



NEGATIVE PRESSURE WOUND THERAPY FOR NON-HEALING FOOT ULCERS: A CASE SERIES OF 8 CASES

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ABSTRACT:

Background: Addressing non-healing foot ulcers has become clinical concern, necessitating effective prevention and treatment strategies. NPWT is a comprehensive treatment of non-healing foot ulcers.

Objectives: To study the clinical efficacy of NPWT regarding granulation and post-operative recovery in treating non-healing foot ulcers of various etiologies.

Methodology: Case series of 8 cases of non-healing foot ulcers of various etiologies were taken. After admission, application of NPWT was done and outcomes assessed after 3 weeks.

Results: Out of 8 cases, one case was 12 years old, two belong to age group 21 to 40 years (21 years and 38 years), three belong to 41 to 60 age group (51, 53 and 57 years) and remaining two were aged >60 years (61 and 69 years). 6 patients were males and 2 were females. Three cases were of post-traumatic (post-road traffic accident crushed injury) with non-healing ulcer on left lateral foot and left leg, two cases had non-healing Diabetic Ulcer over dorsal left foot and right Heel, two cases had necrotizing fasciitis with cellulitis on left dorsum of foot with non-healing ulcer and one case presented with vegetative non-healing ulcer over left leg. All the cases were admitted and underwent wound cleaning and debridement. Negative Pressure wound Therapy was applied for a period of 3 weeks and granulation was achieved. Harvesting done and Skin graft was applied on affected area and after 3 weeks wound was assessed. The graft was taken successfully and further management was un-eventful. Wound was found to be healing and healthy in all eight cases.

Conclusion: NPWT is an effective and safe treatment to treat non-healing ulcers of different aetiologies which makes it possible for maximum granulation of a wound in a shorter time. It promotes and accelerates the healing process with few or no complications.

Key Words: Negative Pressure Wound Therapy, Non-Healing Foot Ulcers, Diabetes, Crush Injury, Skin Graft.

INTRODUCTION:

Damage to the epidermis, or outermost layer of skin, and the ensuing loss of underlying tissue can result in the formation of an ulcer. The International Consensus on the Diabetic Foot defines a foot ulcer as a wound that penetrates the entire thickness of the skin below the ankle⁽¹⁾. 15% or more of DM patients are said to have experienced foot ulcers at some point in their lives⁽²⁾. Foot ulcers in diabetic patients significantly lower their quality of life related to their health, especially when it comes to their ability to operate physically and their ability to fulfill their roles because of emotional and physical problems⁽³⁾. Amputation may be necessary if ulcers cannot heal, and individuals with diabetes mellitus have a 10- to 20-fold increased chance of losing a lower limb, or a portion of a lower limb, due to non-traumatic amputation⁽⁴⁾.

Addressing non-healing foot ulcers has become a pressing clinical concern, necessitating effective prevention and treatment strategies. The comprehensive treatment of non-healing foot ulcers demands a multidisciplinary approach involving surgical debridement, vascular recanalization, decompression treatment, blood glucose control, and supportive care. Crucially, controlling wound infection and fostering tissue repair are pivotal in preventing amputation or mitigating its extent⁽⁵⁾. Negative pressure wound therapy (NPWT), introduced by German physician Fleischmann in 1993, has emerged as a valuable intervention, recognized for its effectiveness in improving wound drainage, enhancing perfusion, and promoting granulation tissue growth⁽⁶⁾.

In 2016, the Wound Healing Society of the United States recommended NPWT for diabetic foot ulcers, emphasizing its role in reducing edema, eliminating bacterial products, and facilitating wound edge approximation⁽⁷⁾. Similarly, the European Wound Management Association reported in 2017 that NPWT accelerates diabetic foot ulcer healing by promoting granulation tissue proliferation⁽⁸⁾. The International Working Group on the Diabetic Foot endorsed NPWT for ulcer healing in its 2019 international guidelines on diabetic foot management⁽⁹⁾. Despite NPWT's three-decade development, rapid advancements in research and clinical applications have occurred, particularly in diabetic foot wound management. In the present case series, we presented 8 cases of non-healing foot ulcers of various etiologies who underwent NPWT and outcomes of the therapy was assessed.

METHODOLOGY:

In the present case series, 8 cases of non-healing foot ulcers of various etiologies were taken. Their history was taken in detail and local examination was carried out. This was followed by application of Negative Pressure wound Therapy. After three weeks, the outcome of the therapy was assessed in all eight patients of non-healing foot ulcers.

