Effect of negative pressure wound therapy for legs in complex wound diabetic patients: Therapeutic challenge and review

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Abstract
Diabetic foot is one of the main chronic complications caused by diabetes mellitus and can lead to limb amputation. Among the various wound treatment options, negative pressure wound therapy is a treatment modality based on vacuum-sealed drainage and vacuum-assisted closure to create a localized controlled negative pressure environment. In this case report, the patient sought medical attention and underwent surgical debridement of the dorsum of the right foot. Upon worsening of the wound condition, the patient was referred to our hospital for debridement and Renesys Smith Nephew dressing was implanted. After complete coverage of the granulation tissue without infection, elastic suturing was performed in the leg compartment to reduce the size of the dermis and epidermis graft. The patient then underwent a dermal matrix implant procedure, and an epidermis graft was removed from the ipsilateral thigh and placed on the wound. The aim of this study is to report a therapeutic challenge in an extensive wound in diabetic foot using a dressing negative pressure wound therapy and multidisciplinary treatment.

Keywords
Negative pressure wound therapy, diabetic limb salvage, foot ulcer, wound care, diabetes

Introduction
Diabetic foot is one of the main chronic complications caused by diabetes mellitus and is the result of peripheral neurological and vascular changes. Ulcer is a feared complication of diabetic foot that can lead to limb amputation. The prevalence of diabetic foot ulceration in the diabetic population is 4%–10%; the condition is more frequent in older patients.1 A 40-year-old male patient with type-2 diabetes mellitus presented with plantar perforating disease on his right foot, which was not treated by a specialist.

The WIfI Classification System was published in 2014 to provide precise and early risk stratification to patients with threatened lower limbs. It also assists in clinical management, allowing comparisons with alternative therapies, and predicts the risk of amputation in 1 year and the need for revascularization.2

Among the various wound treatment options, negative pressure wound therapy (NPWT) is a treatment modality based on vacuum-sealed drainage and vacuum-assisted closure used to create a localized controlled negative pressure environment. NPWT has shown promise in the treatment of complex wounds in diabetic foot, mainly for chronic wounds, and as adjuvant treatment for temporary closure and preparation of the wound bed before surgical procedures.3

The objective of this study is to describe the multidisciplinary treatment associated with NPWT of a complex wound in the right lower limb of a diabetic patient and to review the literature on negative pressure therapy. Informed consent has been obtained from the patient for publication of the case report and accompanying images.

Case report
A 40-year-old male patient (obese, sedentary, dyslipidemic, and with type 2 diabetes mellitus) presented with plantar perforating disease on his right foot, which was not treated by a specialist.

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The objective of this study is to describe the multidisciplinary treatment associated with NPWT of a complex wound in the right lower limb of a diabetic patient and to review the literature on negative pressure therapy. Informed consent has been obtained from the patient for publication of the case report and accompanying images.

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perforating disease on his right, which was not treated by a specialist. With the decompensation of the diabetes, the wound worsened with hyperemia in the instep, discharge of purulent secretion from the side of the foot close to the orifice, fever, chills, and pain in the lower limb. Without satisfactory wound response after 7 days of initial debridement, fever persisted, along with an increased area of necrosis toward the leg, a foul odor, pain, edema, and discharge of purulent secretion. Due to the worsening of the wound, the patient was referred to our hospital. After admission, empirical antibiotic therapy was started with 4.5 mg tazocin administered intravenously 6/6 hours, 500 mg daptomycin administered once a day and glycemic control. Vascular surgery was performed to assess the wound and vascularization of the right lower limb. Due to the extent of the lesion and edema of the lower limb, palpation of the distal pulses was not possible, and the ultrasonographic evaluation with Doppler demonstrated three-phase arterial flow without trunk injuries, which suggests preserved flow in the right lower limb. In addition, endocrinology assessment was requested with glibenclamide 5 mg BID and dapaglifozin and metformin 5 mg/1000 mg BID prescribed.

The patient was referred to the operating room, and debridement of the right lower limb was performed with the removal of a large amount of necrotic tissue and purulent secretion. Due to the extent and severity of the injury, several tendons and muscles in the dorsum of the foot and leg were resected leading to bone exposure. Debrided tissues were sent for culture and antibiogram. After debridement and thorough cleaning with saline, a Renesys Smith Nephew dressing was implanted with negative pressure at 120 mmHg (Figure 1(a)–(c)).

The first dressing change was performed after 3 days due to the severity, extent of the lesion, and the discharge of a large amount of purulent secretion. The lesion showed a significant improvement, but there was still a large amount of purulent discharge in the anterior compartment of the leg.

Fasciotomy and debridement of the anterior compartment of the leg was performed, and the dressing was placed under negative pressure again at 120 mmHg (Figure 2(a) and (b)).

With each exchange of dressing, the rigor of the debridement of devitalized tissues and thorough cleaning with saline was maintained. In addition, there was a noticeable increase in the amount of granulation tissue, reduction in bone exposure and the amount of secretion drained, as well as clinical and laboratory improvement. Vacuum dressings were changed every 3 or 4 days according to the amount of secretion drained.

