

# Managing diabetic foot ulceration with a new, highly portable NPWT device



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This article examines the use of highly portable negative pressure wound therapy (NPWT) in the management of diabetic foot ulceration, a significant sequelae of diabetes that affects some 61,000 people in the UK at any given time. NPWT is a non-invasive therapy that uses controlled sub-atmospheric pressure in a closed system applied to a wound to promote healing.

**Conflict of interest:** one of the authors is an independent consultant working on behalf of Spiracur Ltd.

### Page points

1. It is estimated that more than 4.6 million people in the UK will have diabetes by 2030
2. In 2010–11, the NHS in England spent an estimated £639m–£662m on diabetic foot ulceration and the management of its complications
3. Generally poor healing outcomes appear to make the use of new technologies as an adjunct to 'best practice' reasonable when managing diabetic foot ulceration

## INTRODUCTION

In 2010, 2.3 million people in the UK were registered as having diabetes, with 3.1 million estimated as having the condition<sup>[1]</sup>. However, the incidence is rapidly rising and by 2030 it is estimated that more than 4.6 million people will have the condition<sup>[1]</sup>. Foot ulceration is seen as one of the most significant sequelae of diabetes, which, for some, even with good preventative and treatment care, is a frequent occurrence. Currently, it is estimated that there are around 61,000 people with diabetic foot ulceration at any given time.

It is estimated that around 6,000 people with diabetes undergo leg, foot or toe amputation each year in England alone<sup>[2]</sup>, with the risk of lower extremity amputation for people with diabetes more than 20 times greater than that of individuals without diabetes<sup>[2]</sup>. Ulceration and amputation substantially reduce quality of life and are associated with high mortality<sup>[2]</sup>.

Foot ulceration places a significant financial burden on healthcare and social care agencies. The inability for an individual to work has multiple economic effects — they are no longer able to financially support their families, they no longer contribute to national productivity and so deplete the job market and the Inland Revenue of tax contributions, while the lack of paid employment places an increased demand on social funding.

In addition, diabetes management and the treatment of diabetic foot ulceration can represent a significant cost to healthcare providers. Diabetic foot ulceration develops in about 15% of individuals with diabetes, and foot disorders are a leading cause of diabetes-related hospitalisation<sup>[3][4]</sup>. In 2010–11, the NHS in England spent an estimated £639m–£662m on diabetic

foot ulceration and the management of its complications<sup>[1]</sup>.

## MANAGEMENT

The National Institute for Health and Clinical Excellence (NICE) states that key elements within the management of diabetic foot ulceration are assessment, investigation and multidisciplinary intervention<sup>[5]</sup>.

Management of any vascular and infection issues must be addressed if successful healing outcomes are to be assured. Worryingly, even if bioburden can be managed and vascularisation can be optimised, healing rates for chronic diabetic foot ulcerations are slow; in a meta-analysis of five prospective diabetic foot ulceration trials, Margolis et al (2000)<sup>[6]</sup> reported an aggregated healing rate of 24% after 12 weeks and 31% after 20 weeks of standard treatment. This means that after 20 weeks of 'standard treatment' approximately 70% of diabetic foot ulcerations remain unhealed.

Failure of a wound to heal may be due to the presence of wound bioburden or itself may provide an environment in which wound bioburden becomes pathogenic<sup>[7]</sup>. Given the poor state of host immune response seen in diabetic individuals<sup>[8]</sup>, and the high risk of poor outcomes when this occurs, it appears reasonable to utilise new technologies as an adjunct to 'best practice' to achieve optimum outcomes when managing diabetic foot ulceration. One of these adjuncts is negative pressure wound therapy (NPWT).

Despite the recent NICE guidance on the in-patient management of diabetic foot ulceration<sup>[5]</sup>, which states that NPWT should only be used as part of a clinical trial or as a rescue therapy to prevent amputation, it could be argued that timely

use of this therapy offers significant benefits in preventing diabetic foot ulceration-related amputation. Indeed, despite the guidance, NPWT is viewed by many clinicians as an essential part of the treatment armoury used in diabetic foot ulceration management.