Equipment required for Negative Pressure Wound Therapy:

1. Alcoholic chlorhexidine (2% chlorhexidine in 70% isopropyl alcohol) or betadine (7.5% povidone-iodine) preparation
2. Sterile drapes, Sterile gauze

3. Sterile small fragment orthopedic surgical instrument tray OR sterile standard wound care surgical instrument tray
4. 0.9% sodium chloride x 3 to 6 liters
5. Non-paraffinized, coated polyester net
6. NPWT pack:
 - a) Specialized negative pressure adhesive dressing (closed wounds)
 - b) Specialized pre-cut or unprepared foam dressing (open wounds)
 - c) Transparent adhesive sealant tape
 - d) NPWT suction device

Preparation of the Patient:

Closed wounds can be managed inside or outside of the OR, depending on the nature of the wound. In either case, the equipment is prepared in a sterile field. The wound site is cleaned with an alcoholic chlorhexidine preparation (if not already surgically prepared in the OR) and allowed to air dry before applying the NPWT dressing. Open wounds require admittance to the OR for initial management and therefore necessitate the pre-operative completion of a written consent form along with patient safety checklists. The consent process should include a discussion about the indications, benefits, and risks of the procedure, with an assurance to tailor each risk to the individual patient in accordance with the Montgomery principles of consent. The equipment is prepared in a sterile field in the OR by the surgical scrub nurse.

The open wound is first sterilized using alcoholic chlorhexidine and then surrounded by a sterile field using sterile drapes as per standard surgical preparation protocols. Once a sterile field has been established, the wound bed itself requires careful preparation before applying the VAC device. This is because any necrotic or infected tissue which remains will impair wound healing through the compromised blood supply and colonization of bacteria.

Thorough debridement of infected or necrotic tissue should be carried out (only indicated at the first application of the VAC device unless further necrosis is identified), followed by a washout of the wound with a copious volume of 0.9% sodium chloride. Following wound bed preparation, the wound should be dried with sterile gauze and protected with a sterile, atraumatic, non-adhesive wound contact layer. Current practice favors a non-paraffinized, coated polyester net.

Technique or Treatment:

The patient should be positioned to suitably expose their wound site and the area may be draped off. Closed wounds are covered with a specialized adhesive dressing, the edges of which are reinforced with wide strips of transparent adhesive sealant tape to create a firm, airtight seal around the dressing. This is the single most essential part of any of the NPWT, as, without an adequate seal, the sub-atmospheric pressure cannot be achieved, and therapy will not be delivered.

Open wounds are covered with a specialized porous foam dressing, which is cut by hand to the exact dimensions of the wound unless it is available in a pre-cut formulation. The foam dressing must cover the whole wound, ideally in a single piece; if the wound is too large, multiple pieces may be utilized to gain adequate coverage. It is essential to document the number of pieces utilized, as this is important for when the dressing is changed to avoid retaining any pieces of foam inside the wound bed.

The foam dressing is covered in turn by large strips of transparent adhesive sealant tape to create a firm, airtight seal around the foam dressing. Depending on the VAC system to hand, a suction drain tube is either placed over the foam dressing before applying the transparent adhesive sealant tape or applied as part of a separate adhesive dressing that is placed on top of the transparent adhesive sealant tape. Upon completion of the wound dressing, the NPWT suction device should be connected to the suction drain tube to test successful therapy delivery, which is indicated by an electronic signal on the suction device.



Fig 1. Negative Pressure Wound Therapy suction device

RESULTS:

Out of 8 cases non-healing foot ulcers, one was of age 12 years, two belong to 21 to 40 years age (21 years and 38 years), three belong to 41 to 60 age group (51, 53 and 57 years) and remaining two were aged >60 years (61 and 69 years). 6 patients were males and 2 were females.

Three cases were of post-traumatic (post-road traffic accident) crushed injury with non-healing ulcer on left lateral foot and left leg, two cases had non-healing Diabetic Ulcer over dorsal left foot and right Heel, two cases had necrotizing fasciitis with cellulitis on left dorsum of foot with non-healing ulcer and one case presented with vegetative non-healing ulcer over left leg. Two cases were known case of diabetes, one with type II DM and other with type 1 DM. one case was known case of Hypertension since 12 years, on Tab Met XL 12.5mg OD

Following history, all the cases were admitted in the wards under surgical department and details examination was done. All the cases underwent wound cleaning and debridement. Antibiotics were started in all patients and blood sugar levels were controlled in both diabetic patients.

Later when all patients were stabilized, Negative Pressure wound Therapy was applied for a period of 3 weeks and granulation was achieved. Harvesting done and Skin graft was applied on affected area and after 3 weeks wound was assessed. The graft was taken successfully and further management was un-eventful. Wound was found to be healing and healthy in all eight cases.



