Negative pressure wound therapy for treating diabetic foot ulcers

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Article points

1. The author highlights areas to consider when using negative pressure wound therapy (NPWT) on diabetic foot ulcers.
2. Clinicians should be aware of the risks and contraindications.
3. The article includes practical advice when applying NPWT.

Key words

- Diabetic foot ulcer
- Multidisciplinary team
- Negative Pressure Wound Therapy
- Surgical debridement

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Negative pressure wound therapy (NPWT) has become more mainstream over the past 20 years and healthcare professionals are more likely than ever before to care for patients with this intervention, as an alternative to standard wound dressings. It can be used as part of the overall care package for diabetic foot ulcer (DFU) patients where the wound bed is prepared appropriately and the foot care team are supporting. NPWT has a number of benefits including increased perfusion, reduction of oedema and increased granulation tissue formation. The risks and contraindications should also be understood when caring for a patient where NPWT is considered. This article provides an overview of the benefits, risks and contraindications, as well as practical considerations for the DFU.

Diabetic foot ulcers (DFUs) have a significant detrimental effect on healthcare and society. Guest et al (2018) estimated that the mean cost of wound care to the National Health Service (NHS) over 12 months was £7,800 per DFU, with the highest costs associated with amputations. As would be expected, a healed wound was associated with the lowest cost (Guest et al, 2018). Patients with DFUs require more hospital days, healthcare at home, emergency department visits and outpatient appointments (Rice et al, 2014).

Negative pressure wound therapy (NPWT), also known as topical negative pressure (TNP) and vacuum-assisted closure (VAC), has become increasingly used for treating a variety of wound types (Hunter et al, 2007; Apelqvist et al, 2017). Initially developed for the treatment of chronic wounds (Argenta et al, 2006), it has also become popular for acute wounds, including traumatic wounds, surgical wounds for delayed closure, surgical wounds intended to heal by secondary intention and dehisced wounds. The National Institute of Clinical Excellence (NICE, 2019) recommend considering NPWT after surgical debridement for DFUs when advised by the multidisciplinary foot care service. The author has noted an increase over recent years in the number of patients being discharged from hospital with this intervention in place.

Reported benefits of NPWT include increased blood supply, angiogenesis, increased granulation tissue formation, bacterial clearance, and reduction of oedema. Some adverse effects have also been reported, including fistula formation, bacterial colonisation, and overgrowth of granulation tissue. Since this is a medical device, a thorough understanding of the system is required before proceeding with application and care of a patient with NPWT in place. It is essential to refresh knowledge periodically to ensure awareness of any new developments or understanding and maintain competencies.

The NPWT system

NPWT consists of a dressing, tubing and a suction pump. The dressing may be an open pore foam or

antimicrobial gauze fitted to the wound, covered with a semi-permeable adhesive film and attached to a pump providing subatmospheric pressure via a tube (Banwell and Téot, 2006; Hunter et al, 2007) (*Figure 1*). The nature of the dressing provides a seal, converting an open wound into a closed one (Argenta and Morykwas, 1997), and the size of the suction pump now varies from something that fits on the wearer's belt, to a larger device that can be carried by the patient or attached to the patient's bed. Various modifications have been developed that also allow the instillation of irrigation fluid to meet the demands of more complex wound issues, such as infection. There are also now dressings designed for incision sites and shallower wounds, with single patient use disposable pumps, such as PICO™, Avelle™ and V.A.C.VIA™. These have the advantage of being easier for self or shared care and are more aesthetically acceptable, and generally allow activities of daily living to be better managed.

Mechanisms of action

NPWT is understood to increase healing rates by enhancing blood flow, reducing oedema, increasing granulation tissue formation, wound retraction, aiding removal of exudate and biochemical reduction of the concentration of proteases, known to impair healing (Morykwas et al, 2001; Saxena et al, 2004; Apelqvist et al, 2017),

Morykwas and Argenta (1997) identified enhanced blood flow caused by the application of suction (negative pressure) to be the reason for increased perfusion to the wound. However, since then, advances in understanding mechanism of action have demonstrated that the removal of interstitial fluid leads to an overall reduction of oedema, which in turn is now accepted to cause the improved nutritive blood flow to the area (Apelqvist et al, 2017).