## NEGATIVE PRESSURE WOUND THERAPY

NPWT has been utilised in the treatment of wounds of differing aetiologies for over 15 years. It is a non-invasive therapy that uses controlled sub-atmospheric pressure in a closed system applied to a wound to promote healing. Despite criticisms that the therapy lacks a comprehensive evidence-base<sup>[9]</sup>, it has been the subject of multiple peer-reviewed clinical trials and case studies and there is a vast amount of clinical data showing the clear benefits of using this therapy in practice<sup>[10,11]</sup>. Many of these studies have included subjects with diabetic foot ulceration.

The reported benefits of using NPWT include<sup>[12]</sup>:

- **Increased local blood flow to the wound through increased dilation of arterioles**
- **Reduced tissue oedema through the removal of excess fluid**
- **Stimulation of granulation tissue, resulting in progressive wound closure**
- **Stimulation of cell proliferation**
- **Removal of free radicals from the wound**
- **Removal of slough**
- **Reduction in wound volume**
- **Protection from outside contaminants**
- **Decrease in wound bioburden**
- **Maintenance of a moist wound healing environment.**

## SNAP

The SNaP® device (Spiracur) is a unique highly portable NPWT system which does not rely on external electrical power supply (battery or mains) to operate. The system uses patented integral 'memory springs' — a proprietary spring mechanism that generates consistent, even levels of pressure — to drive the unit and achieve sustained sub-atmospheric pressure at pre-determined levels (-75mmHg, -100mmHg and -125mmHg)<sup>[13]</sup> at the wound interface. This makes the system silent, light, highly portable, disposable and easy to operate. The system is useful for the treatment of low to moderately exuding wounds (less than 120mls/week).

Despite its relative simplicity, a randomised control trial of 100 patients has demonstrated that treatment with SNaP achieves the same clinical outcomes as a 'Gold Standard' electrically-powered

device<sup>[14]</sup>. In the study, SNaP use was associated with reduced cost of treatment and significantly improved ease of application and use.

SNaP is used in conjunction with a dedicated hydrocolloid film dressing which has an integral drainage tube. This tube can be cut to the desired length for safe and easy placement of the cartridge. The product is available with both foam and antimicrobial (AMD) gauze interface dressing

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Figure 1. High exudate levels and slough leading to peri-wound maceration and excoriation.



Figure 2. Therapy was commenced at -125mmHg and the dressing was covered with a wound pad and retention bandage.



Figure 3. Exposed tendon is visible.



Figure 4. The foot at the time of discharge.



Figure 5 and 6 (above left and right). NPWT with SNaP continued.



Figure 7 and 8 (above left and right). Mr M's wound continues to heal with Figure 8 showing full healing.

options. The dressing, cartridge and interface materials are changed twice-weekly.

The system's ease of use, portability and non-interference with patients' lifestyles makes it an ideal product for managing the diabetic foot ulceration, particularly in the community environment.

## CASE STUDY

### Background

Mr M is a middle-aged, self-employed surveyor who lives and works in London. Due to his work and social circumstances, Mr M prefers to opt for private healthcare provision. He has a private general practitioner and if required receives hospital care in a large private hospital in central London. His work means that he spends considerable time on building sites, liaising with workmen and directing construction work.

Mr M developed type 2 diabetes mellitus some 10 years ago. While he generally manages his blood sugars well, long working days and the unpredictability of his daily routine can pose challenges and long periods of standing, linked

with the need to use rigid safety boots, has caused Mr M a number of foot-related issues in the past. This resulted in the development, on two separate occasions, of a diabetic foot ulcer on the lateral border of his left foot.

At each occurrence, clinical investigations identified good vascularity, but highlighted a significant degree of neuropathy. Each episode of ulceration also resulted in underlying osteomyelitis.

Previous treatments for diabetic foot ulceration required the surgical exploration of the wound, removal of infected bone and non-viable tissue, and the use of systemic antibiotics, often over prolonged time periods. At each surgical episode the wound was left to drain and heal by secondary intention. To manage exudate and control wound bioburden, as well as stimulating angiogenesis and wound granulation, NPWT was initiated.