Before Therapy

After Therapy

Case 1. 69-year female patient with Dorsal left foot non-healing Diabetic Ulcer



Before Therapy

After Therapy

Case 2. 61-year male patient with vegetative non-healing ulcer over left leg



Before Therapy

After Therapy

Case 3. 57-year male patient with post-traumatic infected non-healing ulcer



Before Therapy

After Therapy

Case 4. 21-year female patient with post RTA left leg crushed injury and exposed tendons



Before Therapy

After Therapy

Case 5. 53-year male with necrotizing fasciitis with non-healing ulcer on left dorsum of foot



Before Therapy

After Therapy

Case 6. 38-year male patient with traumatic non-healing ulcer on left lateral foot



Before Therapy

After Therapy

Case 7. A 51-year male patient with necrotizing fasciitis with cellulitis on left dorsum of foot.

**Before Therapy****After Therapy**

Case 8. 12-year male patient with Right Heel Diabetic non-healing Ulcer (Type-I DM)

DISCUSSION:

NPWT is a non-invasive therapy system that removes fluid from open wounds using a sealed dressing or a foam dressing coupled to a collection container utilizing sub-atmospheric pressure. The regulated negative pressure created by the vacuum device is used to promote wound healing⁽¹⁰⁾. The filler material (foam vs. nonadherent antimicrobial gauze), the connecting suction catheter (integrated with pressure sensor vs. flat drain), and the intensity of negative pressure (ranging from 50 to 200 mmHg) intermittently or continuously are some of the differences between the various systems⁽¹¹⁾.

In this case series, we have covered eight instances of non-healing foot ulcers with different causes. We find that the NPWT is extremely effective in treating these wounds because it can reduce the granulation time by up to 40%. It seems that NPWT is no less safe than conventional treatments in terms of side effects, re-amputations, and surgical asepsis.

Nowadays, wound closure is widely recognized and considered to be facilitated by keeping a humid environment⁽¹²⁾. But it seems that keeping the wound moist enough isn't enough; other things need to happen to help the healing process along. Consequently, several advanced pharmacological medicines and alternate wound-care methods have been developed⁽¹³⁾. But many of these have dubious scientific backing and are associated with increased costs⁽¹⁴⁾. The NPWT is integrated into these therapies and new technologies in response to the need to treat chronic wounds and those that present closure issues⁽¹⁵⁾. The NPWT is increasingly becoming accepted globally for the care and treatment of all types of wounds, in contrast to alternative therapies⁽¹⁶⁾.

Argenta and Morykwas's research⁽¹⁷⁾ offers an explanation for the NPWT's efficacy. According to their proposal, this innovative approach to treatment reduces bacterial colonization, gets rid of excess interstitial liquid, encourages angiogenesis, and speeds up the development of granulated tissues in response to the mechanical forces generated by the negative pressure that passes through the sponge. Other authors have confirmed these views⁽¹⁸⁾. Moreover, it has long been postulated that the components of excess liquid may act as chemical and physical barriers to the wound's ability to heal if it is not adequately removed from the incision during surgery⁽¹⁹⁾.

Since the central suctioning system generates the negative pressure required for the device, patients getting this treatment must be hospitalized to the hospital. This can result in an extended hospital stay. Unlike other projects that use an industrially constructed device to deliver the negative suction system^(14,16), this project uses components that are widely available in any community hospital and that match the functional standards and specifications⁽²⁰⁾. It is clear that the materials used in this investigation are less expensive than those needed when using industrial equipment, even though a cost evaluation is missing. Furthermore, studies investigating the relationship between cost-effectiveness and the suctioning system are known to exist^(21,22).

Data indicate that the NPWT can be used as a stand-in therapy for the main closure by second intention or as a substitute treatment for the secondary closure with other techniques provided a sufficient granular wound bed is created⁽²³⁾. All of the patients in this trial who had non-healing foot ulcers received NPWT, which sped up the healing process.

CONCLUSION:

We concluded that the Negative Pressure Wound Therapy is an effective and safe treatment to treat non-healing ulcers of different aetiologies. The treatment with NPWT makes it possible for maximum granulation of a wound in a shorter time. It promotes and accelerates the healing process with few or no complications. Furthermore, this method creates an appropriate wound bed for a possible application of skin graft and flap surgery.

Although excellent results are documented with the use of NPWT, further studies are needed on the cost-effective relationship as well as on the quality of life. Also, there is need to better define its optimal pressure level and the use of intermittent or continuous pressure.

