Mechanical dNPWT made easy

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Introduction

The treatment of wounds with negative pressure wound therapy (NPWT) has revolutionised practice over the past decade. Advances in technology have helped to combat the complex implementation of conventional electrically powered NPWT systems, opening access to NPWT and widening its use in acute and post-acute settings. The development of mechanically powered NPWT devices has improved access to treatment, allowing a greater range of patients to benefit from NPWT, particularly in a home or community setting (Wounds International, 2017). This document discusses the use of disposable NPWT (dNPWT) devices, including the SNAP™ Therapy System and the NANOVA™ Therapy System (Acelity). The systems are easy to use, accessible and portable, allowing for potentially earlier discharge from the hospital and helping to reduce costs and improve patients' quality of life.

What is NPWT?

Negative pressure wound therapy (NPWT) is the continuous or intermittent application of subatmospheric pressure to the wound bed, which has been shown to help improve the wound environment, kick-start healing and help reduce the time to closure of the wound (Cutting et al, 2013); this can be particularly beneficial in hard-to-heal wounds at risk of complications and extended healing time.

While the origins of NPWT date back to the late 1980s, when Chariker described a gauze-based negative pressure drainage therapy, the therapy became more popular in the late 1990s. This was when the use of subatmospheric pressure through an open-pore structure polyurethane foam was introduced and reported to expedite wound healing (Argenta and Morykwas, 1997).

Today, NPWT is a well established treatment for a variety of acute and chronic wounds, and has a number of known clinical effects that help to promote healing responses in a variety of wound types (Wounds International, 2017). Technological advancement of the equipment used to deliver NPWT, greater awareness of the therapy and evolving techniques has enabled the continued innovation of NPWT.

How does NPWT work?

NPWT uses a closed drainage system to apply controlled suction (vacuum) to a wound bed. The wound is first filled with an open-pore wound filler (most commonly foam) fitted to the contours of the wound, allowing pressure to be distributed evenly to the wound bed. The wound is then sealed with an adhesive (such as polyurethane drape or hydrocolloid), which helps protect the wound environment from outside contaminants. Tubing with a connection pad is then applied over a hole in the adhesive and connected to a vaccum pump, which suctions wound fluid into a canister.

NPWT has been shown to help promote wound healing due to a few key mechanisms of action, including helping to manage exudate, maintain a moist wound healing environment and mechanical stimulation of the wound bed. NPWT increases macrostrain (the visible stretch that occurs when negative pressure contracts the foam) and microstrain (the microdeformation at the cellular level, which leads to cell stretch). In doing so, several healing effects are promoted. Macrostrain helps to contract the wound edges and remove exudate and infectious materials; microstrain reduces tissue oedema, increases cellular proliferation and migration, and promotes perfusion and the formation of granulated tissue. Also, since NPWT dressings require fewer dressing changes as compared to traditional dressings, this may help reduce contamination and the risk of infection.

The biological effects of NPWT on the wound bed depend on the type of dressing and the negative pressure setting applied. The properties of the wound interface (contact layer) determine most of the effects of NPWT on the wound bed. Foam wound fillers cause a mechanical effect on the wound, stimulating the tissue surface and triggering the cells to divide and rebuild to strengthen the tissue (Borgquist et al, in press). Mechanical stress to the wound edges alters tissue perfusion, resulting in angiogenesis and the formation of granulation tissue.

How is mechanical dNPWT different?

Since the initial development of NPWT in the early 1990s (Sinha et al, 2013) the technology has evolved to include the introduction of disposable devices (dNPWT). Traditionally, NPWT devices have been powered electrically. This meant that the units required an electrically powered pump that was generally only available in an in-patient setting (Fong and Marston, 2012). As such, treatment of some wounds that may have benefited from NPWT was impractical, particularly smaller-sized wounds. Conversely, dNPWT units are available 'off-the-shelf', promoting easier and more widespread use.

