Comparison of negative pressure wound therapy with an ultraportable mechanically powered device vs. traditional electrically powered device for the treatment of chronic lower extremity ulcers: A multicenter randomized-controlled trial

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ABSTRACT

The purpose of this study was to compare the ultraportable mechanically powered Smart Negative Pressure (SNaP®) Wound Care System to the traditional electrically powered Vacuum-Assisted Closure (VAC®) Therapy System in the treatment of chronic lower extremity wounds. This 12-center randomized-controlled trial of patients with noninfected, nonischemic, nonplantar lower extremity wounds had enrolled 65 patients, as of January 5, 2010, at the time of a planned interim analysis. Subjects were randomly assigned to treatment with either the SNaP® or VAC® Systems. The trial evaluated treatment for up to 16 weeks or till complete closure was achieved. Fifty-three patients (N=27 SNaP®, N=26 VAC®) completed at least 4 weeks of therapy. Thirty-three patients (N=18 SNaP®, N=15 VAC®) completed the study with either healing or 16 weeks of therapy. At the time of planned interim analysis, no significant differences (p=0.99) in the proportion of subjects healed between the two devices evaluated were found. In addition, the percent wound size reduction between treatment groups was not significantly different at 4, 8, 12, and 16 weeks, with noninferiority analysis at 4 weeks of treatment reaching the p-value < 0.05 significance level (*p=0.019). These interim data suggest no difference in wound closure between the SNaP® System and the VAC® System in the population studied. We look forward to the final analysis results.

Chronic wounds of the lower extremity, including diabetic foot ulcers and venous stasis ulcers, are a major healthcare problem.[1–4] Negative pressure wound therapy (NPWT) has benefit in treating these types of wounds with improved granulation tissue formation and decreased time to healing compared with modern moist dressings.[5–8] Numerous NPWT systems are available, including the widely used VAC® Therapy System. However, utilization of these systems may be limited by their weight and bulk, need for an electrical power source, difficult procurement process, cost, and impact on patient quality of life. This study evaluates the Smart Negative Pressure (SNaP®) Wound Care System, a novel light weight NPWT device that does not require an electrically powered pump.[9] Instead, the SNaP® System utilizes specialized springs to generate a preset continuous subatmospheric pressure level to the wound bed.

Previous studies have shown that negative pressure delivered by the SNaP® System has similar characteristics to the VAC® Therapy System in biomechanical testing and in an animal wound-healing model.[10] Most recently, a study comparing SNaP®-treated patients to modern treatment protocols for highly refractory lower extremity ulcers demonstrated healing time improvements similar to studies using electrically powered NPWT devices.[11]

This study was developed to directly compare the SNaP® Wound Care System to the VAC® Therapy System for the treatment of lower extremity chronic wounds in a prospective, multicenter, randomized-controlled study design. Importantly, this study was designed as a noninferiority trial with predetermined primary endpoints and a planned interim analysis.

METHODS

This study recruited subjects from 12 sites in the United States and was conducted in compliance with the 1975 Declaration of Helsinki and under presiding institutional review board approval. The study was registered at clinicaltrials.gov under number: NCT00951080. Wounds that healed $> 30\%$ during the first week after enrollment where excluded from the study, and the total period from enrollment to initiation of NPWT therapy was 2 weeks for both treatment conditions. Subjects were evaluated on a weekly basis to complete wound closure (defined as complete reepithelialization without drainage) or for up to

16 weeks of therapy. Dressing changes were performed following manufacturer recommended instructions and (2x/week for SNaP®, 3x/week for VAC®, or more). Wound debridement was performed as part of standard wound care. The exact techniques used by the investigators to debride wounds was left to the individual investigators as long as it was not an advanced modality (such as ultrasound). The only stipulations were that the same techniques for a given wound type should be used for both treatment conditions and the maximum frequency of allowable debridement for each wound was 1×/week. The Profore® (Smith & Nephew, Durham, NC, USA) four layer compression bandage system was used for all venous ulcer patients. The standard off-loading orthotics used by the participating study centers were utilized for diabetic patients in both treatment conditions. Wound sizes were evaluated using wound tracings captured by the Visitrak wound measurement system (Smith & Nephew).