REFERENCES:

1. Apelqvist J, Bakker K, Van Houtum WH, Nabuurs-Franssen MH, Schaper NC. International consensus and practical guidelines on the management and the prevention of the diabetic foot. *Diabetes/metabolism research and reviews*. 2000 Sep;16(S1):S84-92.
2. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA* 2005;293(2):217-28.
3. Ribu L, Hanestad BR, Moum T, Birkeland K, Rustoen T. A comparison of the health-related quality of life in patients with diabetic foot ulcers, with a diabetes group and a non-diabetes group from the general population. *Quality of Life Research* 2007;16(2):179-89.
4. Wrobel JS, Mayfield JA, Reiber GE. Geographic variation of lower limb extremity major amputation in individuals with and without diabetes in the Medicare population. *Diabetes Care* 2001;24(5):860-4.
5. Everett E, Mathioudakis N. Update on management of diabetic foot ulcers. *AnnNYAcad Sci*. 2018 Jan;1411(1):153–65.DOI: 10.1111/nyas.13569.

6. Bakker K, Apelqvist J, Lipsky BA, Van Netten JJ. International Working Group on the Diabetic Foot. The guidance documents on prevention and management of foot problems in diabetes: development of an evidence-based global consensus 2015 IWGDF. *Diabetes Metab Res Rev*. 2016 Jan;32(Suppl 1):2–6.
7. Lavery LA, Davis KE, Berriman SJ, Braun L, Nichols A, Kim PJ, et al. WHS guidelines update: Diabetic foot ulcer treatment guide lines. *Wound Repair Regen*. 2016 JanFeb;24(1):112–26.
8. Apelqvist J, Willy C, Fagerdahl AM, Fraccalvieri M, Malmsjö M, Piaggese A, et al. EWMA Document: Negative Pressure Wound Therapy. *JWound Care*. 2017 Mar 1;26(Sup3):S1–154.
9. Schaper NC, van Netten JJ, Apelqvist J, Bus SA, Hinchliffe RJ, Lipsky BA, et al. Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update). *Diabetes Metab Res Rev*. 2020;36(Suppl 1):e3266. doi: 10.1002/dmrr.3266.
10. Nain PS, Uppal SK, Garg R, Bajaj K, Garg S. Role of negative pressure wound therapy in healing of diabetic foot ulcers. *J Surg Tech Case Rep* 2011; 3: 17-22
11. Center EE. BP-negative pressure wound therapy device. Technology assessment report. Prepared Agency Health c Res Qual (AHRQ). Contract No. 290-2007-10063. Project ID: WNDR1108. Rockville, MD: AHRQ, March 30, 2009
12. Olsen S, Nolan MF, Kori S. Pain measurement. An overview of two commonly used methods. *Anesthesiol Rev*. 1992;19:11–5.
13. Banwell PE. Topical negative pressure therapy in wound care. *J Wound Care*. 1999;8:79–84.
14. Eginton MT, Brown KR, Seabrook GR, Towne JB, Cambria RA. A prospective randomized evaluation of negative-pressure wound dressings for diabetic foot wounds. *Ann Vasc Surg*. 2003;17:645–9.
15. Fleischmann W, Strecker W, Bombelli M, Kinzl L. Vacuum sealing as treatment of soft tissue damage in open fractures. *Unfallchirurg*. 1993;96:488–92.
16. McCallon SK, Knight CA, Valiulus JP, Cunningham MW, McCulloch JM, Farinas LP et al. Vacuum-assisted closure versus saline-moistened gauze in the healing of postoperative diabetic foot wounds. *Ostomy Wound Manage*. 2000;46: 28–32. 4.
17. Argenta LC, Morykwas MJ. Vacuum-assisted closure: A new method for wound control and treatment: Clinical experience. *Ann Plast Surg*. 1997;38:563–76 discussion 77.
18. FAY, Margaret F. Drainage systems. Their role in wound healing. *Aorn Journal*, 1987, 46.3: 442-455.
19. Blume PA, Walters J, Payne W, Ayala J, Lantis J. 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. *Diabetes Care*. 2008;31:631–6.
20. Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W. Vacuum-assisted closure: A new method for wound control and treatment: Animal studies and basic foundation. *Ann Plast Surg*. 1997;38:553–62.

21. Philbeck Jr TE, Whittington KT, Millsap MH, Briones RB, Wight DG, Schroeder WJ et al. The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare medicare patients. *Ostomy Wound Manage.* 1999;45:41–50.
22. Braakenburg A, Obdeijn MC, Feitz R, van Rooij IA, van Griethuysen AJ, Klinkenbijnl JH et al. The clinical efficacy and cost effectiveness of the vacuum-assisted closure technique in the management of acute and chronic wounds: A randomized controlled trial. *Plast Reconstr Surg.* 2006;118:390–7 discussion 8-400.
23. Armstrong DG, Lavery LA. Negative pressure wound therapy after partial diabetic foot amputation: A multicentre, randomized controlled trial. *Lancet.* 2005;366:1704–10.

