Initial Clinical Experience Using a Novel Ultraportable Negative Pressure Wound Therapy Device

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Abstract: Background. Traditional negative pressure wound therapy (NPWT) devices, such as the electrically powered V.A.C.® Therapy System (KCI, San Antonio, TX), are important tools in the treatment of both acute and chronic wounds. The following describes the first clinical experience using a novel, non-electrically powered, ultraportable NPWT device called the Smart Negative Pressure (SNaP™) Wound Care System (Spiracur, Sunnyvale, CA).

Methods. Twelve consecutive adult subjects with chronic wounds ranging from neuropathic wounds to venous stasis ulcers were treated with the SNaP System at an academic outpatient dermatology clinic. Subjects were followed biweekly for complications and wound healing progression over a 4-week period.

Results. Of the 12 subjects treated, 5 achieved complete wound healing within 4 weeks. All subjects demonstrated healing after treatment with the SNaP System, and statistically significant healing was reached at 4 weeks \((P < 0.01)\) for patients who were able to complete the treatment protocol. Use of the SNaP System promoted cleaner wound beds with robust granulation tissue formation. There were no serious adverse events directly related to the device. The most common complaint was mild or moderate wound pain in 3 of 12 subjects.

Conclusion. These findings support the safety and potential clinical utility of a new ultraportable NPWT device for the treatment of chronic wounds.

Negative pressure wound therapy (NPWT) is an important tool for treatment of acute and chronic wounds, including traumatic and post-surgical wounds, diabetic ulcers, venous stasis ulcers (VSU), and pressure ulcers.1–6 The most widely used NPWT device is the V.A.C.® Therapy System (KCI, San Antonio, TX). This and other currently available NPWT devices use an electrically powered pump to deliver negative pressure. Currently available systems can be heavy, bulky, noisy, expensive, difficult to procure, and often interfere with a patient’s normal activities. With the limitations of current systems in mind, the SNaP™ (Smart Negative Pressure) Wound Care System (Spiracur, Sunnyvale, CA) was developed. The present study represents the first human experience using this device. The first generation (Gen 1.0) of the device and dressing was tested. The tested devices
weigh less than 4 oz, do not require an electric pump, are completely silent, and are fully disposable after use. Benchtop testing demonstrated that the device was able to deliver NPWT at a near constant level over extended periods of time in a similar fashion to electrically powered pumps (see Supplemental Online Appendix*). This first experience using the SNaP device on human subjects was designed to evaluate the safety, feasibility, and efficacy on a small group of consecutive subjects with chronic wounds over a 4-week period at an academic outpatient dermatology clinic.

(*Editor’s Note: The Supplemental Appendix will accompany the article on the WOUNDS website the week of September 20, 2010.)

Methods

SNaP Wound Care System. The SNaP System (Gen 1.0) is a wearable dressing that consists of five basic elements: the vacuum/exudate cartridge, reset key, wound interface layer (gauze), hydrocolloid layer with integrated nozzle, and extension tubing (Figure 1, interface layer not depicted). It can be worn on a subject’s leg for lower extremity ulcers (Figure 2). Three different pre-set pressure levels (-75 mmHg, -100 mmHg, and -125 mmHg) are available. The total exudates capacity of each cartridge is approximately 80 mL. Instead of an electrically powered pump, a constant force spring creates negative pressure, allowing a near-constant level of negative pressure to be delivered even in the face of wound exudates. The first generation device was tested in these experiments, though new generations of the device are now available. The SNaP System is a gauze-based system; however, these early experiments were performed using a medical grade foam interface layer for experimental purposes only. At the time, the authors were still defining the optimal materials for the device.

Subject recruitment and selection. All subjects were enrolled after approval from the Stanford Human Subjects Institutional Review Board and the trial was registered at www.clinicaltrials.gov prior to initiation. Subjects were recruited from patients receiving treatment in the Stanford Dermatology Clinic or from printed media advertisements.

Inclusion criteria were: lower extremity or other wound < 6 cm in widest diameter with intact epithelium of > 2 cm surrounding the wound edges. The ulcer must not have healed for > 14 days using traditional treatments. Subjects also had to be willing and able to give informed consent.

