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SYMPOSIUM

The SNaP™ Wound Care System: A Case Series Using a Novel Ultraportable Negative Pressure Wound Therapy Device for the Treatment of Diabetic Lower Extremity Wounds

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Abstract

Although there is significant evidence supporting the use of negative pressure wound therapy (NPWT) for the treatment of lower extremity diabetic ulcers, currently available electrically powered NPWT systems are not ideally suited for treating smaller diabetic foot ulcers. The Smart Negative Pressure (SNaP™) Wound Care System is a novel, ultraportable device that delivers NPWT without the use of an electrically powered pump. It was specifically designed to meet the wound care needs of patients with diabetes. The SNaP System is compact, silent, mobile, easy-to-use, and available off-the-shelf. It is fully disposable and may offer other important benefits over electrically powered systems to both the clinician and patient. We review the evidence for use of NPWT for the treatment of diabetic wounds and discuss the potential benefits of this new NPWT technology for patients with diabetes. We also present a case series of four difficult lower extremity diabetic ulcers that were successfully treated with the SNaP System. This study suggests that the SNaP System may be a useful addition to the armamentarium of the diabetic wound care clinician.

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Introduction

Lower extremity ulceration is one of the most serious complications of diabetes. The Centers for Disease Control and Prevention estimated that 20.8 million people suffered from diabetes mellitus in the United States in 2005. Worldwide, the problem is even larger, with the World Health Organization estimating that by the year 2025, more than 325 million people worldwide will be diagnosed with diabetes. It is estimated that among patients with diabetes, the prevalence of foot ulcers ranges from 4 to 10%.[1,2] Diabetic foot wounds often become infected and are associated with frequent hospital admissions.[3] In addition, approximately 50% of diabetic foot wounds become infected during their life cycle, and 20% of these patients will require some form of lower extremity amputation.[3] Diabetic foot ulcers are a major burden to the health care system, with estimated costs

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Abbreviations: (AMWT) advanced moist wound therapy, (FDA) U.S. Food and Drug Administration, (NPWT) negative pressure wound therapy, (SNaP) smart negative pressure, (VAC) vacuum assisted closure

Keywords: Apligraf®, chronic ulcers, diabetic foot ulcers, NPWT, negative pressure wound therapy, SNaP™ System, topical negative pressure, ultraportable negative pressure wound therapy, wound VAC®

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as high as $45,000 per patient, not counting the associated psychosocial, quality-of-life, and lost productivity costs.[3,4]

Substantial evidence has been published supporting the use of negative pressure wound therapy (NPWT) as a safe and effective modality in the treatment of diabetic foot ulcers, including at least three prospective randomized controlled trials.[2,5,6] In 2003, Eginton and colleagues reported the results of a randomized crossover-design trial comparing wound healing between conventional moist dressings and NPWT in diabetic foot ulcers.[6] They found that NPWT treatment resulted in a significantly greater decrease in wound volume and depth compared to moist gauze dressings (59 versus 0%, and 49 versus 8%, respectively).[6] In 2005, another randomized control study was published by Armstrong and associates in *The Lancet*.[5] This study examined 162 diabetes patients at 18 centers in the United States who had partial foot amputation up to the transmetatarsal level. Subjects were randomly assigned to either NPWT or modern dressings. A greater proportion of patients in the NPWT group had healed wounds than in the control group (56 versus 39%) by the end of the study ($p < .040$). In addition, they found that NPWT-treated wounds also healed faster ($p < .05$) with faster granulation tissue formation ($p < .002$). Most recently, Blume and colleagues published their multicenter randomized controlled trial in 342 diabetic foot wound patients with outcomes that supported the findings of the Armstrong study.[2] In this trial, NPWT was compared to advanced moist wound therapy (AMWT) with standard off-loading therapy as needed. Blume and colleagues found that a greater proportion of foot ulcers completely healed with NPWT (73 of 169, 43.2%) than with AMWT (48 of 166, 28.9%) within the 112-day active treatment phase ($p = .007$). The Kaplan–Meier median estimate for 100% wound closure was 96 days (95% confidence interval, 75.0–114.0) for NPWT and was not determinable for AMWT ($p = .001$).

