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## Use of a Portable, Single-use Negative Pressure Wound Therapy Device in Home Care Patients with Low to Moderately Exuding Wounds: A Case Series

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## Abstract

Negative pressure wound therapy (NPWT) is widely used in the management of acute and chronic wounds. The purpose of this 8-week study was to evaluate outcomes of using a new canisterless, portable, single-use NPWT system in patients with wounds treated in a Canadian community healthcare setting. The device is designed to provide negative pressure at  $80 \pm 20$  mm Hg, 24 hours a day of continuous usage, for a maximum wear time of 7 days. Data on wound outcomes, including exudate levels, wound appearance, and wound area, were collected weekly by a Registered Nurse as part of routine practice. When treatment was discontinued, patients and nurses were asked to rate their satisfaction with the device. Data from patients who had used a conventional NPWT device to manage their wounds were retrospectively abstracted from their medical records. In the prospective study, conducted between October 2011 and July 2012, 326 patients (median age = 61 years; range 17–91 years) with wounds of mixed etiology (53 pressure ulcers, 21 venous leg ulcers, 16 diabetic foot ulcers, and 15 traumatic and 221 surgical wounds) were treated for a maximum of 8 weeks with the portable NPWT device. The majority of patients (228 out of 326; 68%) achieved complete wound closure within 8 weeks of treatment. The Kaplan-Meier estimate of median time to healing of all wounds was 9 weeks. The majority of patients (318 patients, 97%) reported they were pleased or satisfied with the dressing performance. Nurses indicated satisfaction with the dressing performance for all but two patients (99%). The majority (89%) of patients managed with conventional NPWT ( $n = 539$ ) had an open surgical wound with moderate or high levels of exudate. Healing rates in the portable and conventional NPWT group were similar (10% to 11% per week). Portable, single-use NPWT has the potential to deliver good wound outcomes in community care settings and simplify the use of negative pressure for nurses and patients. Additional research is needed to evaluate treatment efficacy and cost effectiveness.

**Keywords:** case reports, negative-pressure wound therapy, wounds, community health care

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**Potential Conflicts of Interest:** Mr. Trueman and Mr. Rossington are employees of Smith & Nephew, Hull, United Kingdom.

Negative pressure wound therapy (NPWT) is a commonly used treatment modality for a range of chronic and acute wounds — ie, wounds that have failed to proceed through an orderly and timely reparative process to produce anatomic and functional integrity and/or wounds healing by secondary intention.<sup>1,2</sup> These wounds include pressure ulcers, venous leg ulcers, and diabetic foot and acute wounds. The mechanical forces created by NPWT may facilitate wound healing through a number of mechanisms, including removal of excess exudate, reduction in periwound edema, and increased perfusion.<sup>3</sup> Combined with the physical forces exerted by the negative pressure, which draw the wound edges together, this can result in improved wound outcomes.

Evidence of the effect of negative pressure in wound therapy dates back to the 1970s.<sup>4</sup> However, commercial negative pressure systems for wounds have been available only for the last two decades. During this time, the body of evidence on the use of NPWT systems has increased. Several studies comparing NPWT to standard therapy (commonly gauze or bolster dressings) have shown improved clinical outcomes following the use of NPWT. Improved outcomes were reported in a multicenter, randomized trial by Armstrong et al<sup>5</sup> in patients with diabetic foot wounds following partial amputation and in a large, retrospective study by Frykberg and Williams<sup>6</sup> that included a lower incidence of new amputations in patients with diabetic foot ulcers following introduction of NPWT when compared to standard wound dressing therapy. In venous leg ulcers, Vuerstaek et al's<sup>7</sup> randomized, controlled study reported improved time to healing; the study compared intervention with NPWT with the conventional therapy for wound bed preparation before skin grafting. Improvements in wound outcomes have been reported in robust studies of closed (sutured) surgical wounds, including randomized controlled trials, notably in spinal and orthopedic trauma reported by Labler et al<sup>8</sup> and Stannard et al.<sup>9</sup> The clinical evidence is complemented by two economic studies<sup>10,11</sup> that suggest that despite having a higher acquisition cost than conventional wound therapies, NPWT may be a more cost-effective option as a result of the potential for improved healing rates and reductions in the use of other healthcare resources (eg, nursing time, hospitalizations, and surgical procedures).