Twenty vacuum dressing changes were performed in 70 days, with an average change every 3.5 days, maintaining a continuous negative pressure of 120 mmHg. After complete coverage of granulation tissue without infection, elastic suturing was performed in the leg compartment to reduce the
size of the dermis and epidermis graft (Figure 3(a) and (b)). It was not possible to use the elastic suture in the dorsum of the foot due to the distance between the edges. After cleaning the wound, the vacuum dressing was installed again. On the 71st day of hospitalization, the patient underwent a dermal matrix implant procedure, and an epidermis graft was removed from the ipsilateral thigh and placed on the wound (Figure 4(a)–(c)). He was discharged 22 days after the grafting procedure with good recovery and no areas of necrosis around the graft. Throughout the hospitalization period, motor physiotherapy was performed in order to prevent ankle ankylosis and loss of muscle and to allow the recruitment of other muscle fibers to maintain the natural physiology of foot flexion and dorsoflexion.

Daily hydration with Dersani® was performed in order to avoid dryness of the epidermis. There was a small loss of skin on the lateral side of the foot, which the patient was instructed to dress with saline and neutral soap daily until closing by second intention. Approximately 5 months after grafting, the two areas with tissue loss had recovered adequately with a gradual reduction in size. The foot was slightly equinus/varus, but without loss of sensation or motor function (Table 1). In addition, the patient had controlled diabetes, was in a food reeducation program, and was undergoing motor physiotherapy to keep the foot functioning (Figure 5(a) and (b)).

**Discussion**

NPWT has been used to treat open wounds since the 1940s. However, vacuum-assisted closure systems, a type similar to the negative pressure dressing, began to be developed in the treatment of anecdotal open wounds and in small studies from the 1980s onwards. In 1989, Chariker et al. developed a suction drainage system using gauze at pressures of 60–80 mmHg to treat incisional and skin fistulas. They believed that their system was effective in promoting fluid drainage, thereby helping the formation of granulation tissues. As their system required fewer dressing changes compared to those required by traditional methods, they concluded that it would be more profitable in the long run. In 1993, Fleischmann...
s.\textsuperscript{5} described a more commercial approach and the use of open-pored polyurethane sponge with excellent results in the management of open fractures.

The negative pressure dressing has primary mechanisms and secondary effects on the wound healing process. Generally, the action of the primary mechanisms can be divided into four aspects: wound shrinkage or macrodeformation; microdeformation at the foam-wound surface interface; fluid removal; and stabilization of the wound environment. There are also several secondary effects likely involved in mechanotransduction pathways that alter the biology of wound healing including angiogenesis, neurogenesis, cellular proliferation, differentiation, and migration. This treatment modality promotes granulation of tissue growth and wound healing, increasing local blood flow, reducing edema of tissues, removing exudates and pro-inflammatory cytokines, inhibiting bacterial growth, and stimulating cell hyperplasia. The main indications are for chronic wounds and adjuvant treatment for temporary closure and preparation of the wound bed before surgical procedures.\textsuperscript{6}

In view of the complexity of the wound with involvement of the dorsum of the foot, anterior compartment of the leg and a large amount of necrotic tissue and purulent secretion, multidisciplinary treatment with physiotherapy, nutrition, endocrinology, and vascular surgery was essential for the result with limb salvage. Perhaps for a team that had no experience in vacuum dressing and the associated patience and persistence, many would indicate amputation. However, as the patient was young and with only one comorbidity, we discussed and decided to try performing debridement and vacuum dressing initially.

Extensive debridement of the dorsum of the foot with tendons, muscles, and bone exposure was necessary. In the first exchange, after 3 days, we noticed that there was a considerable improvement in the appearance of the wound and, clinically, of the patient. However, we noticed a large amount of purulent secretion coming out of the anterior leg compartment and decided to perform fasciotomy. As a result, we were able to evaluate all the compartments of the leg and debride the devitalized tissues, further increasing the bone exposure of the tibia, tendons, and muscle. Therefore, we learned that the greater the debridement and removal of tissues, the greater the contact area of the vacuum dressing foam, which enhances the suction of accumulated secretions and stimulation of granulation tissue. In addition, it is important to fill all compartments with foam because when turning on the negative pressure, dead space can be left without drainage and accumulation of secretions. On very extensive wounds, it is advisable to use the Y-connector to help redistribute forces from the vacuum dressing and potentiate secretion suction.