Inclusion criteria included patients aged $\geq$18 years; lower extremity venous ulcer or diabetic ulcer with a surface area $< 100\,cm^2$ but $> 1\,cm^2$, and $< 10\,cm$ in widest diameter. Wounds were to have been present for > 30 days despite appropriate wound care before admission. Admission criteria also required adequate blood perfusion defined as either transcutaneous oxygen measurements of the dorsum of the foot $> 30\,mmHg$, skin perfusion pressure $> 30\,mmHg$, or an ankle/brachial index between 0.7 and 1.2. The wound was required to be in a location amendable to creation of an airtight seal using the provided dressings.

Exclusion criteria included active infection (redness, swelling, pain, purulent exudate), untreated osteomyelitis, pregnancy, allergies to wound care products used in the study, etiologies of the wound that included malignancy, burn, collagen vascular disease, sickle cell, vasculopathy, or pyoderma gangrenosum. Further grounds for exclusion included a diagnosis of Active Charcot arthropathy, wound location on toes or plantar surface of foot, uncontrolled hyperglycemia (HbA1C $> 12\%$), end-stage renal disease requiring dialysis, active chemotherapy treatment, previous treatment with a NPWT device, growth factors, hyperbaric oxygen, or bioengineered tissue product within 30 days of enrollment. Patients were not enrolled if they exhibited $> 30\%$ wound surface area reduction in size at 1 week after the screening visit.

Randomization

Randomization was accomplished using blocks of numbers from Pocock.[12] Stratification was performed by treatment center and wound type. Sealed opaque envelopes contained the assigned treatment and patient identification number. Envelopes were sequentially numbered before clinical trial site distribution. At patient randomization, treatment was assigned on the basis of the next sequentially labeled envelope. Patients were randomized to receive either the VAC device (K.C.I., San Antonio, TX) or the SnAP® device (Spiracur Inc., Palo Alto, CA).

Statistical analysis

To establish noninferiority to traditional NPWT, this study was designed assuming 80% wound closure with an 18.5% standard deviation (derived from previous study wounds treated with the SNaP® System[13]) for both groups at 16 weeks using a margin of noninferiority of 12.5%. An interim analysis was planned using an α of 0.005, and the α to be used for the final analysis was adjusted to 0.0482 to account for this interim analysis. The statistical method applied was the two-sample Student's t test assuming the two treatment groups have approximately the same percent decrease in wound area. Percent decrease in wound area was evaluated at 4, 8, 12, and 16 weeks. If a wound was completely healed or a subject had discontinued before completion, the last observation was carried forward for the intent-to-treat analysis. To further evaluate the treatment effect, a Kaplan–Meier survival analysis was performed comparing completed healing between treatment groups. Primary healing analysis was performed on the Visitrak data and the reported wound closure outcomes. Statistical analyses were performed using SAS version 9.1.

Secondary outcome analysis

Secondary endpoints such as time for dressing change and patient exit survey data were collected, and statistical analysis was performed to evaluate any differences in outcomes. Serious adverse events, device-related adverse events, and complications were also collected and reported.

RESULTS

Sixty-five patients were enrolled at the time of the planned interim analysis. Fifty-three patients (N=27 SNaP®, N=26 VAC®) completed at least 4 weeks of therapy. Thirty-three patients (N=18 SNaP®, N=15 VAC®) completed the study with either healing or 16 weeks of therapy. Table 1 shows patient demographics and comorbidities. In addition, of those patients with diabetes, 69.3% of patient randomized to the SNaP®-treatment group and 72.4% of those patients randomized to the VAC®-treatment group had loss of pressure sensation found on five-point Semmes-Weinstein 10 G monofilament testing.