When NPWT initially was introduced, it was reserved for use on the most complex wounds. However, today NPWT is more widely used, and the number of NPWT devices available to healthcare professionals has increased substantially and includes portable systems. Conventional NPWT systems consist of a suction pump to generate negative pressure and canisters for the collection of wound exudate, along with a variety of wound dressing kits to deliver the therapy to the wound site. Although this type of NPWT system has been most widely used and studied, challenges remain with regard to patient and user acceptance. These systems can be bulky and in some cases have been reported to impede an

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### Key Points

- The authors describe the use of a portable, single-use NPWT device in 326 home care patients with a variety of wounds that had low levels of exudate.
- Most wounds healed within the 8-week study period, few patients withdrew from the study, and patient/nurse satisfaction was good.
- Prospective, controlled clinical studies are needed to evaluate the efficacy and cost-effectiveness of this NPWT device to other available treatment modalities.

individual's ability to go about his/her activities of daily living, such as ability to lead an acceptable social life.<sup>12</sup>

More recently, portable NPWT systems have been developed that redefine access to NPWT, particularly in non-hospital settings. One portable NPWT system was designed to address potential patient mobility concerns related to the presence of a vacuum system connected to large canisters. PICO™ (Smith & Nephew, Hull, United Kingdom) is the first simplified, portable NPWT system that does not require a canister.<sup>13,14</sup> It is a single-use device that can be discarded after use, reducing the need for reprocessing, as is the case with conventional NPWT systems. Each system kit consists of a pump and two sterile dressings. The pump maintains constant negative pressure at 80 mm Hg (nominal)  $\pm$  20 mm Hg to the wound surface. The portable device is approximately the size of a pager and can be carried by the patient in a pocket or handbag or attached to a belt-loop. Traditional NPWT pumps are much larger and typically require a small backpack/shoulder bag for portability. In the new system, exudate is managed by a foam contact layer dressing, over which a superabsorber layer and a film top layer allow for absorption and evaporation of moisture. This obviates the need for a canister to collect the wound exudate and enhances portability. The system is indicated for wounds with low to moderate levels of exudate (<300 mL/week) and is designed to remain in place for a maximum of 7 days. According to manufacturer's recommendations, the duration of treatment may be <7 days if clinical practice or other factors such as wound type, wound size, rate or volume of exudate, orientation of the dressing, or environmental conditions require more frequent dressing changes.<sup>15</sup>

A healthcare professional applies the portable, single-use NPWT and performs dressing changes. The dressings are compatible with standard gauze and foam fillers used in conventional NPWT where this is clinically appropriate, such as in wounds >0.5 cm in depth. In this case, the dressing change interval should be the same as with conventional filler-based NPWT (two to three times a week).

It is the responsibility of the healthcare professional to determine whether the dressing needs to be changed (eg, at day 3 or 4) and the second dressing applied. In many cases, with low levels of exudate, a single dressing will last for 1 week. Clinicians should use gauze to loosely fill to the surface of the wound, taking care to not overpack the wound. Currently, it is not indicated for patients to change their own dressings.

The purpose of this study was to evaluate the effect of this portable NPWT device on healing wounds of varying etiologies and ascertain user satisfaction among patients in a community care setting in Canada.

## Methods

**Patients.** This prospective evaluation was conducted between October 2011 and July 2012. Patients were identified from the records of Nursing Practice Solutions, Inc (NPS), Ontario, Canada, which coordinates the management of NPWT across two large community-based organizations and four acute care hospitals that serve a combined population of more than 3 million patients in Toronto, Canada. Patients who were eligible for treatment with NPWT, based on existing local protocols of care, were offered treatment with the portable device instead of conventional NPWT. Local protocols include best-practice wound care principles — ie, management of blood glucose, offloading the wound where applicable, and nutritional advice. NPWT is made available to patients with wounds that fail to respond to initial wound therapy despite adherence to these principles. Patients of both genders who were at least 17 years old were eligible for treatment. Exudate levels were assessed at recruitment on a 5-point scale (scant, low, moderate, large, copious). Patients were excluded from the evaluation if they were younger than 17 years old, were receiving anti-coagulation therapy, and/or had wound(s) >2 cm in depth and >100 cm<sup>2</sup> in area, had wounds with copious levels of exudate (ie, needing daily dressing changes), required levels of NPWT >80 mm Hg of pressure, and/or had nonhealing wounds that failed to respond to non-NPWT/maintenance therapy.