The negative pressure applied to the wound pulls the edges together and allows wound retraction (Apelqvist et al, 2017). This mechanism helps to 'splint' a wound to allow healing and better support for surrounding structures and, as oedema reduces, retraction will increase.

Morykwas et al (2001) suggested the increase in granulation tissue observed in the wound bed could be due to increased cellular proliferation and angiogenesis stimulated by the NPWT. A

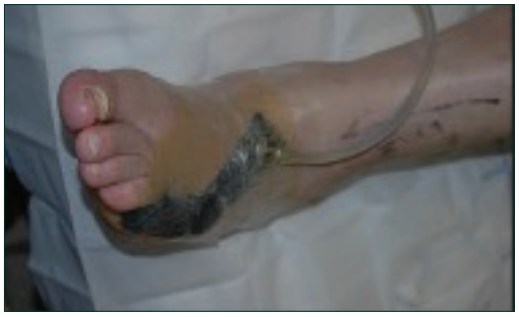

Figure 1. An example of NPWT using open pore foam fitted to the wound.

systematic review and meta-analysis of five studies by Liu et al (2017) on NPWT for DFUs identified a shorter time to achieve over 90% granulation tissue in DFUs, compared with those treated with moist dressings. These results supported an earlier systematic review of four studies by Guffanti (2014), although the reviews only included two identical studies. The presence of increased granulation tissue leads to wounds getting smaller, as the granulation fills the cavity.

Early work suggested that NPWT aids bacterial clearance in wounds (Morykwas et al, 1997; Mouës et al, 2004). A more recent study has identified significantly less Escherichia coli (P<0.0001) and gram negative (P=0.0003) growth in patients with DFUs where NPWT was used, compared with DFUs where conventional dressings were used (James et al, 2019). The sealed nature of NPWT reduces the risk of the transfer of infection from the patient to others, for example in methicillin-resistant *Staphylococcus aureus* (MRSA)-positive patients (Apelqvist et al, 2017). The development of NPWT with instillation allows antibiotics or antiseptics to be applied directly to an infected wound with the dressing in place. There is, as yet, a lack of evidence about how effective this is in practice and whether the system would reduce the need for systemic antimicrobials (Apelqvist et al, 2017).

Risks and contraindications

Argenta and Morykwas (1997) reported the potential for pressure damage to local tissue if the tubing is not carefully positioned, excessive growth of granulation tissue into the foam if the dressing is left for over 48 hours, and the possibility of fistula development and haemorrhage if NPWT is placed

Table 1. Contraindications of NPWT (Smith and Nephew, 2009; KCI, 2014; Apelqvist et al, 2017).

NPWT use should be avoided in patients with:

- Untreated osteomyelitis
- Malignancy (except palliative care or following tumour removal if the tissue margins are disease-free. There are cases where a medical risk assessment and patient choice may lead to NPWT use in malignancy, for example, to establish a hygienic and comfortable way of managing the wound)
- Exposed arteries, veins or organs and vascular anastomoses
- Severe peripheral arterial disease (usually an ankle brachial pressure index [ABPI] < 0.5)
- Unexplored fistulae
- Any cavity/sinus of which the origin is not visible or cannot be probed to indicate origin
- Necrotic tissue with eschar or dry wounds
- Clotting disorders

over-compromised intestine. However, these are reportedly either avoidable or manageable and guidelines for application consider these concerns, including gaining medical agreement and support on a patient-by-patient basis when considering contraindicated application.

A meta-analysis by Liu et al (2017) on DFUs concluded that NPWT neither increased nor decreased the incidence of treatment-related side effects, as compared with the standard dressing change group, but they did highlight that the US Food and Drug Administration cited 12 deaths and 174 injuries associated with NPWT between 2007 and 2011. These deaths were not for any one patient group or wound type and no information was given about why the patient had the device, what type of NPWT was in use or whether they were in the community or acute care when they died. Guffanti (2014) also identified no increased incidence of adverse events in the studies reviewed on NPWT for DFUs although randomised controlled trials (RCTs) often involve patients being more closely monitored by more experienced clinicians than might usually be the case (Liu et al, 2017). Contraindications advised typically include those listed in *Table 1*.