Changing the vacuum dressing every 3 or 4 days prevents maceration of the edges, degradation of the foam, and possible devitalized necrotic tissues. The experience with elastic suture in this case provided approximation of the edges and reduction of the graft area of the dermis and epidermis, reduced costs for the health operator, and improved aesthetics (Table 2).

| Table 1. Patient treatment timeline. |
|-------------------------------------|
| HS 0 | HS 3 | HS 4 a HS 70 | HS 71 | HS 93 | After 5 months |
| -Debridement. | -First dressing change. | -Changes every 3 or 4 days. | -Dermal matrix and epidermis implant. | -Hospital discharge. | -Graft in excellent appearance. |
| -Implant of the vacuum dressing. | -Less amount of purulent secretion. | -Elastic suture. | -Absence of purulent secretion. | -Preserved motricity and discreet echinovaro foot. |
| -Multidisciplinary assessment. | -Presence of granulation tissue. | -Absence of purulent secretion. | -Complete coverage of granulation tissue. |

HS: hospital stay.

Figure 5. (a) and (b) After 5 months of the graft, the two areas where there was tissue loss recover adequately with a gradual reduction in size.
A meta-analysis of eight studies, including 669 patients, showed that negative pressure therapy resulted in shorter healing time, greater reduction in the ulcer area and a higher rate of ulcer healing. Patients undergoing NPWT also had significantly fewer major amputations.

A randomized, multicenter controlled clinical trial was developed to assess the role of NPWT in the treatment of diabetic foot wounds after partial amputation to the transmetatarsal level. In total, 162 patients were enrolled and randomly assigned to NPWT or postoperative wet wound therapy. The results revealed that more NPWT patients healed, with a reduction in the healing time and a faster formation of granulation tissue.

Another multicenter randomized controlled study involved 342 patients. A greater proportion of foot ulcers achieved complete ulcer closure with NPWT than with advanced moist wound therapy (AMWT). The median Kaplan–Meier estimate for 100% ulcer closure was 96 days for NPWT and not determinable for AMWT. NPWT patients had significantly fewer secondary amputations. In the safety assessment, no significant difference was observed between the groups in terms of treatment-related complications, such as infection, cellulitis, and osteomyelitis at 6 months.

Raskin et al., in 1993, described the method of elastic suture using sterile rubber bands, avoiding tension closures, or the need for skin grafts to cover wounds left open. The technique of elastic suture is the approximation of the opposite edges of the wound by means of circular elastic rubber bands. The technique consists of a suture encompassing the elastic and one of the vertices of the wound with a 2–0 silk thread; the elastic is pulled and folded over itself to form an “X,” and each side is fixed with stitches to the edges of the wound, until the other vertex is reached. Care must be taken not to pull the elastic too much in order to avoid excessive tension on the skin, even if there are exposed areas. With each change, the elastic is pulled further, in order to stimulate the approximation of the edges.

**Conclusion**

Diabetic foot ulcers require a multidisciplinary approach and are difficult to treat. Negative pressure therapy is useful and should be considered in order to reduce limb amputation rates.

**Author contributions**

All authors contributed to the study design, contribution to the surgery, data acquisition, data analysis, drafting of article, and critical revision of the article.

**Consent for publication**

Informed consent has been obtained from the patient for publication of the case report and accompanying images. Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article.

**Declaration of conflicting interests**

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

**Ethical approval**

For this type of study formal consent is not required. Our institution does not require ethical approval for reporting individual cases or case series.

**Funding**

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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**References**

1. Abbott CA, Carrington AL, Ashe H, et al. The North-West Diabetes Foot Care Study: incidence of, and risk factors for,
new diabetic foot ulceration in a community-based patient cohort. *Diabet Med* 2002; 19(5): 377–384.

2. Mills JL Sr, Conte MS, Armstrong DG, et al. The society for vascular surgery lower extremity threatened limb classification system: risk stratification based on Wound, Ischemia, and foot Infection (WIFI). *J Vasc Surg* 2014; 59(1): 220–234.

3. Saxena V, Hwang CW, Huang S, et al. Vacuum-assisted closure: microdeformations of wounds and cell proliferation. *Plast Reconstr Surg* 2004; 114(5): 1086–1096.

4. Chariker ME, Jeter KF, Tintle TE, et al. Effective management of incisional and cutaneous fistulae with closed suction wound drainage. *Contemp Surg* 1989; 34: 59–63.

5. Fleischmann W, Strecker W, Bombelli M, et al. Vacuum sealing as treatment of soft tissue damage in open fractures. *Unfallchirurg* 1993; 96(9): 488–492.

6. Penny HL, Dyson M, Spinazzola J, et al. The use of negative-pressure wound therapy with bio-dome dressing technology in the treatment of complex diabetic wounds. *Adv Skin Wound Care* 2010; 23(7): 305–312.

7. Zhang J, Hu ZC, Chen D, et al. Effectiveness and safety of negative-pressure wound therapy for diabetic foot ulcers: a meta-analysis. *Plast Reconstr Surg* 2014; 134(1): 141–151.

8. Armstrong DG and Lavery LA; Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. *Lancet* 2005; 366(9498): 1704–1710.

9. Blume PA, Walters J, Payne W, et al. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. *Diabet Care* 2008; 31(4): 631–636.

10. Raskin KB. Acute vascular injuries of the upper extremity. *Hand Clin* 1993; 9(1): 115–130.