Exclusion criteria were: active wound infection, 2+ or greater lower extremity pitting edema; ankle brachial index (ABI) < 0.6, history of malignancy at wound site, uncontrolled diabetes, thick eschar at wound base after debridement, wound location not amenable to forming an air-tight seal for device placement, ulcers due to inflammatory conditions (eg, pyoderma gangrenosum, rheumatoid arthritis, vasculitis, cryoglobulinemia, active necrobiosis lipoidica diabeticorum, lupus or pancreatic
panniculitis, cryofibrinogenemia, calcinosis cutis (and scleroderma), Raynaud’s syndrome, current immunosuppression, current smoker (must have quit for at least 3 weeks), wounds with exposed bone, blood vessels, or tendon, pregnancy, inability to give informed consent, or inability to comply with study procedures, including lack of telephone access.

**Wound treatment protocol.** After a full medical history, physical examination, and photographic documentation were performed, subject wounds were debrided per standard of care. The periwound skin was then cleaned and shaved. Silverlon® Negative Pressure Dressing ([NPD], Argentum Medical, Chicago, IL) was cut to size and placed directly onto the wound; sterile foam dressing was then placed over the Silverlon NPD. A modified hydrocolloid dressing (Duoderm®, ConvaTec, Skillman, NJ) with an integrated nozzle was placed over the sponge. If the surrounding skin was friable, a protective layer of Duoderm was placed around the wound. Mastisol® ointment (Ferndale Laboratories, Ferndale, MI) was used with some subjects to improve dressing adhesion. Finally, the cartridge was attached to the dressing and negative pressure was activated. Subjects were started at -125 mmHg; NPWT was reduced to -100 mmHg or -75 mmHg if the pressure level was not tolerated due to discomfort. Tegaderm® dressings (3M, St. Paul, MN) were used to reinforce the dressing seal when necessary. A compression dressing was utilized with the device for patients with venous stasis disease. Subjects were taught how to use the device at home. They were instructed to return to clinic for adjustment of the dressing within 24 hours if the cartridge became full or an adequate seal could not be maintained. If they were unable to return within this timeframe, subjects were instructed to remove the SNaP System and to resume traditional dressing changes. In some cases, the patient was given an extra cartridge and taught to change the cartridge themselves if their exudates canister became full. Subjects were seen in the clinic 2–3 times per week for dressing changes, depending on the treating clinician’s impression of the wound. At follow-up visits, a brief subject questionnaire was given and the dressing was changed. The wound was photographed and assessed to evaluate for complications such as further skin breakdown or infection. Wound size was determined by Visitrak® (Smith & Nephew, Fort Lauderdale, FL) tracing analysis. The wound size at 4 weeks was compared to baseline size using a paired $t$-test (two-tailed). The values were considered to be significant at a level of $P < 0.05$.

**Results**

A summary of patient results is shown in Table 1. Average patient age was 56.8 (SD ± 20.9) years. Average age of wounds treated was 6.1 (SD ± 8.6) months. All twelve patients who were treated with the device experienced wound healing within the first 4 weeks of treatment. However, only 6 of the 12 patients were able to complete all study requirements (Table 1 lists reasons for early exits), 5 of whom were able to completely heal their wounds within 4 weeks. Figure 3 shows subject 3, whose wound completely healed during the study. The patients who did not heal were either lost to follow-up,

![Figure 3](image-url). Subject 3 with traumatic lateral ankle ulcer. Note near closure of the wound after 2 weeks of treatment and complete healing by 3 weeks.
were subsequently found to have underlying cancer in the wound, or were unable to maintain an adequate seal due to wound characteristics. All subjects and/or their caretakers were able to learn how to use the SNaP System within 10 minutes of instruction. There were no serious adverse events related to the study device; the most common adverse event was mild or moderate wound pain in 3 of 12 subjects, not necessarily related to device use. Additionally, 3 of 12 subjects reported peri-wound irritation or pain, which was mild or moderate. Of the 11 individuals who used the device on the lower extremity, 3 noted mild or moderate ipsilateral knee pain. There were no wound infections or wound enlargements during the study for any subject.

Visitrak results. The six patients who were able to complete the study experienced an average 97.2% reduction in wound surface area at 4 weeks after initiation of treatment \((P < 0.01, \text{ Figure 4})\). Five of the six subjects who were able to complete the study achieved complete healing. Subject 1 was a patient with burned-out necrobiosis lipoidica diabeticorum (NLD) and she experienced a 3.8% decrease in wound size at 3 weeks before discontinuation of the study. However, subject 1 demonstrated significant granulation tissue formation during treatment (Figure 5). Additionally, subject 7 achieved 86% wound closure by day 9, but was unable to comply with the protocol due to transportation-related issues.