It was not necessary to seek Institutional Review Board (IRB) approval for the evaluation because execution of the study was considered the use of an approved product in line with current treatment guidelines and no randomization was involved — ie, approved medical devices in Canada are not required to submit to the IRB process. Patients were informed of the use of the new device and were offered the opportunity to withdraw from the evaluation at any time; only verbal consent to participate needed to be provided. Confidentiality/anonymity of patient level data was maintained, and product evaluation at the time of introduction formed part of the organization's quality improvement program.

**Treatment.** The portable device was applied once a patient had been identified as eligible for NPWT and met the inclusion criteria. The dressing was applied and inspected at routine visits by a nurse. Eight advanced practice nurses were responsible for application and change of the dressing as well as for capturing routine data for the evaluation of the product. Dressings were changed according to standard wound management guidelines, typically every 3 to 4 days. The manufacturer provides guidance on when the dressing is saturated with exudate and requires changing through visual aids designed for nurses.

Treatment with the portable NPWT was provided for a maximum of 8 weeks. Treatment was stopped if the wound healed within this time or was deemed to be on a healing trajectory and could be optimally treated with an advanced wound dressing, such as a foam dressing, to complete closure. Healing was defined as the complete closure of the wound. Patients who did not achieve healing during the evaluation period with portable NPWT were managed according to local wound care protocols.

**Data collection.** Data were collated from existing patient records as well as evaluation questionnaires designed for the purposes of this study. Patient gender and age, wound etiology, and previous treatments were derived from patient records. Wound area and volume were recorded at nurse visits at week 3, 6, and 8 by measuring the maximum wound width, length, and depth using a tape measure; wound characteristics (duration of wound, wound area/volume, wound exudate level, change in wound area over time, and healing status) were noted at the same visits. The NPWT pump only needs to be changed weekly, but the nurse could determine if changes should be more frequent. On completion of therapy, patients were asked to report their satisfaction with the product using a nurse-administered questionnaire designed for the purposes of the study. Responses comprised a 3-point scale (pleased, satisfied, dissatisfied) regarding the impact of therapy on activities of daily living specific to showering or bathing, going to work, social engagements, dressing, recreational activities (eg, sports, gardening), climbing stairs, housework, cutting grass, cooking, laundry, and sleep. The nurses asked the questions and documented the answers.

Nurse satisfaction with the qualities assessed by patients also was evaluated using the same 3-point scale administered to patients (pleased, satisfied, dissatisfied). Nurses also were asked, "How long did it take to apply the dressing?" Responses were provided via a categorical scale of options including 5 to 10 minutes, 10 to 15 minutes, 15 to 20 minutes, 20 to 30 minutes, 30 to 40 minutes, or 40+ minutes. Satisfaction with the device and the dressing were assessed separately. Nurses were asked to rate their satisfaction in relation to each patient treated at the completion of their treatment. In relation to the patient and nurse satisfaction questionnaires, it was not possible to blind patients or nurses to their treatment allocation, given the physical differences between the portable and traditional NPWT devices.

**Table 1. Patient and wound characteristics of portable negative pressure wound therapy (NPWT) and conventional NPWT patient groups.**

	Portable NPWT (prospective)	Conventional NPWT (retrospective)	P value
Number of patients	304	539	
Male (%)	49%	43%	
Mean age in years (median)	57 (60)	50 (52)	<0.001
Mean duration of wound (weeks) (range)	8.8 (1–68)	6.6 (0–75)	<0.001
Median wound area at baseline (cm <sup>2</sup> )	20 (range: 0.1–99)	24 (range: 2–99)	<0.001
Median wound volume at baseline (cm <sup>3</sup> )	42 (range: 0–220)	77 (range: 5–396)	<0.001
<b>Wound type</b>			
- Pressure ulcers	53 (16%)	33 (6%)	
- Leg ulcers	21 (6%)	3 (1%)	
- Diabetic foot ulcers	16 (5%)	15 (3%)	
- Surgical/open	221 (68%)	482 (89%)	
- Trauma	15 (5%)	6 (1%)	
<b>Level of exudate</b>			
- Light	85%	8%	
- Moderate	15%	92% (May include data of large amounts of exudate)	

All data collected were maintained in the patient's record. For the purposes of the evaluation, de-identified data were extracted from patient records and entered into a single database by a statistician employed by NPS, Inc. for analysis.