Percent decrease in wound area

The percent decrease in wound area as measured from Visitrak tracings was compared for those subjects randomized to either treatment with the SNaP® System or the VAC® System, and results are shown in Table 2. At 4 weeks, the SNaP®-treated subjects demonstrated noninferiority *p-value < 0.05 (*p=0.019) with SNaP®-treated subjects reporting $51.22\% \pm 41.47\%$ wound closure and the VAC®-treated subjects reporting $37.27\% \pm 47.31\%$ wound closure. As this was performed as part of the interim analysis, this p-value did not meet the stop-criteria per the O'Brien-Fleming stopping rule (*$p < 0.005$). At 4, 8, 12, and 16 weeks, there were no statistical differences identified between treatment groups with a similar mean percent reduction in wound area and standard deviation. (Table 2). This indicated that both treatments had a similar effect on the wounds; however, two VAC®-treated patients who had $> 100\%$ increase in their wound size during treatment were excluded in this analysis as outliers because inclusion of their data would have heavily skewed the mean reductions in wound size in favor of the SNaP® System and increased the variance in the data set. To

Table 1. Demographics and comorbidities

	VAC®	SNaP®
Age	65.1 ± 17.6	65.8 ± 13.5
Wound duration (months)	13.7 ± 20.8	8.3 ± 8.7
Initial wound size (cm^2)	8.8 ± 9.7	4.3 ± 4.1
Male (%)	50.0	48.0
Race (% white)	68.8	64.0
Current smoker (%)	12.5	20.0
Diabetes mellitus (%)	43.8	64.0
Venous stasis disease (%)	71.9	88.0
Lower extremity edema (%)	58.1	76.0
Peripheral arterial disease (%)	19.4	28.0
Peripheral neuropathy (%)	34.4	44.0
Respiratory disease (COPD/asthma) (%)	6.7	20.0
Renal disease (%)	6.5	16.0
Cardiac disease (%)	41.9	48.0
Anticoagulation/coumadin (%)	32.3	40.0
Immobility (%)	25.0	32.0
Steroid use (%)	12.9	8.0
Immunosuppressed (%)	3.1	4.0
Poor nutrition (%)	3.2	8.0
Other morbidity (%)	9.7	4.2

VAC®, Vacuum-Assisted Closure; SNaP®, Smart Negative Pressure.

account for early subject withdrawal and other confounding elements in the intent-to-treat analysis, the data were analyzed based on those subjects who completed the entire study protocol (either healed or had follow-up data through 16 weeks of treatment). Again, there were no statistically significant differences (*p=0.611) found between treatment groups with SNaP®-treated patients having a reduction of 85.03% SD ± 38.91 and VAC®-treated patients having a reduction of 91.11% SD ± 25.58.

Table 2. Percent decrease in wound area

	VAC®		SNaP®			
Week	Mean (%)	SD	Mean (%)	SD	p-value¥	p-value§
4	−37.27	47.31	−51.22	41.47	0.019*	0.2674
8	−55.74	55.34	−55.84	51.91	0.2028	0.8750
12	−64.73	51.25	−57.07	57.291	0.3765	0.6548
16	−66.15	51.06	−61.26	52.69	0.3020	0.7892

¥p-value is for a test of noninferiority with a 12.5% noninferiority margin.
§p-value is for a test of a difference between treatment groups.
Statistically significant ($p < 0.05$).
VAC®, Vacuum-Assisted Closure; SNaP®, Smart Negative Pressure.

Proportion of wounds healed and Kaplan–Meier survival curve

The proportion of wounds healed at 4, 8, 12, and 16 weeks is provided in Table 3 and the Kaplan–Meier estimates are shown in Figure 1. There was no significant difference (p=0.99) in the proportion of subjects healed over time, indicating that the effect of the SNaP® System was not significantly different than that of the VAC® System in promoting complete wound closure in the population studied.

Device application time and exit survey data

Time from initiation of dressing application as measured from the time an open wound bed was ready for a dressing application to the delivery of successful negative pressure to the wound bed without leaks was recorded during dressing changes. Mean application time for the VAC® Therapy System was 20.98 minutes (SD ± 11.18 minutes), while mean application time for the SNaP® System was 8.58 minutes (SD ± 5.23 minutes). The mean application time for the SNaP® System was significantly shorter (*$p = < 0.0001$) than that of the VAC® System at all timepoints (Figure 2).

