# NICE guidance update supports use of negative pressure wound therapy for the diabetic foot

*Graham Bowen*

**Over recent years, there has been an increase in the use of negative pressure wound therapy (NPWT) for the treatment of diabetic foot ulceration, predominantly as part of the inpatient management process. Now, for the first time, NPWT has been included within the National Institute for Health and Care Excellence diabetic foot problems guidance, as outlined by the statement 'consider negative pressure wound therapy after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service'. The following article explores the evidence base, clinical indications and benefits of NPWT, specifically looking at how PICO◊ (Smith & Nephew) might fit within a treatment pathway for diabetic foot ulceration.**

With the cost of diabetic foot problems reaching an estimated £650,000 per annum (Gooday and Berrington, 2015), an average of 61,000 active ulcerations at any time in England, and an annual mortality rate of 80% (5 years post-incidence) for patients with diabetic ulceration and amputation (Kerr, 2012), there is a need for equitable and efficacious care for people with diabetes. In August 2015, the National Institute for Health and Care Excellence (NICE) released new guidelines entitled *Diabetic Foot Problems: Prevention and Management of Foot Problems in People with Diabetes*. These guidelines incorporate previous advice, combined with new recommendations based on a number of areas related to the diabetic foot and, for the first time, support the use of negative pressure wound therapy (NPWT): 'consider negative pressure wound therapy after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service' (NICE, 2015).

## The evidence for negative pressure wound therapy

NPWT has been used as an advanced treatment modality across a broad range of wound indications since its invention 15 years ago, with over 1,000 peer-reviewed papers published on its efficacy and safety (Vig et al, 2011). This non-invasive treatment option delivers a localised negative-pressure environment to the wound area, encouraging healing by creating a moist wound environment, reducing oedema, and promoting the formation and perfusion of granulation tissue (Blume et al, 2008).

In a literature review published in 2012, the authors found the present evidence base for NPWT is strongest in the treatment of diabetic foot ulcers (DFUs), compared with the weakest evidence base in venous leg ulcers (Vig et al, 2011). NPWT can be used to treat various types of wound associated with diabetic lower limb disease (Laney et al, 2009); it can be applied to chronic recalcitrant DFUs and to wounds on the lower limb following debridement or partial amputation (Caravaggi et al, 2009; Chadwick et al, 2009).

A multicentre randomised controlled trial that enrolled 342 patients compared the clinical efficacy and safety of NPWT with advanced moist wound therapy (AMWT) in the treatment of diabetic foot problems. Results showed that NPWT appears to be more efficacious than

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### Article points

1. New National Institute for Health and Care Excellence guidance supports use of negative pressure wound therapy in the treatment of diabetic foot ulceration for the first time.
2. Selection of the most appropriate negative pressure therapy device for each wound is important.
3. PICO is an easy-to-use, portable system that fits within a diabetic foot treatment pathway, after appropriate wound preparation.

### Key words

- Advanced treatments
- National Institute for Health and Care Excellence
- Negative pressure wound therapy

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**Page points**

1. In August 2015, new NICE guidance supported use of NPWT in the diabetic foot for the first time.
2. There is a strong evidence base for use of NPWT as a diabetic foot treatment.
3. An appropriate NPWT system should be chosen based on the individual wound.

AMWT, with 43.2% of foot ulcers achieving complete closure (defined as skin closure with 100% re-epithelisation) with NPWT, compared with 28.9% for AMWT. Moreover, patients receiving NPWT had significantly fewer secondary amputations compared with those receiving AMWT ($P$=0.035). Closure was achieved at an estimated 96 days (Kaplen-Meier median estimate; 95% confidence interval 75.0–114.0) for NPWT, while this was undeterminable for AMWT. There were no significant differences between the two treatment groups in terms of treatment-related complications, such as infection, cellulitis and osteomyelitis (Blume et al, 2007).

In light of this addition to the NICE guidelines, and the evidence that NPWT is a cost-effective and efficacious treatment for diabetic foot wounds, it is important to understand how NPWT might be utilised in practice.