**Retrospective data.** Following completion of the evaluation, data were retrieved from records of patients treated with conventional NPWT in the same community care setting between August 2009 and July 2012. Attempts were made to identify a cohort of patients treated with conventional NPWT (V.A.C. Therapy®, KCI, San Antonio, TX; and RENASYS, Smith & Nephew, St. Petersburg, FL). The previously mentioned statistician reviewed records of all patients treated with traditional NPWT. To match patients to the portable NPWT-treated population, data were excluded from the analysis if patients were <17 years of age, were receiving anti-coagulation therapy, had a wound of >2 cm depth, a wound and/or wound area >100 cm<sup>2</sup>, and/or copious levels of exudate (equivalent to needing daily dressing changes). Because traditional NPWT delivers >80 mm Hg of suction, that variable was different from the portable NPWT group.

No attempts were made to match other patient variables.

**Data analysis.** All data were entered into and analyzed by SAS version 9.1.3 SP4 (SAS Institute, NC). Descriptive statistical methods were used to report the categorical variables; findings were presented as percentages and absolute values. Findings were reported as integer values and as such rounding errors may occur in the presentation of the findings. A Kaplan-Meier estimate also was used separately for

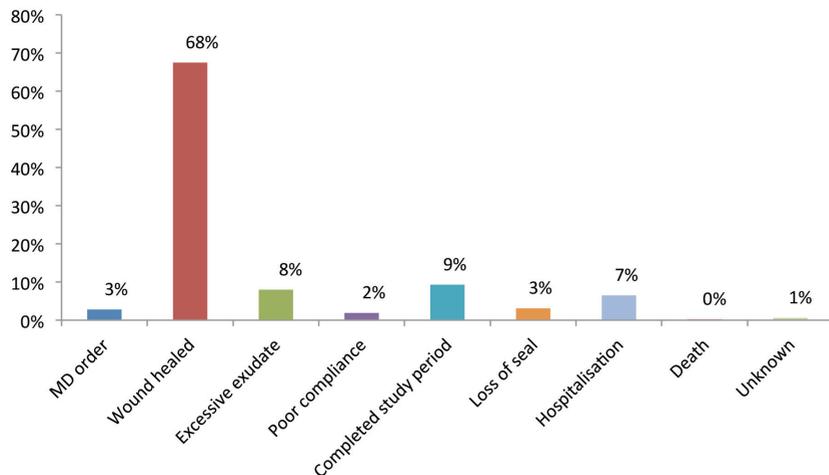
the median time to healing; corresponding 95% confidence intervals were used to calculate median time to wound healing. Wound area was monitored at each visit, and the mean percentage reduction in wound area calculated at weeks 3, 6, and 8.

## Results

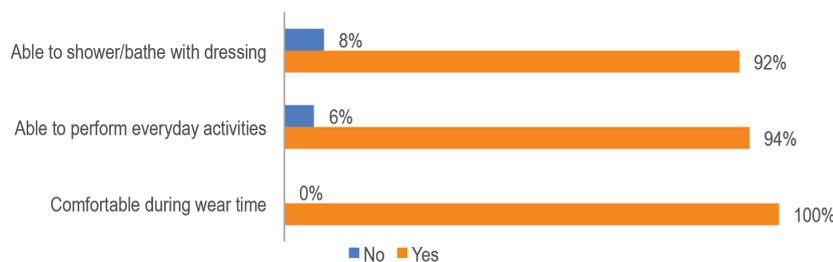
A total of 326 patients were treated with the portable, single-use NPWT device over the course of the evaluation; of these, 164 (51%) were women, and the mean age of patients treated was 57 years (median 61 years, range 17 to 91 years). The wounds were of mixed etiology: 105 (approximately 32%) were chronic and 221 (68%) were unhealed surgical wounds being managed in the community following discharge. The mean duration of wounds before treatment with portable NPWT was 9 weeks (median 8 weeks, range 1 to 68 weeks). The mean wound area at baseline was 20 cm<sup>2</sup> (median 14 cm<sup>2</sup>, range 0.1–99 cm<sup>2</sup>). Mean wound volume at baseline was 45 cm<sup>3</sup> (median 31 cm<sup>3</sup>, range 0–269 cm<sup>3</sup>).