Although numerous NPWT systems are available on the market today, including the KCI Wound VAC® (vacuum assisted closure) (KCI Licensing, Inc., San Antonio, TX) and the Smith & Nephew RENASYS® (Smith & Nephew, Inc., St. Petersburg, FL) systems, these systems have a number of drawbacks. Some of these shortcomings relate to their size and bulk, time-consuming dressing application process, noise level, need for an electrical power source, difficult procurement process, and associated administrative costs.[7-9] In addition, these powered systems were originally designed for very large complex wounds such as complete midline abdominal wound dehiscence or large sarcoma resection sites, and are not ideally suited for use on smaller wounds. However, according to Margolis and colleagues who examined data from over 31,000 diabetic neuropathic foot ulcers, the mean and median size of diabetic foot ulcers are only 5.886 and 1.18 cm^2, respectively.[10] In spite of the compelling evidence for the benefits of NPWT for the treatment of diabetic foot ulcers, it is often impractical to treat the smaller-sized ulcers in active patients with current bulky electrically powered NPWT systems. This is especially true in the outpatient wound care clinic setting where many of these patients receive care and procurement of rental-based NPWT systems that can be difficult and time-consuming. These considerations have translated to relatively few diabetic ulcer patients receiving therapy with NPWT. There is a need for a NPWT device that is easy to procure in the outpatient clinic setting and specifically designed to address the requirements of the diabetic wound care patient.

SNaP™ Wound Care System

The Smart Negative Pressure (SNaP) Wound Care System (Spiracur, Inc., Sunnyvale, CA) is a novel ultraportable NPWT device (**Figure 1**). The SNaP System is the first device of its kind cleared by the U.S. Food and Drug Administration (FDA) to promote wound healing in a wide variety of wound types. This system does not require an electrically powered pump. Instead, it utilizes specialized springs to generate continuous negative pressure at the wound bed. Unlike current powered NPWT devices, the SNaP Wound Care System is specifically designed to address smaller wounds such as the typical

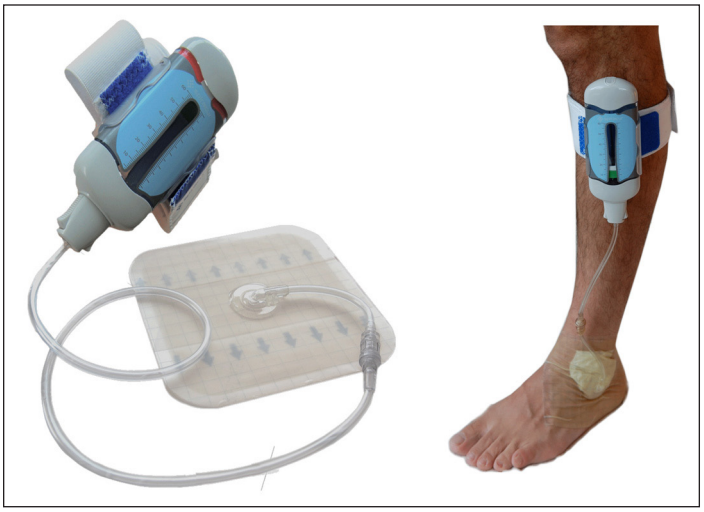

Figure 1. The ultraportable SNaP NPWT System. Note that the red indicator (left) is seen at the top of the cartridge when full and the green indicator (right) is seen when negative pressure is being delivered.

diabetic lower extremity wound. Because it is fully disposable and does not require a rental model for procurement, the SNaP Wound Care System is available "off-the-shelf" for immediate use just like any other dressing stocked by the clinic.

The SNaP System consists of three basic elements: a cartridge, a hydrocolloid dressing layer with integrated nozzle and tubing, and an antimicrobial gauze wound interface layer. The cartridge is capable of delivering three different preset pressure levels (–75, –100, and –125 mmHg). Unlike other systems, the source of the negative pressure doubles as the storage canister, allowing the device to be reduced in size to roughly that of a modern cell phone. Because of its reduced size and weight (approximately 2.2 oz), the SNaP System can be worn discreetly on a patient's leg, completely hidden under normal clothing. Also, because the system does not require an electric pump, it is completely silent, giving patients a discreet method of treatment not possible with traditional electrically powered NPWT systems.