**Box 1. Factors relating to negative pressure wound therapy (NPWT) device selection.**

**Wound-related factors (author's clinical experience)**

- NPWT should be considered after surgical debridement for diabetic foot ulcers on the advice of the multidisciplinary foot care service (NICE, 2015)
- Diabetic foot TEXAS classifications A1 and A2 (Armstrong et al, 1998) represent wounds that are most appropriate for NPWT
- Any size of wound can be assessed for NPWT suitability — for example, amputation site/dorsal/plantar ulceration — as long as NPWT can be easily applied
- NPWT can be considered for use on any location of the foot, as long as appropriate offloading is considered
- If there is infection, it is suggested the infection is managed, then the wound reassessed.

**Other considerations (Henderson et al, 2010)**

- Frequency of wound dressing changes: is the wound producing excessive exudate? Does the ulcer need to be dressed three or more times per week due to high levels of exudate?
- Treatment setting: can the patient step down from inpatient care using the NPWT device?
- Patient compliance: is the patient able to comply with and understand the NPWT system? Will the NPWT device impact on the patient's activities of daily living?

**Contraindictions for NPWT (Smith & Nephew, 2015)**

- Patients with malignancy in the wound bed or margins of the wound (except for palliative care to enhance quality of life)
- Previously confirmed and untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Necrotic tissue with presence of eschar
- Exposed arteries, veins, blood vessels, nerves or organs
- Anastomotic sites
- Emergency airway aspiration
- Pleural, mediastinal or chest tube drainage
- Surgical suction.

## When to use negative pressure therapy

Although NPWT is an advanced treatment option that may impose greater costs than standard therapy, these costs can be justified if treatment results in improved ulcer healing, reduced morbidity, fewer lower-extremity amputations and improved patient functional status (Greer et al, 2012).

Use of NPWT requires advanced clinical decision-making and should be carried out only by practitioners with appropriate skills and anatomical knowledge (TRIEpodD-UK, 2012). A wide range of NPWT products are available, that vary in terms of mechanism, size, capacity to manage exudate and portability. *Box 1* presents a number of factors to be considered when making a decision between different NPWT systems. It is critical to select the most appropriate NPWT device, based on clinical presentation and patient assessment (Henderson et al, 2010).

Selection of the most appropriate device for the wound will depend on the patient's history and the existence of any contraindications to NPWT; the treatment setting; and the overall presentation of the foot ulcer (Henderson et al, 2010). The clinician should ascertain the goals of NWPT treatment following a thorough assessment; a strategy and timeline of care should then be put in place for each individual patient (Vowden, 2014).

## A single-use, portable system

PICO◊ (Smith & Nephew) is an easy-to-use, pocket-sized, single-use NPWT system that can be used for up to 7 days, and has shown positive outcomes for patients with (Edwards, 2012; Hudson et al, 2013; Hurd, 2013; Selvaggi et al, 2014):

- Open wounds
- Closed surgical incisions
- Skin grafts.

The system comprises a disposable, one-button pump attached to a dressing, which allows for fluid absorption. Since the PICO system is canister-free, the pump is discrete enough to fit in the palm of a hand (Hurd, 2013). As such, it is a useful 'step-down' option from larger, powered NPWT devices, ideal for transitioning

***"In line with the new NICE guidance, any NPWT system should be considered within the treatment pathway after the wound has been suitably prepared and surgically debrided, with support gained from the multidisciplinary foot care service for the decision."***

**Box 2: If yes, choose PICO...**

- Has the wound been present for >6 weeks and static for at least 2 weeks?
- Does the wound meet the suggested TEXAS/SINBAD classification scores?
- Has offloading been considered?
- Has the wound been suitably prepared (i.e. surgical debridement)?
- Could the patient benefit from step-down treatment?
- Is the wound producing <300 ml of exudate?

from hospital to the community. The PICO pump generates an effective negative pressure environment of –80 mmHg (Malmsjö et al, 2014), and is connected to a conformable, innovatively designed dressing, which:

- Can be easily applied and removed, minimising skin trauma (Hurd, 2013)
- Delivers negative pressure across the wound bed or closed incision (Hudson et al, 2013)
- Is designed to reduce the risk of pressure points and supports patient comfort (Smith & Nephew, Data on File)
- Manages fluid from the wound or closed incision through a unique combination of absorbency and evaporation (Hudson et al, 2013; Malmsjö et al, 2014).

## Where does PICO fit?

Since selection of the most appropriate NPWT system is vital to positive outcomes, *Box 2* presents a number of questions that should precede the choice of PICO, according to the author.