At the baseline visit, 180 and 116 patients (91%) had low or moderate levels of exudate, respectively. Although the portable device is indicated for low to moderately exuding wounds, a small number of patients showed scant (12, 4%) and large (18, 6%) levels of exudate, met local protocols for accessing NPWT, and were deemed to be suitable for inclusion in the evaluation in the opinion of the treating physician.

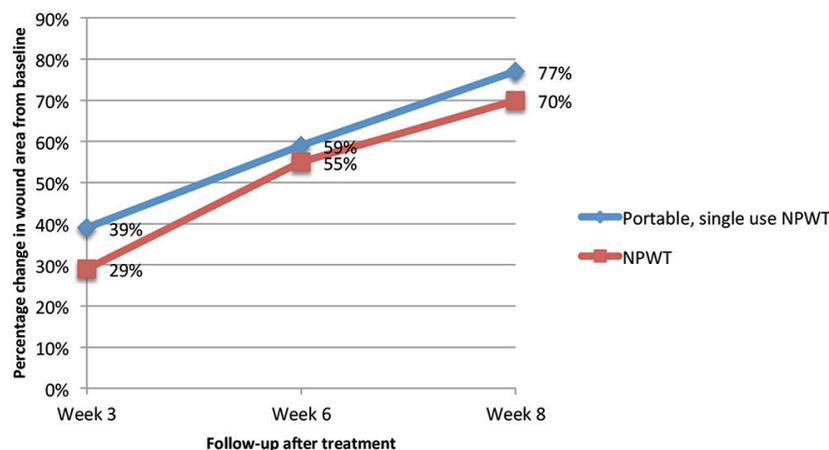
**Treatment outcomes.** The median wound area of all wounds decreased 35% from baseline at week 3, 62%



**Figure 1. Reason for discontinuation of portable NPWT treatment (n=326).**



**Figure 2. Impact of portable, single-use NPWT on patients' (n=326) activities.**



**Figure 3. Percentage change in wound area in patients treated with portable (n=304) or conventional NPWT (n=539).**

from baseline at week 6, and 78% from baseline at week 8. The average time wounds were treated with the device was 7.8 (range 1–17) weeks. Median wound area reduction at discontinuation of treatment or discharge from the evaluation was 100% (mean = 83.1, range 0–100) in all wound etiologies.

The majority of patients (218, 68%) discontinued treatment with portable NPWT as a result of their wound healing within the 8-week evaluation period. The proportion of wounds completely healed during the 8-week evaluation was higher in surgical wounds (167 out of 219, 76%) than in nonsurgical wounds (51 out of 104, 49%); 30 patients (9%) discontinued treatment as a result of the study period ending. An additional 21 patients (7%) discontinued therapy due to hospitalization and nine (3%) due to doctor's orders (the reason for this decision was not documented). Twenty-six patients (8%) discontinued treatment due to excessive exudate. Excessive exudate was more commonly reported during treatment in nonsurgical than in surgical wounds (14 out of 104 [13%] versus 12 out of 219 [6%], respectively). Device-related reasons for discontinuation were loss of seal (10, 3.1%) and poor compliance (ie, patient removed device or asked for it to be removed; six [1.9%]). Poor compliance was reported more commonly in nonsurgical wounds, although the numbers remained small (five out of 104, 5%). For five patients, reason for discontinuation was unknown or unreported; there was one death (see Figure 1).

**Patient satisfaction and experience.**

Using the three options (pleased, satisfied, and dissatisfied) in response to the question, “How satisfied are you with the treatment received for your wound?” patients reported high levels of overall satisfaction with the product. Only eight (3%) reported they were dissatisfied with treatment; 55 (17%) reported they were satisfied, and 263 (81%) reported they were pleased. One patient reported discomfort during wear time, 294 (more than 90%) reported they were able to shower/bathe, and 304 could perform everyday activities (see Figure 2).

**Nurse satisfaction.** Nurses were asked to rate their satisfaction with portable NPWT treatment using the same 3-point scale used to assess patient satisfaction regarding the portable NPWT device for the management of each patient; 268 (82%) were pleased with the performance of the device, and 56 (17%) were pleased with the performance of the dressing. Only two nurses (1%) were dissatisfied with dressing performance.

