of the underlying disease were evaluated in all patients. The final results were considered as failed treatment if reamputation was required. Conversely, reaching 90% of wound granulation was considered to be a successful endpoint. NPWT delivered through the VAC System TM (KCI, San Antonio, Texas, USA) was administered in the present study (13). The system used in this case consisted of two components, a negative pressure-generating unit with a disposable canister and a pad with an evacuation tube. The system unit was programmed to deliver controlled negative pressures ranging from 50 mmHg to 200 mmHg. NPWT was applied to the ulcer as specified by the manufacturer's guidelines.[15]

Data analysis

The data were evaluated using SPSS for Windows 15.0 software (SPSS Inc, Chicago, Illinois, USA). The descriptive statistics were calculated as frequencies and percentages for the categorical variables, and as mean, standard deviation, and median for the numerical variables. As the numerical variables did not require normal distributions, the comparison of the two independent groups was performed using the Mann–Whitney U test. The χ^2 test was used to compare the rates in the groups. The significance level was set at 0.05.

Results

There was no statistically significant difference in the patients' demographics between the two groups (Table 1). The regions where the DFUs newly formed were as follows: sole region 43% (28 patients), metatarsal region 30.7% (20 patients), and phalanx region 26.1% (17 patients).

The average time to reach 90% granulation tissue was significantly lower in group A (7.8 $\pm$ 1.2 weeks vs. 11.1 $\pm$ 1.2 weeks; $p < 0.001$) (Figure 1). However, there was no significant difference regarding the reamputation requirements; 38.7% (12 patients) in group A and 41.2% (14 patients) in group B, ($p = 0.839$) (Table 1). The only predictive factor which was related to the success of the treatment (90% tissue granulation) in both groups was found to be the Wagner type 2 ulcer ($p = 0.042$) (Figure 2).

Discussion

This study suggested that the VAC therapy system yielded faster times to wound closure in the treatment of diabetic wound ulcers after partial foot amputation when compared to the moist dressing. However, there was no difference regarding the reamputation requirements. VAC is a well-tolerated technique which generates robust granulation tissue and is becoming a popular treatment modality in the current practice of wound care compared to other available therapies.[10,11,15,16] Thus, we planned to use VAC therapy in the treatment of DFU. In their study, McCallon et al. reported that the mean treatment duration for VAC therapy and moist dressings was 22.8 and 42.8 days, respectively. In the VAC group, the mean duration for changes in the size of the ulcers was 3 weeks less than in the moist dressing group.[17] In contrast to the criterion that McCallon et al. used in their study, we used the formation of adequate granulation tissue as an endpoint rather than complete wound regeneration, and we obtained similar results. Ravari et al. evaluated the effectiveness of VAC therapy on the size and the depth of the ulcer, and they found a significant improvement in the wound owing to reduced diameter and depth.[7] The strength of our study is that our study population particularly included patients with DFU

Table 1. Patient demographics and results.

		Group A	Group B	*p*
Age, mean ± SD (min–max)		60.6 ± 11.6 (38–81)	58.3 ± 8.0 (47–75)	0.349
Sex	Women	6 (19.4)	7 (20.6)	0.901
	Men	25 (80.6)	27 (79.4)	
Type of DM	Type 1	2 (6.5)	3 (8.8)	1.000
	Type 2	29 (93.5)	31 (91.2)	
Current tobacco use, *n* (%)		11 (35.5)	11 (32.4)	0.790
Current alcohol use, *n* (%)		7 (22.6)	6 (17.6)	0.619
Ulcer duration (month), mean ± SD (min–max)		3.6 ± 2.1 (1–8)	2.9 ± 1.6 (1–7)	0.215
Wagner's scale	Grade 2	4 (12.9)	6 (17.6)	0.736
	Grade 3	27 (87.1)	28 (82.4)	
Size of ulcer (cm^2), mean ± SD (min–max)		18.3 ± 3.1 (12–24)	17.6 ± 3.3 (10–24)	0.372
Depth of ulcer (mm), mean ± SD (min–max)		11.5 ± 1.6 (9–14)	11.4 ± 1.8 (8–15)	0.841
Initial amputation level, *n* (%)	Phalanx	9 (29.0)	8 (23.5)	0.614
	Trans-metatarsal	7 (22.6)	10 (29.4)	0.531
	Tarsometatarsal	10 (32.3)	11 (32.4)	0.993
	Chopard	5 (16.1)	6 (17.6)	0.870
Endpoint reached, *n* (max–min)	90% tissue granulation	19 (61.3)	20 (58.8)	
	Reamputation requirement	12 (38.7)	14 (41.2)	0.839
Time of 90% tissue granulation (week), mean ± SD		7.8 ± 1.2	11.1 ± 1.2	<0.001

SD: standard deviation; DM: diabetes mellitus.