Mechanically powered NPWT uses a pump with a spring mechanism to generate a preset level of subatmospheric pressure to the wound bed. This technology has demonstrated similar efficacy and increased usability for both clinicians and patients when compared with electrically powered NPWT devices (this was a non-inferiority study, where the wounds treated with electrically powered NPWT were larger), while providing extra benefits in terms of practicality and convenience (Fong and Marston, 2012).

Mechanical dNPWT made easy

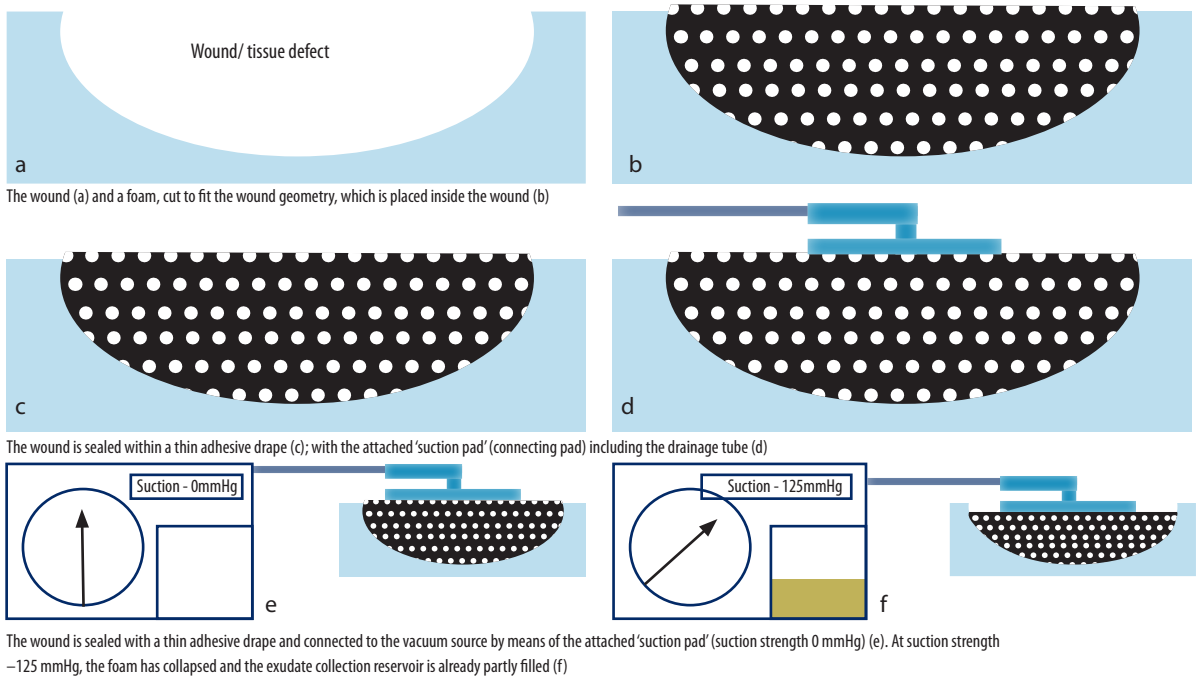

Figure 1: How negative pressure wound therapy (NPWT) works

Table 1: Comparison of negative pressure wound therapy (NPWT) treatment options (adapted from Wounds International, 2017)

		Disposable NPWT	Traditional NPWT
Clinical	Goal of therapy	■ Promote wound healing ■ Exudate management	■ Granulation tissue ■ Exudate management
	Wound surface area	≤ 13cm x 13cm (SNAP Therapy System) ≤ 10cm x 20cm (NANOVA Therapy System)	> 2.5cm^2
	Wound depth	Shallow cavity wounds ≤ 3cm (SNAP Therapy System ≤ 2cm (NANOVA Therapy System)	Larger, deeper wounds > 1cm
	Exudate management	Thin-to-medium viscocity exudate: ≤ 180ml/week	> 180ml/week
Patient QoL	User interface	Mechanical activation	Tactile screen/buttons
	Portability	Approximately 70g	Varies between 500 and 1000g
	Alarms	Visual only	Audible and visual
Economic	Facility economics	Simple application (reduced application time) May help reduce time to heal Off the shelf availability	More complex application (moderate application time) May help reduce time to heal