### Current problem

Mr M was admitted to hospital with further ulceration to the lateral border of his left foot. Mr M was managed by a multidisciplinary team, which

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## Useful links

NPWT settings and dressing choices  
Made Easy

included his surgeon and tissue viability nurse specialist (as recommended by NICE, 2011<sup>[5]</sup>).

On examination, Mr M had an extensive re-ulceration overlying his previous ray amputation (whereby the phalanx is removed along the metatarsal head and a portion of the metatarsal bone). There was slough present and exudate levels were high, leading to periwound maceration and excoriation [Fig 1]. Pain was not an issue in his ulcer presentation. Wound swabs revealed heavy bacterial colonisation and he was commenced on parenteral antibiotics.

### Treatment

Following discussion within the care team it was decided to treat the wound with NPWT using the SNaP device.

The objectives of therapy were to:

- **Manage wound exudate**
- **Prevent further infection**
- **Assist in autolysis of necrotic matter**
- **Maintain independence and mobility**
- **Facilitate wound granulation**
- **Obtain wound closure and healing.**

The SNaP device was selected as it offers proven ability to deliver the benefits of NPWT, notably the promotion of wound granulation and wound healing. It is also portable, has a low weight and is easy to operate.

The wound bed and periwound skin was thoroughly cleansed and the ulcer was covered with moistened AMD gauze-interface material. The hydrocolloid dressing was cut to size to enable placement over the area. It was decided to place the drainage port directly over the wound area to minimise the risk of displacement. This could be reviewed when Mr M recommenced mobilisation. Therapy was commenced at -125mmHg and the dressing was covered with a wound pad and retention bandage to provide additional security [Fig 2]. The cartridge was attached to the patient's calf with the adjustable carry clip provided. Mr M was instructed on how the SNaP therapy system is managed and how to re-prime the dressing cartridge if required.

Mr M remained an in-patient for a further week during which time arrangements were made to continue oral antibiotic therapy in the community. His dressing was changed twice weekly. Improvement was seen in the periwound skin health and new granulation was apparent. One area (in the centre of the wound) was found to contain exposed tendon. However, this tendon was considered viable and it was hoped that the NPWT could facilitate its coverage with

granulation tissue [Fig 3].

On discharge, Mr M was advised to limit his mobilisation [Fig 4]. The foot was protected with padding and bandages and he was fitted with an orthotic shoe. Although being advised to remain non-weight bearing, Mr M insisted on returning to work to undertake 'light duties' following discharge. This did raise some issues, namely, the inability to elevate his foot resulted in increased exudate levels, and increased foot movement did produce an occasional break in the air-tight dressing seal.

However, Mr M was able to manage these himself and his therapy continued as planned. Granulation was seen to increase in the wound bed and covered the exposed tendon. Wound contraction occurred despite the presence of foot oedema and the wound margin showed signs of epidermal regeneration and migration.

### Results

Mr M was able to maintain self-care, including continuation of work during the latter stages of his wound management [Figs 5 and 6]. There were no secondary infection issues and peri-wound skin health improved. Wound healing was initiated during therapy resulting in a significant reduction in wound size. This continued following cessation of NPWT and the wound closed [Figs 7 and 8].

Mr M is one of the few individuals to have been treated with three different types of portable NPWT device. Compared with battery-powered units, he found the SNaP system light, portable and easy to use. The silent system did not disturb his sleep and prevented his work colleagues becoming aware that he was undergoing active treatment.

## CONCLUSION

Achieving good wound healing outcomes is essential in managing diabetic foot ulceration if amputation is to be avoided. However, patients often need to deal with work pressures that can compromise their ability to rest. NPWT enhances healing of intransigent wounds, including diabetic foot ulcers. The SNaP system offers a method of delivering NPWT that enables patients to maintain independence and meet many of the social and economic demands they face, while providing a wound environment that promotes healing.

## AUTHOR DETAILS

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