

# Advice Statement

## Negative pressure wound therapy (NPWT) in chronic, acute and surgical wounds



### Advice for NHSScotland

- Negative pressure wound therapy (NPWT) should be considered for people with diabetes who require treatment for either post-operative foot wounds or foot ulcers.
- There is inadequate evidence to determine whether NPWT is clinically and cost effective in the following wound types: pressure ulcers; venous leg ulcers; burns; open traumatic wounds; open abdomen; wounds healing by primary intention (including split-thickness skin grafts, caesarean section wounds and closed incision wounds); surgical wounds healing by secondary intention; and sternal wound infections after cardiothoracic surgery.

### Consensus statements to guide best practice

- Exploratory work by SHTG highlighted the need for guidance on the appropriate and safe use of NPWT in NHSScotland. Therefore consensus statements to guide best practice have been produced by a group of clinical experts. These have been published as a supplement to this advice statement.
- Consensus was reached on seven statements of best practice. These included NPWT contraindications, NPWT precautions and the need for all staff involved in the provision of NPWT to have device specific training.
- Consensus was not reached on the wound types for which NPWT was clinically indicated.

*NHSScotland is required to consider the Scottish Health Technologies Group (SHTG) advice.*

## Why is SHTG looking at this topic?

This topic was referred to SHTG in March 2018 by Heather Hodgson (Lead Nurse Tissue Viability, NHS Greater Glasgow and Clyde), who requested that we update a Health Technology Assessment (HTA) published by Quality Improvement Scotland in 2010. Initial exploratory work highlighted that the extent of NPWT use in NHSScotland was not supported by randomised controlled trial (RCT) evidence. In addition, clinicians reported anecdotal concerns surrounding inconsistent, and possibly unsafe, use of the technology. Evidence Note 88 was produced by Healthcare Improvement Scotland to review the recent literature. In addition, consensus statements to guide best practice across NHSScotland were developed by a group of clinical experts.

## Background

NPWT is a widely used treatment in NHSScotland. It has been used for approximately 20 years and its' use has expanded to include a variety of different wound types. It is used by many clinical specialities, including tissue viability, podiatry, trauma and surgery. NPWT involves the use of sealed negative pressure (a vacuum) over a wound. The clinical intent of NPWT is to progress a wound towards healing.

However, there are anecdotal concerns that NPWT is used inconsistently, and sometimes inappropriately, across different healthcare professionals and boards in NHSScotland.

The clinical- and cost-effectiveness evidence (2013-2018) was reviewed (Evidence Note 88). The wound types included in the identified reviews/studies overlapped, and categorising the results by wound type was challenging. The categories of wounds reported in this advice statement (and associated evidence note) are imperfect, and reflect the published evidence. The generalisability of the evidence for one wound type to different wound types/patient groups is not clear.

None of the evidence identified related to paediatric populations.

## Clinical effectiveness

### Wounds associated with diabetes mellitus

- A search limited to the last five years (2013-2018) identified eight systematic reviews which evaluated the use of NPWT in people with wounds associated with diabetes mellitus.
- The most recent systematic review was from 2017 (Liu *et al*), and it included 11 RCTs (encompassing 1044 patients). The comparator was 'standard dressing changes'. The authors performed meta-analyses and the main findings are reported below:
  - Complete healing rate: the results from five studies were pooled, and compared with standard dressing changes, NPWT had a higher rate of

complete healing of ulcers: relative risk (RR) 1.48; 95% confidence interval (CI) 1.24 to 1.76;  $p < 0.001$ .

- Time to complete healing: the results from two studies were pooled, suggesting ulcers treated with NPWT had a shorter time to complete healing compared to standard dressing changes: mean difference (MD) -8.07 days; 95% CI -13.7 to -2.45;  $p = 0.005$ .
  - Change in ulcer size: the results from six studies were pooled, and patients in the NPWT group had a greater reduction in ulcer area compared with standard dressing changes (MD 12.18cm<sup>2</sup>; 95% CI 8.5 to 15.86;  $p < 0.00001$ ). The pooled results from three studies suggested that NPWT also resulted in a greater reduction in ulcer depth (MD 40.82mm; 95% CI 35.97 to 45.67;  $p < 0.00001$ ).
  - Amputation: The results of three studies were pooled, suggesting fewer amputations in the NPWT group (RR 0.31; 95% CI 0.15 to 0.62;  $p = 0.001$ ).
  - In addition, the review reported that granulation tissue formed faster in the NPWT groups (four studies); quality of life was improved (one study); resource use was lower with NPWT (two studies); and that there was no significant difference in treatment-related adverse events (three studies).
- The other systematic reviews generally agreed that there is moderate-quality evidence supporting the use of NPWT compared to conventional treatments in wounds associated with diabetes. However, several reviews also noted the need for additional robust RCT research to consolidate the existing evidence.

### **Trauma wounds**

- For open fracture wounds, a good quality systematic review reported no statistically significant difference between NPWT and standard care in the proportion of wounds healed at 6 weeks (based on one robust RCT).
- The same systematic review concluded that it was uncertain whether there was a difference in risk of wound infection, adverse events, time to closure or coverage surgery, pain or health-related quality of life between NPWT and standard care for any type of open traumatic wound (including open fracture wounds).

### **Other wound types**

- In the following wound types, evidence from robust RCTs is either lacking, insufficient and/or inconsistent: pressure ulcers; venous leg ulcers; burns; open abdomen; wounds healing by primary intention (including split thickness skin grafts, caesarean section wounds and closed incision wounds); surgical wounds healing by secondary intention; and sternal wound infections after cardiothoracic surgery.