Initially used primarily in a hospital setting, the development of disposable, mechanically powered systems facilitated ambulatory treatment in the home care setting, leading to earlier patient discharge from the hospital. Reducing duration of hospital stays and encouraging patients to participate in their care at home can have a significant impact on quality of life, enabling patients to regain independence and resume everyday activities. Mobility is improved and the chances of contracting high-risk hospital-acquired infections are reduced. These potential benefits may translate to substantial cost savings: compared with the use of NPWT in the acute setting, NPWT in the community was estimated to save £4,814 per patient across the duration of their care (average duration: 20.4 days; Dowsett et al, 2012).

Patient acceptability and adherence to treatment is a vital factor that may be enhanced through the use of mechanically powered dNPWT, as the treatment devices are lightweight, discreet and ultraportable. For instance, the NANOVA Therapy System and SNAP Therapy System are small enough to be hidden under

TREATMENT GOALS OF MECHANICAL DNPWT

- Accelerated healing (new or stalled wounds)
- Exudate management and improved wound bed condition through autolysis
- Transitional therapy (step down from VAC or step up from AWD treatment)
- Care setting transition
- To allow other necessary medical procedures to proceed in a timely manner
- Management through to healing

BENEFITS OF MECHANICAL DNPWT

- Portability – small and lightweight, allows ambulatory care
- Accessibility – intuitive, easy to use mechanical system
- Discrete qualities improve acceptability and concordance – easy to hide under clothing and silent
- Facilitates early hospital discharge and self-care, while providing the trusted and clinically proven level of –125mmHg pressure
- Enhanced quality of life – patients regain independence and return to normality more quickly
- Potentially reducing nursing time and overall costs

normal clothing; the SNAP System includes a strap so the device can be worn on a patient's leg, arm, or belt. In practice, this has been found to improve concordance and quality of life. For example, the devices may facilitate a return to work. The devices have been found to be simple to use; application with the SNAP System is quick and easy, while the NANOVA System's absorbent dressing allows for a simple peel-and-stick dressing application.

As the mechanically powered units do not require mains power or batteries, there are added environmental and cost benefits (i.e. there is no need to buy or dispose of batteries). This also means that patients do not have to worry about battery life being an issue. Additionally, battery-powered devices can be less discreet for users, with pump sound levels causing potential problems.

The ability of patients to understand and contribute to their own care is an advantage and may also help to cut down on nurse visit time; however, it is important that this is encouraged only in suitable patients and after adequate training has been provided by the clinician. For example, patients need to be well engaged and able to visually check devices once every 8 hours. Even in suitable patients, monitoring is still required to ensure that the patient is using the device correctly.

How does the level of negative pressure provided compare?

In order to validate the efficacy of disposable, mechanically powered NPWT devices, pre-clinical bench-top and animal studies were performed at Stanford University that demonstrated equivalent delivery of NPWT and equivalent wound healing between the SNAP Therapy System and other electrically powered pumps (Fong et al, 2010).

The same air density reduction was achieved in the devices, which resulted in the delivery of identical negative pressure by both mechanisms at the level of the wound bed.

The NANOVA and SNAP Therapy Systems use alternative mechanisms for generating negative pressure, as outlined in detail below.

The NANOVA™ Therapy System: an advanced wound dressing, enhanced with –125 mmHg negative pressure

The NANOVA Therapy System combines NPWT with an absorbent dressing that retains exudate, helping to minimise the risk of maceration and removing the need for a separate fluid reservoir. The system comprises both upper and lower pressure distribution layers, which ensures that negative pressure is maintained regardless of the amount of fluid absorbed. The functions of absorption and pressure transfer are independent of one another.

SENSASEAL™ Protective Seal Technology combines silicone and acrylic/polyurethane to produce and maintain a seal for negative pressure, while helping to reduce pain and trauma to the wound bed. The primary contact layer on the border is also silicone, which is perforated to expose windows of acrylic adhesive that aid in maintaining the seal necessary for achieving effective negative pressure. Once a seal is achieved, the therapy unit will deliver continuous negative pressure (–125 mmHg). Its operation is intuitive. One to three compressions of the plunger are needed to deliver regulated and continuous negative pressure.