Response data concerning the user experience with their NPWT device were available on 25 (12 VAC®-treated and 13 SNaP®-treated) subjects upon exit from the study. These questions covered areas such as activities of daily living, mobility, sleep, noise disruption, social interactions, pain and discomfort, and perceived effectiveness and satisfaction with NPWT device treatment (Table 4). Importantly, for those patients randomized to VAC® Therapy treatment, 83.3% of the subjects surveyed were using the Acti-VAC® System, the lightest and most portable VAC® Therapy System available at the time of patient enrollment. The remaining 16.7% had treatment with the Freedom VAC®, the second most portable VAC® Therapy System. There were no differences in reported pain, perceived effectiveness, and patient satisfaction between the devices used to apply negative pressure. However, the SNaP® System interfered less with overall activity, sleep, and social interactions than the VAC® System.

Adverse events and incidence of infection

The proportion of patients experiencing one or more device-related adverse events was similar between the VAC® and SNaP® treatment groups (Table 5). Percent of patients with clinically determined infection was 3.0% vs. 6.3%, maceration was 12.1% vs. 9.4%, and allergic reaction to dressing material 3.0% vs. 3.1% for VAC® and SNaP® groups, respectively. Other device-related adverse events reported included increase in wound size > 100%,

Table 3. Proportion of subjects healed

	Proportion healed			
Weeks of treatment	4	8	12	16
VAC® (%)	0	13.6	36.7	64.8
SNaP® (%)	0	11.8	38.2	59.7

VAC®, Vacuum-Assisted Closure; SNaP®, Smart Negative Pressure.