Survey results. Upon exit of the study, survey results were collected to evaluate subject opinions. Overall, subject feedback was overwhelmingly positive (Table 2). Subjects agreed that learning to use the device was easy with only 1 subject disagreeing. The SNaP System allowed all subjects to perform most activities of daily living (ADLs), including normal social activities, walking,
Activity changes from using the device were restricted to day-to-day activities such as running, swimming, and playing kickball. One patient who wore shorts and skirts felt that the device interfered with her social activities, but the remainder of subjects did not note any interference with social activities. One patient reported difficulty positioning the device during sleep. At the final visit, 9 of 11 subjects would reuse the device if another chronic wound occurred. Almost all subjects (10 of 11) strongly agreed that the device was worthwhile for their wounds.

**Discussion**

Acute and chronic wounds are a major healthcare burden. In developed nations, chronic leg ulcers affect 1%–2% of the adult population. Treatment of these wounds requires 1%–2% of the total national healthcare budget of some countries.7–9 Numerous clinical publications demonstrate the efficacy of NPWT for the treatment of both acute and chronic wounds.1–6,10,11 This study reports the first experience using a new ultraportable NPWT device to treat a series of 12 consecutive adult subjects at an academic outpatient clinic. All subjects had either complete healing or marked improvement in their wound. Subject satisfaction was very high for the device. Activity changes from using the device were restricted to daily activities such as running, swimming, and playing kickball. One patient who wore shorts and skirts felt that the device interfered with her social activities, but the remainder of subjects did not note any interference with social activities. One patient reported difficulty positioning the device during sleep. At the final visit, 9 of 11 subjects would reuse the device if another chronic wound occurred. Almost all subjects (10 of 11) strongly agreed that the device was worthwhile for their wounds.
high impact physical activities. No major safety issues arose during the study.

In 2008, Keskin and colleagues reported that patients treated with the V.A.C. demonstrated a statistically significant increase in anxiety as scored on two separate anxiety evaluation tools. They argue that anxiety may be one reason some patients were not willing to continue therapy with the device. Additionally, they suggest that restriction of mobility may have been one of the major contributing factors to their observed outcome. Leijnen et al also suggest that immobilization from NPWT may have clinically important effects. They published two case reports where V.A.C.-treated patients experienced reduced mobility and had thromboembolic events. Because immobility is a major risk factor for the development of deep venous thrombosis and thromboembolism, their experience led them to recommend the use of antithrombotic prophylaxis when the V.A.C. is used on the extremities as an outpatient. Because the SNaP System does not utilize an electrically powered pump and weighs less than 4 oz, it may not have the same issues resulting from mobility restriction as traditional NPWT devices.

Another potential advantage of a non-electrically powered NPWT system may be increased safety. A major concern for NPWT is the risk of life-threatening exsanguinations, and several cases have been reported. A recent FDA alert concerning this potential complication was published November 13, 2009. Without an electrically powered pump mechanism, this type of exsanguinations would be impossible with the SNaP System.

**Conclusion**

This case series demonstrates the potential clinical utility of the SNaP System. Although the commercial version of the SNaP System is a gauze-based system, sterile foam was used in this small initial case series for experimental purposes and data should be interpreted with this in mind. Data from subsequent studies utilizing antimicrobial gauze with the SNaP system have shown similar, possibly superior, outcomes to foam-based studies for the targeted wound type. This ultraportable NPWT delivery system has several advantages over traditional pumps including increased mobility, silent operation and improved discreteness, simplified application and usage, less time-consuming procurement, and potential decreased cost. These qualities may render the SNaP System a significant addition to the armamentarium of the wound care specialist. Many other potential applications of the SNaP System to wound care are currently being actively explored, such as utilizing the SNaP System to prepare wounds prior to use of skin grafts or dermal substitutes such as Apligraf® (Organogenesis, Canton, MA), preparation of wounds prior to definitive closure after excisional biopsies, and prevention of wound healing complications after surgical wound closure. Although this initial clinical experience using the SNaP System was encouraging, further studies evaluating the comparative effectiveness of the SNaP System in the clinical setting are still required.

**References**