Even if the NPWT seal is lost, the NANOVA Dressing will continue to absorb drainage, unlike the dressings of conventional powered NPWT devices. If the seal is lost at any time when using the NANOVA system, negative pressure can be easily restored by resealing the dressing and depressing the therapy unit, so there is no need for a nurse visit to fix the unit. The unit can also be easily re-powered at any time with a compression of the plunger, reducing the need for specialist training.

The SNAP™ Therapy System: combines the simplicity of advanced wound dressings with the benefits of negative pressure therapy in a discreet design

The SNAP Therapy System utilises spring technology, which reduces air density within an enclosure in a controlled manner. The specialised springs equilibrate even in the presence of exudate, so that a constant controlled level of negative pressure is applied to the wound bed.

The SNAP System has three cartridges with different preset pressure levels: –75 mmHg, –100 mmHg and –125 mmHg. The variable pressure options may be useful where stepping

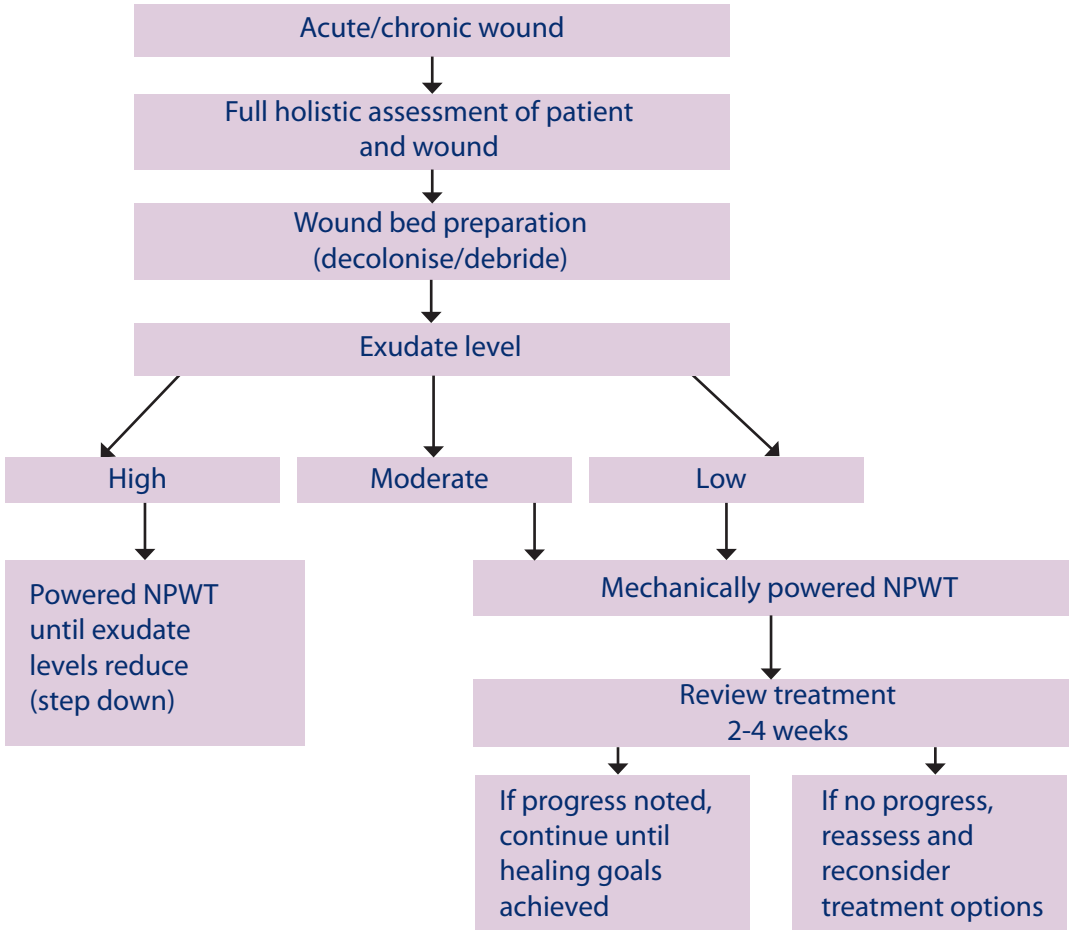

Figure 2: Treatment pathway for use of mechanically powered dNPWT (Wounds International, 2017)

therapy up or down is necessary, or for patients that cannot easily accommodate –125 mmHg (such as patients with venous deficiency).