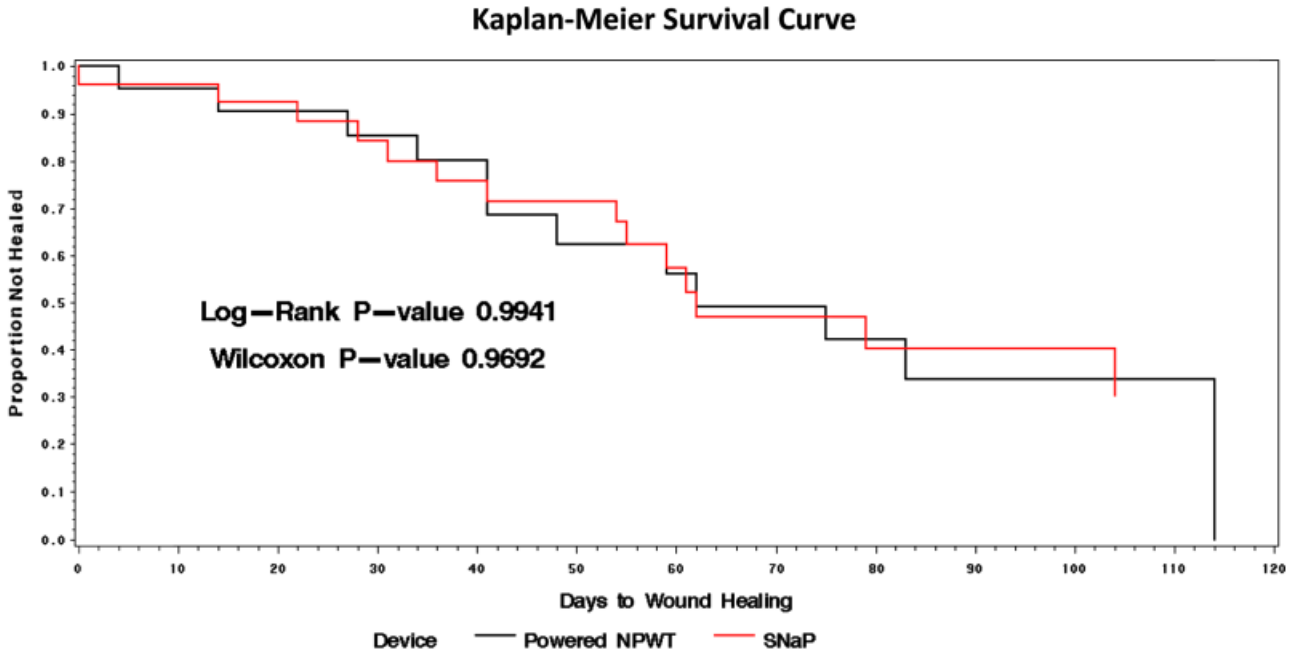

Figure 1. Kaplan–Meier Diagrams showing no significant difference (p=0.99) in the proportion of subjects healed between the the SnaP® System and VAC® Therapy System treatment groups. VAC®, Vacuum-Assisted Closure; SNaP®, Smart Negative Pressure; NPWT, negative pressure wound therapy.

redness due to possible venous thrombus and periwound skin erythema and swelling for the VAC® group (15.2%), and pain at the wound site for the SNaP® group (3.1%).

DISCUSSION

At least three randomized-controlled trials exist demonstrating the use of the VAC® Therapy System is superior to standard care for diabetic foot and venous leg ulcers.[5,6,8] Although these studies were not without limitations, NPWT is now routinely used to treat these types of wounds and evidence for its effectiveness continues to grow. Many NPWT devices are now commercially available, but the Agency for Healthcare Research and Quality report in 2009 found that there were no published studies directly comparing one NPWT system to another, nor published head-to-head comparisons that were able to identify a significant distinction of one NPWT system or component over another.[14] To our knowledge this protocol represents the first prospective multicenter randomized trial comparing the efficacy of two negative pressure therapy systems in chronic wounds. In this planned interim analysis, the data available to date did not find significant differences in wound-healing outcomes between the SNaP® System and the VAC® Therapy System in the treatment of chronic lower extremity ulcers. Wound size healing data further showed noninferiority for those patients completing at least 4 weeks of therapy.

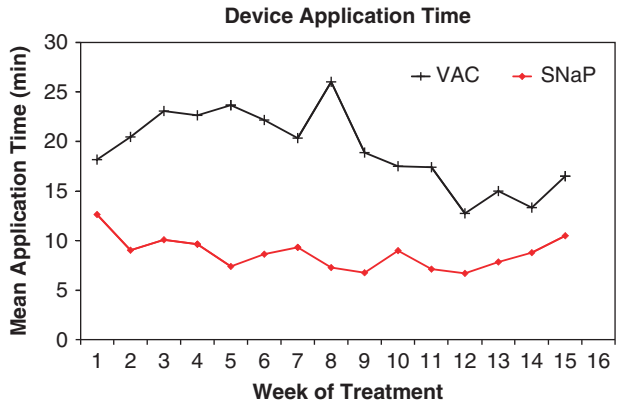

Figure 2. Device application time. Mean device application time at initiation and all follow-up time points. SNaP®, Smart Negative Pressure; VAC, Vacuum-Assisted Closure.

When interpreting these data, several caveats need to be considered. First, it must be emphasized that this is an interim anaylsis. As such, the p-value of the noninferiority analysis did not meet the stop-criteria per the O'Brien-Fleming stopping rule of $*p < 0.005$. Furthermore, two VAC®-treated patients who had wound size increases during the study of $> 100\%$ were excluded as outliers in the wound size analysis. Also, despite randomization of patients to treatment conditions, there were demographic differences found between the two treatment group with more SNaP®-treated patients having diabetes mellitus and peripheral vascular disease and VAC®-treated patients having on average older and larger wounds. Lastly, the frequency of dressing changes was different between the two treatment groups, as each system had dressing changes performed according to manufacturer recommended frequencies. It is important to note that while the data analysis from this initial group of patients does suggest equivalent healing outcomes, the findings may be different when the entire patient cohort is enroled.