### Preparation of the wound and offloading

In line with the new NICE guidance, any NPWT system should be considered within the treatment pathway after the diabetic foot wound has been suitability prepared and surgically debrided, with support gained from the multidisciplinary foot care service for the decision (NICE, 2015).

The concept of TIME (Tissue, Infection, Moisture, Edge) is well recognised as providing a structured approach to wound management (Schultz et al, 2003); for DFUs, the author suggests adapting the acronym 'TIME' to 'TIME-OFF', where OFF refers to offloading, asking: 'Can you afford not to take TIME-OFF?' This addition reminds the clinician to look at the presentation of the wound and ensure overall management of the patient includes appropriate offloading. Inadequate offloading leads to tissue damage and ulceration. In patients with peripheral neuropathy, it is important to offload at-risk areas of the foot to re-distribute pressures evenly (Cavanagh and Bus, 2010).

### Diabetic foot classification systems

There are two diabetic foot classification systems — TEXAS and SINBAD — that can be used to assess suitability for NPWT systems such as PICO. A TEXAS classification of A1 or A2, or a SINBAD score of 4, 5 or 6, indicates the wound is likely to be difficult to heal, suggesting suitability for NPWT (Armstrong et al, 1998; Ince et al 2008). *Table 1* and *Table 2* give an overview of these classification systems.

### Exudate levels

*Table 3* provides a proposed exudate spectrum for choice of NPWT system, indicating when it may be appropriate to choose PICO.

## Clinical case studies

The following clinical case studies demonstrate successful use of PICO for treatment of diabetic foot wounds, highlighting how the system kick-started the healing process and, in turn, improved the patient's quality of life.

### Case study 1

#### Background

Patient 1 is a 60-year-old male with a body mass index of 39.9 and a history of insulin-dependant diabetes, peripheral vascular disease and stage 4 chronic kidney disease.

He sustained an injury to his fifth metatarsal standing on a nail, but the wound failed to heal, resulting in amputation of the fifth toe. Two months post-amputation, he was referred to a specialist wound-care podiatrist as the amputation site was not healing, and he needed daily dressing changes due to heavy exudate and malodour.

The wound site had previously been managed with silver and honey dressings, which were often changed between appointments due to strong odour and leakage.

#### First application of PICO

Following joint assessment by the podiatrist and tissue viability team, it was decided to commence treatment with PICO to kick-start healing. At first application, the wound measured 4 cm × 1.5 cm, the wound bed consisted of 100% adherent slough, the wound edges were uneven and macerated, exudate levels were heavy and malodorous, and the periwound skin was macerated, inflamed, dry and flaky.

### PICO treatment

At first dressing change, the wound had reduced in size to 3.2 cm × 0.9 cm. The wound bed was still sloughy and exudate remained purulent, so ACTICOAT◊ Flex 3 (Smith & Nephew) was applied beneath the PICO dressing as a barrier dressing and to help to reduce odour and bacterial burden.

After 7 days of PICO use (with 3 days using ACTICOAT Flex 3), the levels of exudate and malodour had reduced; the wound measured 2.5 cm × 0.6 cm; and the patient was optimistic about his progress. The wound bed comprised 100% granulation tissue, with some epithelialisation. The surrounding skin was now less inflamed and exudate levels were further reduced. PICO and ACTICOAT Flex 3 were reapplied.

PICO was discontinued after 18 days. ALLEVYN◊ Life (Smith & Nephew) was chosen to manage the final stages of healing, with cushioning to provide extra comfort and protection. The wound went on to heal at 18 weeks. *Box 3* summarises the patient's experiences using PICO.

## Case study 2

### Background

Patient 2 is a 58-year-old male with a history of type 2 diabetes and peripheral arterial disease, who had his first right toe amputated in 2012. The patient presented with a DFU he had been self-managing for 3 weeks, which measured 3 cm × 2.2 cm (6.6 $cm^2$) and was approximately 0.4 cm in depth (no known osteomyelitis). It comprised 30% granulation and 70% slough following debridement, with a high-moderate amount of exudate present. Dressing changes were needed three times per week, with antimicrobial and absorbent dressings required to manage the heavy exudate and odour.