The dressing is made of a proprietary hydrocolloid material that provides excellent periwound protection for the patient's healthy skin, excellent dressing application handling properties, as well as a robust seal about the wound for negative pressure delivery. The suction port and tubing are fully integrated into the dressing, simplifying the application process.

Previous studies have shown that negative pressure delivery by the SNaP System is similar to powered pumps in biomechanical testing and in an animal wound healing model.[11] Clinical series have demonstrated that the SNaP System can be used safely and effectively for treating chronic wounds.[12] In addition, the SNaP System has been cleared by the FDA for the treatment of diabetic ulcers. We present here a clinical series of diabetes patients treated successfully with the SNaP System.

Methods

A prospective observational case series was performed to evaluate the safety and efficacy of the SNaP System for the treatment of difficult lower extremity wounds. The study was performed at the O'Connor Wound Care Center in San Jose, California with the approval of the O'Connor Hospital Institutional Review Board.

Potential subjects were screened for eligibility at the O'Connor Wound Care Center upon referral or during routine treatment visits. Written informed consent was obtained for those patients who met the study eligibility criteria, and NPWT was initiated using the SNaP Wound Care System. Subjects were followed for up to four months or to wound closure, whichever came first.

All outpatients underwent standard wound care clinic intake evaluations, including history, physical exam, and wound assessment. Debridement of necrotic tissue was performed per standard care for the specific wound type. Duration of NPWT was determined by the treating clinician, and NPWT was discontinued if the clinician felt that adequate healing had occurred to no longer require its use.

Case Study Results

Case 1

A 55-year-old insulin-dependent man with diabetes presented with a 2.7 cm diameter nonhealing wound at

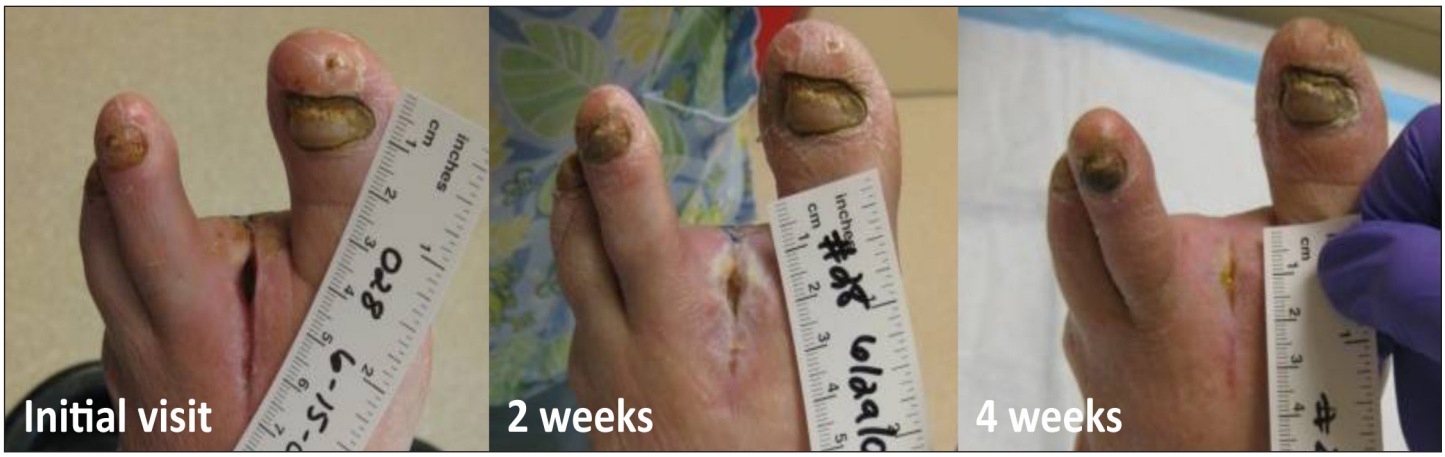

Figure 2. Case 1: A 55-year-old male with diabetes with a toe amputation site wound that healed in four weeks after initiation of SNaP therapy.

a left second toe amputation site (**Figure 2**). The patient's history was significant for tobacco use. He had a toe amputation four months prior due to gangrenous infection and osteomyelitis. The wound was surgically reopened due to an infection three weeks before initiating SNaP therapy. Previous treatments for the ulcer included wet-to-dry dressing changes and offloading, with minimal progression. The patient was treated for four weeks with the SNaP System before observing complete wound closure.