Furthermore, in 280 cases (86%), nurses found the dressing easy to administer. Only seven (2%) reported difficulty in applying the dressing. The median time for a dressing change was 10 to 15 minutes that, based on anecdotal nurse feedback, is comparable to conventional advanced wound care dressings used in this community service. The longest time required for dressing changes was reported as 20 to 30 minutes in five patients.

**Conventional NPWT.** The records of 539 patients treated with conventional NPWT were abstracted (see Table 1). On average, patients treated with conventional NPWT devices were younger and had shorter wound duration treatment than those patients treated with portable NPWT, and most (221) were surgical wounds. Patients treated with portable NPWT had smaller wounds and lower levels of exudate.

The percentage change in wound area over the course of treatment was identified from the historical patient records. Analysis revealed using portable NPWT resulted in a slightly greater change in wound area than use of conventional NPWT over time; the mean reduction in wound area per week was similar in both groups (11%/week, median = 10, range 0–66.7 for portable NPWT compared to 10%/week, median = 9.4, range 1.7–31.7 for conventional NPWT) (see Figure 3).

Attempts to estimate the median time to healing were complicated by the use of different endpoints depending on treatment. In the prospective case series of patients treated with portable NPWT, patients were monitored to determine whether they achieved wound closure; conventional NPWT case series patients were categorized as achieving wound closure or a pre-defined treatment goal (eg, readiness for closure by secondary intent). Kaplan-Meier estimates suggested the median time to healing in the portable NPWT series was 9 weeks; the median time to treatment goal/healing in the conventional NPWT arm was 8 weeks. However, given the differences in endpoints between the two groups and differences in wound etiology and size, these findings need to be considered cautiously.

## Discussion

The findings presented evaluate a new canisterless, portable, single-use NPWT system and suggest this device may be an effective complement to existing NPWT devices, with almost 70% of wounds healed over the course of the 8-week evaluation. Few complications were associated with the device, and patient and nurse satisfaction levels were very high. Further analysis comparing portable to conventional NPWT suggested the two modalities may result in similar

outcomes. A similar conclusion was reached in a recent randomized, controlled trial<sup>16</sup> examining noninferiority of a powered NPWT device and a mechanical ultra-portable device. However, it should be noted that the features of the portable device in the current study limit the system's suitability to patients with wounds that have lower levels of exudate than those treated with traditional NPWT. Nevertheless, the findings of this evaluation suggest the single-use, portable device may redefine access to NPWT for patients with low exuding wounds.

For wound care clinicians, the decision to use conventional or portable, single-use NPWT devices should start with wound characteristics such as size and exudate levels. However, other criteria may be taken into account — particularly, the patient's mobility, lifestyle, and ability to adhere to a treatment regimen. In the population evaluated, all the practitioners administering treatment were highly skilled and experienced in the use of NPWT and were able to allocate patients effectively based on professional judgment. As such, few patients withdrew from the evaluation. The simplicity of portable, single-use NPWT means it not only offers a viable alternative to conventional NPWT, but it also may offer expanded opportunities for the implementation of NPWT where it previously has been unavailable. In many instances, this occurs due to factors such as limited availability of NPWT pumps or concerns about the unregulated use of NPWT by healthcare professionals. For example, patients treated with conventional NPWT in hospital settings may find access limited in community settings following discharge, leading to a lack of continuity of care.<sup>17,18</sup> In these cases, portable, single-use NPWT might be viewed as an opportunity to step down from conventional NPWT upon discharge, if exudate levels are sufficiently controlled.

## Limitations

The design of this study presents inherent limitations, including selection bias. This evaluation considered only patients eligible for NPWT treatment according to local protocols, and nurses chose to use portable NPWT on those patients who were most likely to benefit. The comparison with the retrospectively collected data provides some context but no control. In addition to the limitations of evaluating retrospectively collected data, the patient population and wounds previously managed with conventional NPWT were very different from those managed with the portable device.

## Conclusion

The portable NPWT device used in this evaluation was well received by patients and healthcare providers, and the majority of wounds healed over the course of the 8-week evaluation. Very few complications were observed. Randomized, controlled clinical studies are needed to compare the portable NPWT device to other treatment modalities indicated for these wounds with respect to wound outcomes, cost-effectiveness, and patient quality of life. ■

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