Table 4. Exit survey data

						p-value	
	Yes	No				χ^2	Fisher's exact test
Activities of daily living							
1. Did use of the NPWT device interfere with your ability to perform normal daily activity?							
VAC®% (*N*)	58.3 (7)	41.7 (5)				0.0067*	0.0112*
SNaP®% (*N*)	7.7 (1)	92.3 (12)					
	1–20%	21–40%	41–60%				
2. What percentage of your normal activities was negatively impacted by use of the NPWT device?							
VAC®% (*N*)	14.3 (1)	28.6 (2)	57.1 (4)			0.1801	0.5000
SNaP®% (*N*)	100.0 (1)	0.0 (0)	0.0 (0)				
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree		
3. It was a burden to come to the wound care clinic for my dressing change							
VAC®% (*N*)	8.3 (1)	25.0 (3)	41.7 (5)	25.0 (3)	0.0 (0)	0.2608	0.3311
SNaP®% (*N*)	30.8 (4)	23.1 (3)	23.1 (3)	7.7 (1)	15.4 (2)		
4. The use of the NPWT device restricted many of my normal activities							
VAC®% (*N*)	0.0 (0)	16.7 (2)	25.0 (3)	50.0 (6)	8.3 (1)	0.0214*	0.0056*
SNaP®% (*N*)	61.5 (8)	7.7 (1)	15.4 (2)	15.4 (2)	0.0 (0)		
5. The NPWT device was cumbersome and interfered with my mobility							
VAC®% (*N*)	0.0 (0)	25.0 (3)	33.3 (4)	41.7 (5)	0.0 (0)	0.0019*	4.28E−04*
SNaP®% (*N*)	61.5 (8)	30.8 (4)	7.7 (1)	0.0 (0)	0.0 (0)		
6. I was able to work and do my normal daily activities while being treated with the NPWT device							
VAC®% (*N*)	0.0 (0)	33.3 (4)	33.3 (4)	33.3 (4)	0.0 (0)	0.0068*	0.0038*
SNaP®% (*N*)	0.0 (0)	0.0 (0)	7.7 (1)	46.2 (6)	46.2 (6)		
7. The NPWT device was easy to use							
VAC®% (*N*)	0.0 (0)	16.7 (2)	8.3 (1)	75.0 (9)	0.0 (0)	0.0454*	0.0221*
SNaP®% (*N*)	0.0 (0)	0.0 (0)	0.0 (0)	61.5 (8)	38.5 (5)		
	Less active	Stayed the same	More active				
8. After treatment with the NPWT, how did your overall activity level change?							
VAC®% (*N*)	58.3 (7)	41.7 (5)	0.0 (0)			0.0210*	0.0179*
SNaP®% (*N*)	7.7 (1)	84.6 (11)	7.7 (1)				
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree		
9. The NPWT device was light-weight and portable							
VAC®% (*N*)	0.0 (0)	8.3 (1)	25.0 (3)	66.7 (8)	0.0 (0)	0.0025*	5.19E−04*
SNaP®% (*N*)	0.0 (0)	0.0 (0)	0.0 (0)	30.8 (4)	69.2 (9)		
10. I wish the NPWT device was more light-weight and portable							
VAC®% (*N*)	0.0 (0)	0.0 (0)	33.3 (4)	58.3 (7)	8.3 (1)	0.0028*	7.22E−04*
SNaP®% (*N*)	30.8 (4)	46.2 (6)	15.4 (2)	7.7 (1)	0.0 (0)		

						p-value	
	Never	Rarely	Several times per day	Most of the time	All of the time	χ^2	Fisher's exact test
Noise from device							
1. How often did the noise from the NPWT device bother you?							
VAC®% (*N*)	33.3 (4)	33.3 (4)	16.7 (2)	16.7 (2)	0.0 (0)	0.0052*	4.58E−04*
SNaP®% (*N*)	100.0 (13)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)		
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree		
2. The noise from the NPWT device was bothersome							
VAC®% (*N*)	8.3 (1)	33.3 (4)	33.3 (4)	25.0 (3)	0.0 (0)	0.0004*	3.27E−05*
SNaP®% (*N*)	92.3 (12)	7.7 (1)	0.0 (0)	0.0 (0)	0.0 (0)		