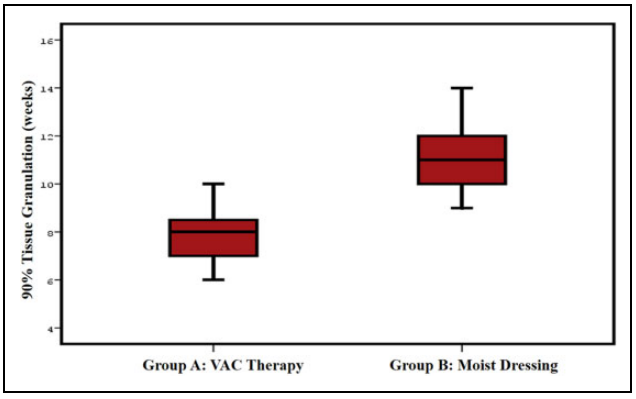

Figure 1. VAC therapy system yielded shorter times to wound closure when compared to moist dressings. VAC: vacuum-assisted closure.

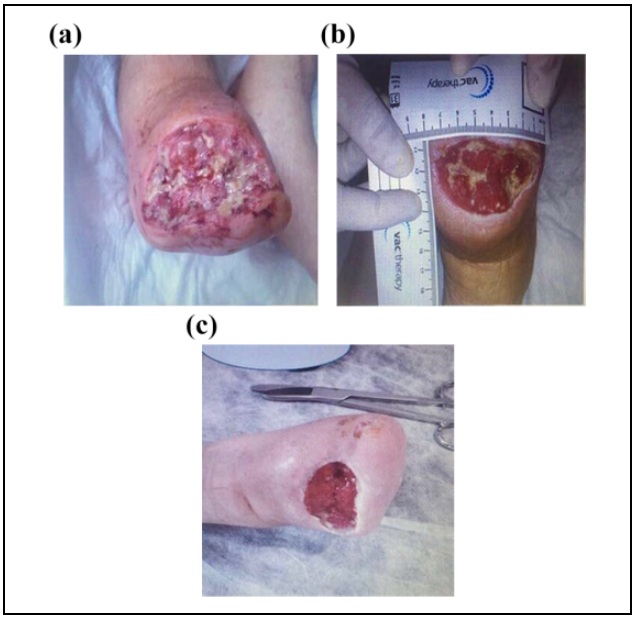

Figure 2. Photograph of a 51-year-old man who had previously undergone tarsometatarsal amputation. (a) The diabetic wound ulcer before the application of VAC therapy. (b) The ulcer size was 8 × 5 cm and classified as Wagner type 3. (c) After 13 VAC applications over 8 weeks, the ulcer size decreased by nearly 50%, and 90% tissue granulation was obtained. VAC: vacuum-assisted closure.

who had undergone partial foot amputation. Partial foot amputation changes the weight-bearing biomechanics of the foot, making patients susceptible to new pressure points that can ulcerate. Adequate blood supply, which is generally present in neuropathic feet, is of paramount importance for success in wound healing with these procedures. However, there is still a risk of re-ulceration and further amputation after partial foot amputations even if the wound has healed.[2] Previous studies primarily focused on DFU in which previous amputation surgery had not been performed. All of these studies reported better and faster wound healing in patients after VAC therapy.[10,15,18] On the other hand, there are only few studies in the literature that focused on the effectiveness of the VAC therapy system in the treatment of patients with DFU who had previously undergone a partial foot amputation surgery. Armstrong and Frykberg reported that, VAC therapy led to a higher proportion of healed wounds, faster healing rates, and less reamputation requirement. They attributed the decreases in reamputations to the faster healing times and higher proportion of healing wounds with the use of VAC therapy.[4]We found a similar superiority in VAC therapy

that provided greater and faster wound coverage in our study population. However, there was no difference with respect to the reamputation requirements between VAC therapy and moist dressing treatments. We think that this was due to the higher frequency of deeper ulcers classified as Wagner type 3 and the longer mean wound duration in our series. The relationship between the chronicity of the ulceration with VAC therapy was evaluated in another study, and they found that wound duration did not have an overt role in the efficacy of the VAC therapy system in patients with large wounds secondary to partial foot amputation.[19] Although we did not classify the wounds as acute or chronic, or compare them based on this timing, this may be the subject of another study.

Equinovarus deformity is the most common deformity after partial foot amputation. There may often be a high-pressure point at the anterolateral aspect of patient's sole. Ulceration at that region can be difficult to manage without tendon-balancing procedure. Also in our study, anterolateral aspect of the sole was the region where new ulcerations occurred the most. However, we have no sufficient data to conclude if the newly formed ulcerations are due to altered foot biomechanics or progressing diabetic disorder.

There are other limitations of this study. First, it was a retrospective study and lacked data on the progression of granulation per week, which limited the strength of our analysis. Second, we did not analyze the patients' gaits, which could alter the biomechanics of weight-bearing. It may be possible to evaluate the relationship between the localization of the ulcerations in partially amputated feet with reamputation requirements.

However, the results of this study allowed us to conclude that NPWT as delivered through the VAC therapy system appears to be an effective treatment for patients with complex DFUs who had previously undergone partial foot amputation. This could lead to a higher proportion of healed wounds and faster healing rates compared to conventional moist dressings. However, there is no superiority of one method over the other regarding reamputation requirements. Future studies are required for the evaluation of the risk factors related to reamputation requirements.

Declaration of conflicting interests

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