Although NPWT is thought to help with bacterial clearance, there have been reports of increased bacterial colonisation in some patients. Chester and Waters (2002) suggest that the sealed environment created by the NPWT dressing could potentiate an anaerobic infection. Hampson and Ridgway (2005) advised administration of prophylactic antibiotics in susceptible individuals and osteomyelitis must be addressed as it is a contraindication, usually with removal of infected tissue, before application of NPWT (Apelqvist et al, 2017).

NPWT for diabetic foot ulcers

Guffanti (2014) systematically reviewed four studies that investigated NPWT for DFUs. In all four trials, wounds were surgically debrided prior to the application of either NPWT or standard wound dressings. Results suggest that NPWT reduces healing time and may reduce the incidence of infection. One trial reported significantly fewer secondary amputations for patients who received NPWT (Blume et al, 2008). They went on to stress the importance of using NPWT as an adjunctive treatment alongside the usual standard elements of care in this group, including optimising glycaemic control and offloading pressure from affected foot.

In their meta-analysis evaluating NPWT for DFUs, Liu et al (2017) appraised 11 studies, identifying a high chance of bias in all but one (Sepúlveda et al, 2009). They found that the NPWT group in the meta-analysis had a shorter time to healing and concluded that the evidence supports the use of NPWT for DFUs and surgical wounds in people with diabetes. One study (Karatepe et al, 2011) evaluated health-related quality of life and observed a positive effect of NPWT, although this did not look at the smaller single use pumps, which may improve quality of life as they are easier to manage, allow better mobilisation and are often quieter.

Cochrane published a review concluding there is low-certainty evidence that NPWT, when compared with standard wound dressings, may increase the number of wounds healed and may increase healing rate for postoperative foot ulcers in people with

diabetes (Liu et al, 2018). They reviewed 11 RCTs and concluded that further trials are required to reduce uncertainty. None of the trials reviewed investigated cost-effectiveness or health-related quality of life, important factors for the patient, their family and the healthcare system. RCTs are not only difficult to set up and complete, but they are not always applicable to practice. Much of the evidence in this field is derived from case reports, supported by evidence demonstrating mechanisms of action. While useful, Cochrane reports should be considered alongside other sources of evidence and guidelines, such as NICE.

NICE guidance originally issued in 2015 and updated in 2019 recommends that NPWT should be considered for DFUs following surgical debridement, if advised by the multidisciplinary foot care service (NICE, 2019). This was a change to earlier guidelines where lack of robust evidence led to the intervention not being recommended, a decision that had raised concern (Yarwood-Ross, 2012).

Adequate nutrition, optimising diabetic control and offloading remain important for these patients as NPWT forms just one part of the care package. Some patients may struggle with aspects of the intervention, such as any noise, the risk of it alarming in a public place, and the appearance of the pump (self-conscious if pump is visible). However, reduced frequency of dressing changes and little risk of wound leakage usually results in patients accepting NPWT, following discussion of the risks and benefits. In the author's experience of DFUs and NPWT, patients are keen to agree to anything that may help the wound heal and avoid hospital stays and surgery.

Apelqvist et al (2017) discuss quality of life and stress for patients with NPWT, stating that in many studies patients report lower quality of life and higher levels of stress while NPWT is in use. Conversely, Liu et al (2017) reported improved quality of life for DFU patients receiving NPWT using the short form 36 (SF-36) (Sun and Sun, 2007), and another showed a positive effect on patients' mental and physical health in comparison with conventional dressings, assessed using the SF-36 (Karatepe et al, 2011). Liu et al (2018) stated that no evidence was available on health-related quality of life or cost-effectiveness for the Cochrane review.