Case 2

A 65-year-old insulin-dependent man with diabetes presented with a 2.3 cm diameter ulcer on the right plantar foot in the region of the first metatarsal head (**Figure 3**). The patient had a history of end-stage renal disease, chronic corticosteroid use, Charcot disease, hyperlipidemia, and hypertension. He reported having multiple previous ulcerations in the same area on his foot, and that the current ulcer was present for five months prior to the SNaP therapy application. Past treatments for the ulcer included offloading, iodoform, wet-to-dry dressing changes, and attempted surgical closure. The patient was treated for four weeks with the SNaP System and an offloading orthotic before observing complete wound closure at five weeks.

Case 3

A 41-year-old insulin-dependent man with diabetes presented with a 3.7 cm diameter nonhealing left lateral ankle ulcer (**Figure 4**). The patient history was significant for poor glucose control and anemia of chronic disease. The patient originally presented with severe swelling of his left ankle and was found to have an abscess requiring surgical drainage and hospital admission. The resulting wound that occurred after drainage was present for five weeks prior to having the SNaP System applied. He noted an increase in wound size during the prior two weeks leading up to application. Previous treatments for the ulcer included wet-to-dry dressing changes, systemic (Zosyn®, daptomycin) and topical antibiotics (Silvadene®, tobramycin), warm water soaks of the foot, and aggressive debridement. The patient was treated for six weeks with the SNaP System until full granulation was achieved. After SNaP therapy, a single Apligraf® (Organogenesis, Inc.,

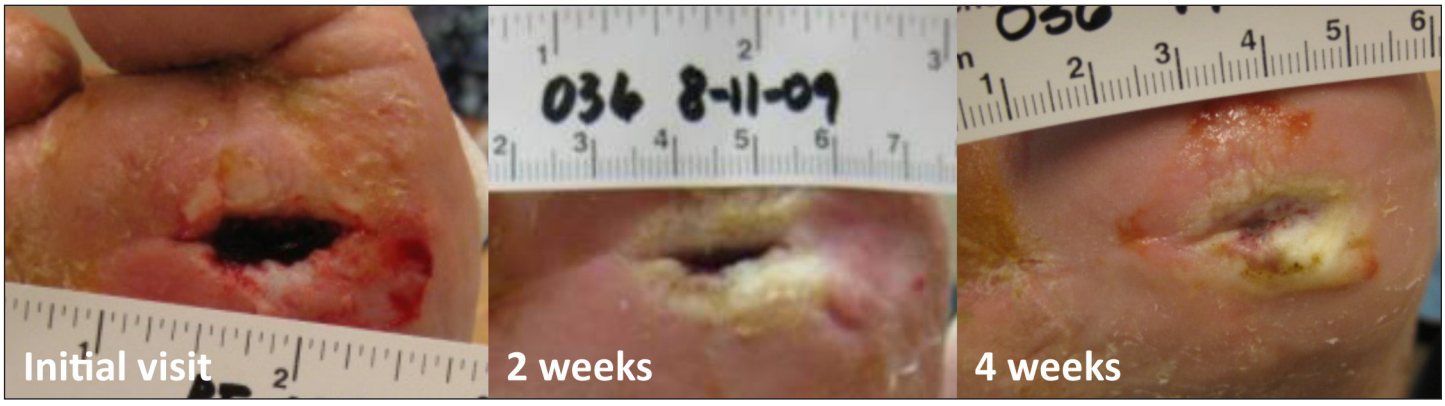

Figure 3. Case 2: A 65-year-old male with diabetes with plantar foot wound that healed in five weeks after initiation of SNaP therapy.

