SNaP[®] Wound Care System: Ultraportable Mechanically Powered Negative Pressure Wound Therapy

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Problem: Negative pressure wound therapy (NPWT) is a well-accepted modality for treatment of difficult wounds, but has traditionally required a bulky electrically powered pump that was difficult to procure and use for both caregivers and patients. Often times, treatment of refractory smaller-sized wounds was impractical even though they may benefit from NPWT.

Solution: Spiracur (Sunnyvale, CA) has developed a simple, easy-to-use, single-use, off-the-shelf, mechanically powered NPWT device that weighs <3 ounces. This device allows for the practical treatment of smaller-sized wounds with NPWT designed specifically for the ambulatory patient being treated at home.

New Technology: The Smart Negative Pressure (SNaP[®]) Wound Care System is a novel light-weight NPWT device that does not require an electrically powered pump. Instead, the SNaP system utilizes specialized springs to generate a preset (–75, –100, and –125 mmHg) continuous subatmospheric pressure level 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.

Indications for Use: Chronic, acute, traumatic, subacute, and dehiscent wounds, partial-thickness burns, ulcers (such as diabetic or pressure), and surgically closed incisions and flaps.

Cautions: Wounds with excess necrotic tissue, active infection, fistulas, exposed vital structures, untreated osteomyelitis, and that are highly exudative. The SNaP system was not designed for wounds that exceed the size of the dressing in surface area or have exudate levels greater than capacity of the cartridge.

UNMET NEED

ACUTE AND CHRONIC WOUND treatment with negative pressure wound therapy (NPWT) is an important clinical tool with many reports demonstrating improved granulation tissue formation and decreased time to heal.^{1–3} Multiple NPWT systems are available on the market, such as the KCI wound V.A.C.[®] and Smith and Nephew Renasys[®] systems. However, these devices have drawbacks, including their size and bulk, lengthy dressing

placement times, difficult procurement process, and cost. In addition, these devices were designed with large wounds in mind, not the smaller wounds that often present to the wound care specialist.

PRODUCT TECHNOLOGY

The smart negative pressure (SNaP[®]) wound care system (see Fig. 1) is a novel ultraportable NPWT device that does not require an electrically powered pump. Instead, the

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Abbreviations and Acronyms

NPWT = negative pressure wound therapy

SNaP[®] = smart negative pressure

VAC = vacuum assisted closure

Figure 1. The SNaP® wound care system. The -125 mmHg cartridge is shown.

SNaP system utilizes specialized springs to generate continuous negative pressure at the wound bed. The SNaP wound care system consists of five basic elements: the cartridge, activation/reset key, hydrocolloid dressing layer with integrated nozzle and tubing, holster with strap, and an antimicrobial gauze wound interface layer. The cartridge is currently produced with three different preset pressure levels (-75 , -100 , and -125 mmHg), and is small enough to be worn on a patient's leg, arm, or belt and may be completely hidden under normal clothing. The cartridge portion of the device weighs <3 ounces and has a canister capacity of ~ 60 mL of wound exudates. Because there is no electrical pump, operation of the SNaP wound care system is completely silent. The SNaP wound care system is also entirely disposable, eliminating the added administrative, and support costs of a rental-based system currently utilized by most electrically powered pumps.

INNOVATION

All marketed devices that are currently cleared by the Food and Drug Administration for NPWT generate negative pressures by reducing air density within an enclosure in a controlled fashion. These devices typically use an electrically powered displacement pump. These electrically powered NPWT devices have a motor that cyclically traps a small section of air within the wound enclosure and expels it to the outside. In contrast, the SNaP wound care system is a disposable, mechanically powered system with a spring technology that reduces air density within an enclosure by expanding the entire volume of a wound enclosure in a con-

trolled manner. Both the electrically powered and disposable, mechanical powered devices achieve the same air density reduction (negative pressure). Thus, identical negative pressures are delivered by both mechanisms at the level of the wound bed and, in turn, the clinical treatment provided to the patient is the same. However, using this technique of negative pressure delivery, a unique ultraportable device can be built that weighs <3 ounces, costs significantly less, and is readily available off-the-shelf just like any other non-NPWT dressing.

PEER-REVIEWED LITERATURE

To validate the SNaP wound care system efficacy for treating wounds, preclinical bench-top and animal studies were performed at Stanford University that demonstrated equivalent delivery of NPWT and equivalent wound healing in an animal model between the SNaP wound care system and the V.A.C. therapy system (an electrically powered pump NPWT device manufactured by KCI, San Antonio, TX).⁴

The SNaP wound care system has also been tested in direct comparison to the V.A.C. therapy system in a multicenter, randomized, controlled trial in diabetic and venous ulcer patients. An interim report from this study included 65 patients from 14 centers across the United States.⁵ The data demonstrated that there were no significant differences in the proportion of subjects healed with either method of negative pressure therapy. In addition, the percent wound size reduction between treatment groups was not significantly different at 4, 8, 12, and 16 weeks, with statistical noninferiority demonstrated at 4 weeks of treatment. Complications or adverse events were also similar between groups. Further, patients in this study were also asked to report on multiple quality-of-life indicators. These data demonstrated that the SNaP system interfered less with overall activity, sleep, and social interactions than the V.A.C. system. Lastly, this study demonstrated that dressing application time was less than half the time for the SNaP system compared with the V.A.C. system. If the data from this interim analysis are confirmed after study enrollment and follow-up are complete, this will provide strong supportive evidence of the benefit of the SNaP system for improving outcomes.

Several other clinical studies have been published to date, including a case series published from the Department of Dermatology at Stanford University School of Medicine⁶ and a case series focused on diabetic foot ulcers from a community

wound care center.⁷ The community study demonstrated that the SNaP system can also be successfully used in conjunction with other advanced wound healing modalities like cell-based bioengineered dressings like Dermagraft® and Apligraf®.⁷ In addition, Lerman *et al.* published a well-controlled 63-patient retrospective study in diabetic and venous ulcer patients, which demonstrates a 50% decrease in time to heal for patients treated with the SNaP wound care system compared with matched historical controls treated in the same wound care center with advanced modern therapy, including Apligraf, Regranex® (recombinant platelet-derived growth factor), and skin grafting.⁸

NON-PEER-REVIEW OBSERVATIONS

The SNaP wound care system has been used for the treatment of acute trauma wounds, post-surgical complication wounds, cancer postbiopsy/excision wounds, in conjunction with dermal substitutes, and over skin grafts.

CAUTION, CRITICAL REMARKS, AND RECOMMENDATIONS

The SNaP wound care system has significant advantages in size and convenience for both patients and clinicians, as compared with electri-

cally powered devices. Although the device is currently not recommended for larger more heavily exudative wounds, the device has been successfully used for many types of smaller wounds, including diabetic foot ulcers, venous ulcers, surgical wound dehiscences, pressure ulcers, acute traumatic wounds, and over skin grafts. The size limitation is mostly due to the size of the dressing currently available, which is 15 × 15 cm. Although larger-sized dressings may be available in the future, current maximum wound sizes that are treatable must be covered by this size dressing with enough overlap to form an airtight seal. Ultimately, by improving appropriate usage of NPWT and patient compliance by making NPWT more practical to use, we believe that the SNaP wound care system can significantly improve patient outcomes.^{7,8}

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None.

AUTHOR DISCLOSURE STATEMENT

Kenton D. Fong is an employee of Spiracur, Inc. William A. Marston is an investigator in clinical trials sponsored by Spiracur, Inc. No ghostwriters were used to write this article.

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