There are two options for the canister within the cartridge, with a capacity of either approximately 60ml, or 150ml (–125 mmHg only), of wound exudate. A visual indicator signals if the canister is full or if there is an air leak. The SNAP System also incorporates BioLock® technology that isolyzes or gels the wound exudate that collects in the cartridge, which helps to control potential contamination and odour. This makes it potentially useful in patients where exudate management is important to the clinician.

The hydrocolloid dressing protects the periwound skin and provides a seal around the wound for effective NPWT delivery. This is used over a wound filling material consisting of a specialised foam dressing that can be customised to the shape and size of the wound.

What wounds are indicated or contraindicated for mechanical dNPWT?

The NANOVA and SNAP Therapy Systems were developed to allow NPWT to be used on a wider range of wound types. Many of the chronic wounds that could benefit from NPWT, such as diabetic foot ulcers, are relatively small in size. Therefore, these mechanically powered systems were designed to deliver NPWT effectively to small-to-medium sized, hard-to-heal wounds.

The NANOVA and SNAP Systems can also be used in wounds where exudate levels are not sufficiently high for standard NPWT, but where other dressing options are not able to manage exudate effectively (Wounds UK, 2014). They are indicated for removal of small amounts of exudate (low to moderate) from:

- Chronic wounds (e.g. diabetic, venous or pressure ulcers)
- Traumatic/acute wounds
- Subacute and dehisced wounds
- Surgically-closed incisions
- Flaps and grafts.

Supported by an educational grant from Acelity.
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As with most NPWT devices, use of the NANOVA and SNAP Systems should not be used over:

- Actively infected or bleeding wounds
- Inadequately drained wounds
- Necrotic tissue such as eschar or adherent slough
- Exposed blood vessels, anastomotic sites, organs, tendons or nerves
- Wounds containing malignancy
- Fistulae
- Untreated osteomyelitis
- Wounds with high levels of exudate.

What wound or patient characteristics are ideal for mechanical dNPWT?

Mechanical dNPWT is ideal for a range of patients and wounds. See Table 1 for more information on selecting the appropriate NPWT option for the individual patient and wound type.

In wounds where NPWT has been identified as an appropriate treatment, it may be useful to use a structured pathway to decide which device would be the most beneficial according to the specific clinical scenario (see Figure 2).

Evidence for mechanical dNPWT

Clinical trial data has shown equivalent outcomes with dNPWT to electrically powered NPWT devices, with similar biomechanical properties and functional wound-healing benefits. In a case series of 63 patients with diabetic and venous ulcers, Lerman et al (2010) found that the SNAP System resulted in a 50% improvement in time to healing. This was further supported by a multicentre randomised controlled trial (RCT) comparing the outcomes of the SNAP System and an electrically powered system in 132 patients with lower extremity diabetic and venous ulcers (in this study, the wounds treated with electrically powered NPWT were larger). The two systems gave similar outcomes in terms of wound healing (Armstrong, 2012) while superior results were shown for the SNAP System in terms of quality of life.

Other trials have focused on the cost benefits of dNPWT compared with traditional NPWT and other modern dressings. A comparative study by Hutton et al (2011) used a decision analytical modelling approach to analyse the costs associated with both types of negative pressure therapy in the treatment of diabetic lower extremity wounds. They found the SNAP Therapy System represented a cost saving of $2,774 (17%) versus electrically powered negative pressure, based on fewer dressing changes and with comparative healing time. Furthermore, the SNAP Therapy System was found to represent a $9,699 (42%) cost saving over the standard of care (modern dressings) because it helped to promote superior healing, avoid longer treatment times and avoid complications.