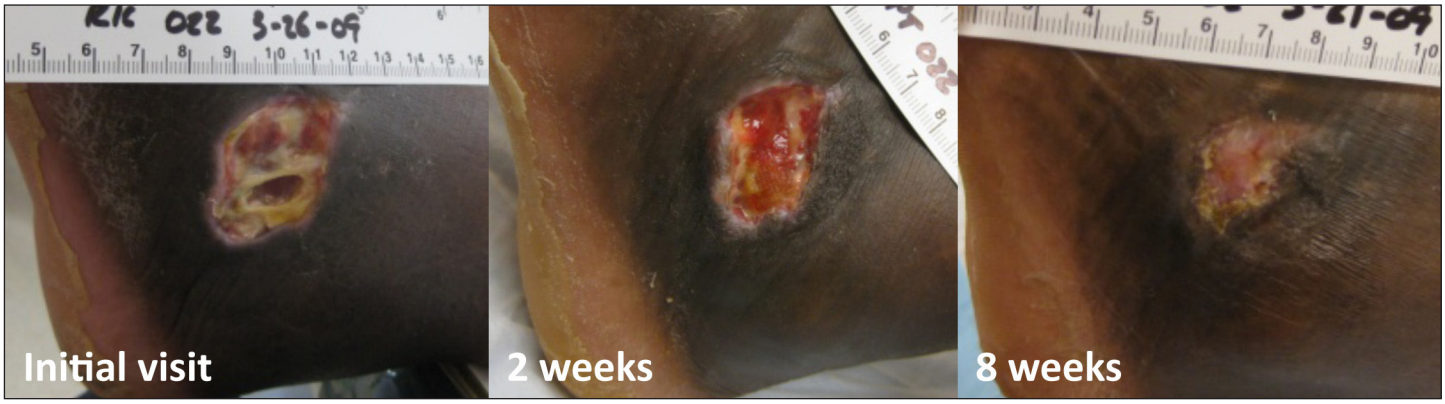

Figure 4. Case 3: A 41-year-old male with diabetes with ankle wound that healed in six weeks after initiation of SNaP therapy and a single Apligraf application.

Canton, MA) application was then performed, with complete closure of the wound at eight weeks.

Case 4

A 69-year-old man with diabetes with a history of peripheral vascular disease, venous stasis disease, and hypertension presented with an 8.3 cm diameter left posterior heel ulcer (**Figure 5**). The ulcer first developed as a pressure sore 19 years ago during an intensive care unit admission for a 50% total body surface area burn, and had received multiple treatment modalities in the past, including failed skin grafting, multiple Apligraf placements, and powered NPWT treatment. Since the wound first occurred, he had never had complete wound closure with any intervention. Biopsy of the wound was negative for malignancy. The patient had a history of noncompliance with therapy; for example, he would disconnect the tubing from his previous powered NPWT device from the pump during ambulation. The patient was treated with aggressive debridement, layered compression, and SNaP therapy, which the patient was able to fully comply with. Complete granulation of the wound bed occurred at four weeks at which point the patient finished treatment with the SNaP System and was then skin-grafted. The patient achieved complete wound closure at approximately eight weeks after initiation of SNaP therapy.

Discussion

The SNaP Wound Care System was shown to be a safe and effective therapy for the treatment of difficult-to-treat lower extremity diabetic ulcers at our clinic. While there is significant evidence that NPWT can be an important adjunctive tool in the treatment of this disease,[2,3,5,6] the number of diabetic ulcers that receive NPWT treatment remains low due to several issues with the most widely available electrically powered systems. Specifically, powered NPWT devices are bulky, restrictive of patient activity, difficult to procure in the outpatient setting, expensive, and time-consuming to apply. These powered devices were designed for much larger wounds and are not ideally suited for the needs of the smaller wounds typically found in patients with diabetes.[10] The SNaP Wound Care System was specifically designed for the treatment of smaller lower extremity wounds and wounds earlier in the disease process. Its size, "off-the-shelf" configuration, simpler application process, and ultraportability makes it ideal for treating diabetic foot ulcers, especially in this mostly outpatient population.