### First application of PICO

A decision was made 6 weeks after initial presentation — due to the patient's history of amputation, the increasing volume of exudate and failure of previous interventions — to commence treatment with PICO. The aim was to kick-start the healing process and

**Table 1. TEXAS classification system (Armstrong et al, 1998).**

| TEXAS | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| A | Pre- or post-ulcerative lesion completely epithelialised | Superficial not to tendon/capsule or bone | Tendon/capsule but not bone | Probe to bone |
| B | Infected | Infected | Infected | Infected |
| C | Ischaemic | Ischaemic | Ischaemic | Ischaemic |
| D | Ischaemic and infected | Ischaemic and infected | Ischaemic and infected | Ischaemic and infected |

**Table 2. SINBAD classification system (Ince et al, 2008).**

| SINBAD | 0 | 1 | Score |
|---|---|---|---|
| Site | Forefoot | Rearfoot | 0/1 |
| Ischaemia | At least on pedal pulse | Clinical evidence of reduced blood supply | 0/1 |
| Neuropathy | Intact | Not intact 8/10 and less | 0/1 |
| Bacterial load | None | Present | 0/1 |
| Area | <1 $cm^2$ | >1 $cm^2$ | 0/1 |
| Depth | TEXAS 0 or 1 | 2 or 3 | 0/1 |

**Table 3. Proposed exudate spectrum.**

| Exudate level | Dressing change frequency | Suggested NPWT device |
|---|---|---|
| Dry | As indicated | None |
| Low exudate | <2 changes per week | None |
| Moderate exudate <300 ml per week | >3 changes per week | PICO |
| Moderate exudate and deep wound >2 cm <300 ml per week | Daily | PICO |
| High exudate and large, deep wound >300 ml per week | Twice daily | NPWT device with canister/bigger device with greater capacity |

**Box 3: Patient 1 – experiences with PICO.**

- Excellent exudate management and conformability, and pain and malodour were reduced
- Wound reduced in size and improvement in the wound bed was stimulated within 2 weeks
- Complete epithelialisation was achieved 3.5 months post-PICO
- Reduced number of visits to the podiatry clinic required, with only weekly dressing changes rather than daily/alternate days
- Comfortable during application, wear and removal
- Patient experienced an uplift in mood, improved concordance, and increased positivity.

**Page points**

1. Using NPWT systems such as PICO to manage diabetic foot ulceration could lead to cost savings.
2. Although seeking resource from budget holders for advanced therapies can be difficult, the new NICE guidelines provide a framework for NPWT to be used as part of an appropriate diabetic foot management protocol.

move the wound from a static, chronic state to a dynamic healing state.

### PICO treatment

At the first dressing change — after 4 days of PICO use — the wound had reduced in size to 3 cm × 1.7 cm (5.1 $cm^2$), and at seven days it had reduced again to 2.7 cm × 1.7 cm (4.59 $cm^2$). At the next dressing change (after 10 days of PICO use) the wound's dimensions remained the same, but the wound bed now comprised 70% granulation tissue and 30% slough. By day 21, epithelialisation was occurring at the wound edge and the sloughy tissue was easier to remove.

The wound improved consistently, and measured 2 cm × 1.7 cm (3.4 $cm^2$) at day 28. Post-PICO, further improvement in wound size was seen, reducing to 1.4 cm × 0.8 cm (1.12 $cm^2$) at day 56. *Box 4* outlines PICO's benefits to the patient.

## Conclusion

It is clear that NPWT is an important advancement in the management of diabetic foot ulceration. It has been shown to heal wounds quickly and so contribute towards the drive to reduce diabetes-related amputations and improve patient outcomes. NPWT systems may be more expensive than standard therapy options, but these costs can be offset if treatment leads to improved ulcer healing, reduced morbidity, fewer lower-limb amputations and improved patient functional status (Greer et al, 2012). As such, using NPWT systems such as PICO as part of a diabetic foot care pathway could lead to cost savings within local healthcare systems and the wider NHS.

Seeking additional resource from budget holders for advanced therapies such as NPWT for the diabetic foot can be challenging. However, the new NICE guidelines provide a framework for NPWT systems to be used within the management of diabetic foot ulceration as part of an appropriate treatment pathway, and give clinicians a powerful tool to gain the additional resource they need to support this. With this comes the opportunity to gain further evidence to support the use of NPWT in this patient cohort. ■

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**Box 4: Patient 2 – experiences with PICO.**

- PICO kick-started the healing process in a slow-to-heal diabetic foot ulcer
- Exudate was well managed and reduced during treatment
- PICO appears to have helped the wound to continue to improve after discontinuation.


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