- The evidence identified for each of these wound types is summarised in table 1.

Table 1: Systematic and RCT evidence identified for each wound type (2013-2018)

Wound type	Evidence
Pressure ulcers	Three systematic reviews were identified. The most recent (2015) included four RCTs, which were rated as 'very low quality'.
Venous leg ulcers	Four systematic reviews were identified, but these did not include any RCTs on NPWT in venous ulcers not being grafted.
Burns	One systematic review and one HTA was identified. Both included one 'methodologically weak' RCT published as an abstract.
Open abdomen	One systematic review (encompassing two RCTs, two prospective cohorts and four retrospective cohorts) was identified. The risk of bias in the RCTs was 'high'.
Wounds healing by primary intention	Sixteen systematic reviews and seven RCTs across overlapping sub-categories were identified. Overall, the evidence was insufficient/inconsistent. <i>See table 1 in Evidence Note 88</i>
Wounds healing by secondary intention	One systematic review (encompassing two RCTs) was identified. The RCTs had methodological short-comings and were underpowered.
Sternal wound infections	Two systematic reviews were identified, but these did not include any RCTs.
Other surgical wounds	Three systematic reviews and one additional RCT were identified. The patient groups were different in the reviews, but none included good quality RCTs.

## Safety

- According to documentation from the European Wound Management Association (EWMA) in 2017, the following contraindications for NPWT have been established:
  - Clotting disorders (risk of bleeding) and acute mild to moderate bleeding in the wound region after injury/debridement.
  - Exposed organs, vessels and vascular anastomoses, which might be altered or damaged by NPWT.
  - Necrotic wound bed.
  - Untreated osteomyelitis.
  - Neoplastic tissue in the wound area.
- All healthcare professionals who are involved in the provision of NPWT must ensure that they have the necessary knowledge and competence by undertaking device specific training.

## Cost effectiveness

### Wounds associated with diabetes mellitus

- No evidence published between 2013 and 2018 was identified on the cost-effectiveness of NPWT in the treatment of foot ulcers/wounds in people with diabetes.

### Trauma wounds (open fracture wounds)

- A good quality systematic review reported on an RCT on open fracture wounds which included a cost-effectiveness analysis. It compared NPWT to standard care.
- The mean total cost of resource was £678 (95% CI -1,082 to 2,438) more in the NPWT group. QALYs (quality-adjusted life years) were calculated based on results from the EQ-5D and SF-12 questionnaires. Incremental mean QALYs were slightly higher in the NPWT group (0.002, 95% CI -0.0054 to 0.059), though this difference is not statistically significant. This gives an incremental cost-effectiveness ratio (ICER) of £267,910. The authors also assessed the probability of NPWT being cost-effective for open fracture wounds at cost-per-QALY thresholds of £15,000 to £30,000. The probability of NPWT being cost-effective at these thresholds was never more than 27%. The systematic review rated this evidence as 'moderate-certainty'<sup>1</sup>.
- Based on this, the review authors concluded that there is 'moderate-certainty' evidence that NPWT is not a cost-effective treatment for open fracture wounds.

### Other wound types

- A search from 2013-2018 highlighted seven additional economic studies. However, only one was UK-based, and this had some methodological shortcomings. Therefore, it is not possible to make robust conclusions on the cost-effectiveness of NPWT in any other wound type.

## Patient and social aspects

The HTA from 2010 included a review of the literature, and some primary qualitative research with patients who had experience of NPWT. The findings reported in the HTA are still relevant.

Some peer review comments were received from the patient organisation Diabetes Scotland. Some of the patient issues highlighted added to the findings of the 2010 HTA. These included:

- There are many differing types of NPWT device available, and this can be confusing.

- In order to make informed decisions, patients and their families/carers should be advised of the benefits and risks associated with NPWT, what alternative treatment options there are, and what to expect with treatment (for example, frequency of dressing changes and the need for analgesia prior to dressing changes).
- Patients should be made aware that the noise made by NPWT devices may change as they move, or as the wound heals, and this does not necessarily mean the device is not working.

### Context (includes organisational issues)

- NPWT is an NHSScotland contract item and it costs approximately £1 million per annum.
- Pumps for NPWT are either hired from the manufacturers, or provided by the manufacturers free of charge with a volume commitment on dressings purchases.
- Manufacturers offer device-specific training and/or guidance on the use of NPWT. However, training does not always seem to be accessible to certain clinicians (for example, due to rural locations or time constraints).

### Further research

- Current evidence on NPWT appears to be at the assessment stage of the [IDEAL](#) framework.
- There is a need for good quality research evaluating the clinical and cost effectiveness of NPWT for most wound types/patient groups. This was a conclusion of the 2010 HTA.

### Advice context

No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.

It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of publication. An international evidence base is reviewed and thus its generalisability to NHSScotland should be considered by those using this advice to plan services. It is acknowledged that the evidence constitutes only one of the sources needed for decision making and planning in NHSScotland. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical

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<sup>1</sup> The authors state that moderate-certainty evidence means that the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

SHTG Advice Statements will be considered for review if new evidence becomes available which is likely to materially change the advice. Stakeholders may submit a request, highlighting new evidence to [shtg.hcis@nhs.net](mailto:shtg.hcis@nhs.net)

Chair

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