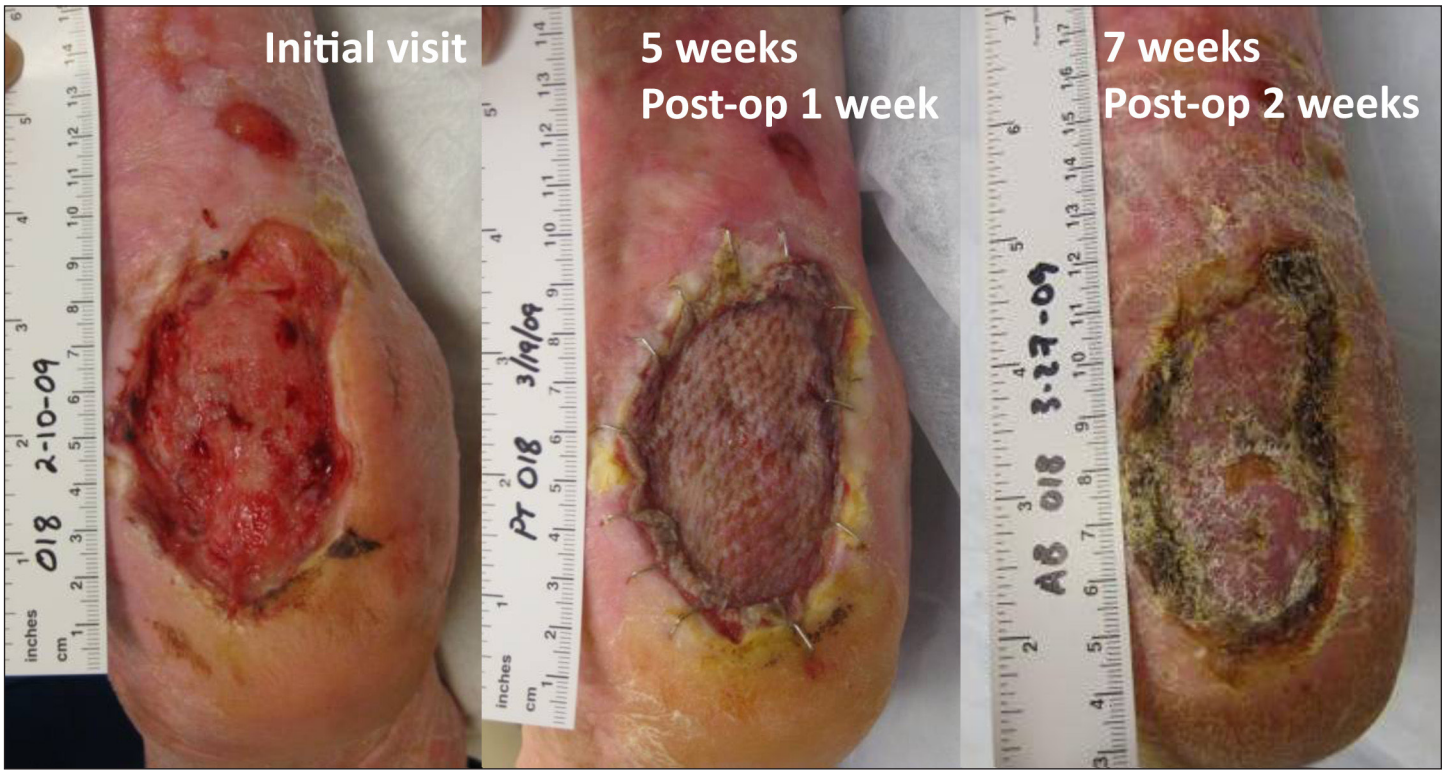

Figure 5. Case 4: A 69-year-old male with diabetes with a 19-year-old heel pressure sore that healed in around eight weeks after initiation of SNaP therapy and skin grafting.

In our clinic, we utilize multiple modalities to heal wounds, including the frequent use of Apligraf, a bilaminar tissue engineered biological dressing that has established effectiveness in treating diabetic and venous ulcers.[13,14] Because the adherence and effectiveness of Apligraf and other tissue-engineered dressings depend on adequate wound bed preparation, NPWT may play an important role in speeding the preparation of the wound bed prior to their use. In this study, we successfully used the SNaP System to prepare wounds prior to Apligraf placement, and we believe that this kind of use of NPWT prior to application improves Apligraf effectiveness and overall wound healing outcomes. However, future studies will be needed to further elucidate this hypothesis.

Conclusion

The SNaP Wound Care System can be an effective tool in treating highly refractory chronic diabetic ulcers, and may be especially suited for the outpatient diabetes patient. The advantages in size and convenience for both patients and clinicians, as compared to powered devices, make the SNaP Wound Care System a desirable choice for us and for our patients with appropriate wounds that would benefit from NPWT. This study is limited to a small case-series, but an ongoing randomized controlled trial of the SNaP Wound Care System may further elucidate the value of this novel technology in the treatment of diabetic wounds.

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Disclosures:

Kenton D. Fong and Justin Ryu are employees of Spiracur, Inc.

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