Practical application and care

Guidance regarding appropriate patient selection and the practicalities of applying NPWT is readily available from companies supplying the system, locally in Trust procedures and internationally, for example, in European publications (Apelqvist et al, 2017). The following practicalities must be considered:

- Multidisciplinary team input
  - Involvement from the foot care team at an early stage (NICE, 2019)
  - Specialist input where appropriate including revascularisation if required
  - Review of patient medication, particularly to ascertain the use of any anticoagulants, including aspirin.
- Debridement
  - Negative pressure effects will not be achieved effectively if the wound is covered with slough or necrotic tissue, hence the need for surgical debridement.
- Competencies of those applying and changing the medical device
  - Competent in assessing, taking medical history; diagnosis and whether to apply NPWT
  - Competent in deciding which method best suits patient needs, reassess (by whom and when).
- Patient education
  - Patients on anticoagulants may need extra support in observing for change in exudate colour and what action to take if it becomes pink or red
  - Foot checks required to ensure no pressure damage, particularly in neuropathic feet.
- Consider contraindications listed in earlier section
  - Exposed vessels or organs should be adequately protected prior to application of the foam or gauze
  - Risk assess to decide whether lining the wound with a contact layer prior to the application of the foam is appropriate, as this may lead to slower progression to healing
  - Discuss with multidisciplinary team any other contraindications and whether to proceed and

what precautions to put in place.

- Magnetic resonance imaging (MRI) and hyperbaric oxygen therapy are not a contraindication to use but the pump should be deactivated and removed from that environment prior to treatment. The dressings can be left *in situ*.
- Regular review
  - Regularly reviewing the need for NPWT will ensure treatment can progress as appropriate, helping to continue cost-effective care.

The foam/gauze should not come into contact with skin, to reduce the risk of damage to healthy skin from the negative pressure. The skin should be clean and dry, with no creams or emollients on to ensure a good seal. It is possible to apply NPWT anywhere on the foot with a good seal and tracking the tubing away from any areas at risk of pressure damage (Doxford, 2007). However, achieving a seal around the toes can often be a challenge, and caution should be taken not to be overzealous with the adhesive film around vulnerable digits to avoid damage and any tourniquet effect.

Optimum pressure applied is -125 mmHg for foam dressings (KCI, 2014) and -80 mmHg for gauze (Smith and Nephew, 2009), but an alternative pressure may be selected for comfort reasons, for example. There may be a risk of the intervention being less effective at lower pressures. European Wound Management Association (EWMA) advise special attention to the pressure level in DFUs, especially when there is a risk of ischaemia (Apelqvist et al, 2017), although ideally any ischaemia will have been addressed prior to application.

Dressing changes usually occur every 48 to 72 hours, but local guidelines should be followed and patient requirements taken into consideration. Single-use NPWT devices, such as PICO, can be left in place for up to 1 week. It is possible to train the patient or carer to change their own dressings, but this is more common with disposable pumps on shallower wounds.

Conclusion

NPWT can be an effective adjunctive for DFUs when used appropriately and with effective wound bed preparation. The benefits of the therapy are well reported in the literature and although evidence from RCTs remains limited, NPWT continues to be consistently and widely used, including in DFUs.

Applying NPWT to a DFU can result in faster growth of granulation tissue and decreased healing time. Healthcare professionals must be trained in application and need to remain mindful of potential risks and contraindications, following up-to-date guidelines. Support from companies providing NPWT devices is useful and shared care may be appropriate in some scenarios. The potential harms reported from NPWT application are largely avoidable if recommendations are followed.

Further information and studies evaluating any differences in outcome between foam and gauze NPWT would be beneficial. Most of the current work has involved foam dressings, but in practice gauze dressings are becoming more popular.

Unfortunately, there remains a paucity of evidence on the patient perspective of NPWT, particularly for the diabetic foot, and more studies are needed on the effect of NPWT on patients' quality of life and concordance. Longer-term follow up on DFU patients who have had NPWT would also be useful along with more information on the cost-effectiveness of the intervention for this patient group. ■

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