More recently, Marston et al (2014) demonstrated greater improvement and higher likelihood of complete wound healing with mechanical dNPWT compared with electronic NPWT. Kaplan-Meier analyses of 40 patients with venous leg ulcers showed greater acceleration in complete wound closure in the mechanical dNPWT group. At 30 days, 50% wound closure was achieved in 52.6% (10/19) of patients treated with mechanical dNPWT, compared with 23.8% (5/21) of patients treated with electronic NPWT. At 90 days, complete wound closure was achieved in 57.9% (11/19) of patients treated with mechanical dNPWT and 38.15% (8/21) of patients treated with electronic NPWT.

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NANOVA CASE STUDY

A 25-year-old male presented with a trauma wound to the right upper tibial area. He had sustained the injury during a rugby match 6 weeks earlier. Two weeks after injury, he presented to A&E with cellulitis, which was treated for 14 days with antibiotics and an absorbent carboxymethylcellulose (CMC) dressing, changed daily. The cellulitis had resolved at 2 weeks. The wound was treated for a further 2 weeks with the CMC dressing and compression therapy (the latter is used as standard therapy for all lower limb wounds with cellulitis).

Despite this treatment and the presence of clean granulation tissue, the wound had stalled and remained deep. On presentation to the outpatient dressing clinic, the wound measured 3.8cm long x 2cm deep x 2.5cm wide; despite the deep cavity, the wound bed was 100% clean. There was a moderate level of serosanguinous exudate, and the patient reported no wound-related pain. NANOVA Therapy System was initiated with dressing changes every 2 days.

Week 1 review (fourth dressing change): The wound had improved considerably, now measuring 2.8cm x 0.5cm x 1cm; a 93% reduction in wound volume from baseline. The wound bed had begun to epithelialise, and the remaining tissue was healthy and granulating.

Week 2 review: The wound had continued to progress towards healing, with 40% epithelialisation and 60% granulation tissue. The wound measured 1.5cm x 0.3cm x 0.8cm – a 98% reduction in wound volume from baseline.

Week 3 review: The wound measured 1.1cm x 0.1cm x 0.5cm (over 99% reduction in volume from baseline), and the wound bed comprised 90% epithelialising and 10% granulating tissue. Exudate levels remained low.

Week 4 review: The wound had healed fully.

Summary

- Trauma wound of 6 weeks' duration
- 93% reduction in wound volume after 8 days
- Complete wound healing achieved at 4 weeks with the NANOVA Therapy System.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

Baseline: 7 May

NANOVA Therapy System *in situ*

Week 1: 14 May

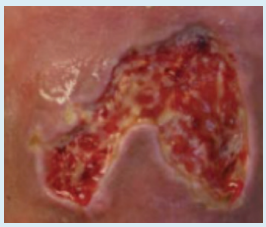
Wound healed: 4 June

SNAP CASE STUDY

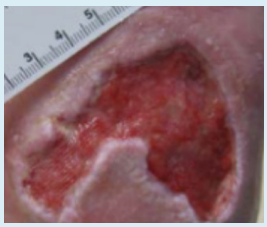
A 68-year-old male presented with a diabetic foot wound after experiencing trauma to the dorsal foot. The patient had several comorbidities and was a smoker.

At baseline, the wound measured 70mm x 54mm with a depth of 4mm without undermining.

The patient was treated with the SNAP Therapy System for 3 weeks until full granulation of the wound bed was achieved. Then the SNAP System was used in conjunction with a cellular tissue product for an additional 5 weeks. Wound closure was achieved at 9 weeks' post-initiation of the SNAP System.



NANOVA™ Therapy System *in situ*



Week 1: 14 May

Wound healed: 4 June

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

Summary

Advances in NPWT and particularly in the development of dNPWT mean that the therapy is now easier and more accessible to use in practice. The SNAP™ and NANOVA™ Therapy Systems (Acelity) are both practical and patient-friendly, particularly in the homecare and community settings, and may improve outcomes, concordance and patient quality of life.