						p-value	
	Never	1–2 nights per week	2–4 nights per week	4–6 nights per week	Every night	χ^2	Fisher's exact test
Sleep disruption							
1. How often did the use of the NPWT device disrupt your sleep?							
VAC®% (*N*)	41.7 (5)	33.3 (4)	25.0 (3)	0.0 (0)	0.0 (0)	0.0455*	0.0288*
SNaP®% (*N*)	84.6 (11)	7.7 (1)	0.0 (0)	0.0 (0)	7.7 (1)		
2. Did the noise from the NPWT device bother you when you were trying to go to sleep?							
VAC®% (*N*)	58.3 (7)	16.7 (2)	25.0 (3)	0.0 (0)	0.0 (0)	0.0339*	0.0149*
SNaP®% (*N*)	100.0 (13)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)		
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree		
3. The use of the NPWT device was disruptive to my sleep							
VAC®% (*N*)	0.0 (0)	41.7 (5)	16.7 (2)	41.7 (5)	0.0 (0)	0.0029*	4.72E−04*
SNaP®% (*N*)	61.5 (8)	30.8 (4)	0.0 (0)	0.0 (0)	7.7 (1)		

						p-value	
	Never	Rarely	About half the time	Most of the time	Always	χ^2	Fisher's exact test
Social situations							
1. In social situations, did you feel that other people noticed the NPWT device?							
VAC®% (*N*)	0.0 (0)	25.0 (3)	16.7 (2)	33.3 (4)	25.0 (3)	0.0012*	9.33E−05*
SNaP®% (*N*)	69.2 (9)	30.77 (4)	0.0 (0)	0.0 (0)	0.0 (0)		
2. In social situations, were you ever bothered by other people noticing your NPWT device?							
VAC®% (*N*)	33.3 (4)	25.0 (3)	33.3 (4)	0.0 (0)	8.33 (1)	0.0377*	0.0195*
SNaP®% (*N*)	84.6 (11)	15.4 (2)	0.0 (0)	0.0 (0)	0.0 (0)		
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree		
3. The NPWT device was rarely noticed by other people in social situations							
VAC®% (*N*)	16.7 (2)	33.3 (4)	8.33 (1)	41.7 (5)	0.0 (0)	0.0108*	0.0042*
SNaP®% (*N*)	0.0 (0)	0.0 (0)	23.1 (3)	30.8 (4)	46.2 (6)		

						p-value	
	N	Sum of scores	Expected sum of scores	SD of sum		Wilcoxon test	*t* test
Pain and discomfort							
1. What was your level of pain associated with dressing changes for the NPWT device?							
VAC®% (*N*)	11	163.5	132.0	15.664		0.0605	0.0245*
SNaP®% (*N*)	12	112.5	144.0	15.664			
2. What was your level of pain associated with just wearing the NPWT device?							
VAC®% (*N*)	11	150.5	126.5	14.434		0.1184	0.0403*
SNaP®% (*N*)	11	102.5	126.5	14.434			
3. What was your overall level of pain associated with treatment with the NPWT device?							
VAC®% (*N*)	12	178.5	150.0	16.89		0.111	0.0696
SNaP®% (*N*)	12	121.5	150.0	16.89			
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	χ^2	Fisher's exact test
4. The NPWT was comfortable to wear							
VAC®% (*N*)	8.3 (1)	25.0 (3)	33.3 (4)	33.3 (4)	0.0 (0)	0.0424*	0.0282*
SNaP®% (*N*)	0.0 (0)	7.7 (1)	7.7 (1)	38.5 (5)	46.2 (6)		
	No discomfort	Minimal discomfort	Low level of discomfort	Moderate level of discomfort	High level of discomfort		
5. What was your overall discomfort from using the NPWT device?							
VAC®% (*N*)	16.7 (2)	33.3 (4)	16.7 (2)	25.0 (3)	8.3 (1)	0.2989	0.3143
SNaP®% (*N*)	53.9 (7)	23.1 (3)	15.4 (2)	7.7 (1)	0.0 (0)		

						p-value	
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	χ^2	Fisher's exact test
Perceived effectiveness/satisfaction							
1. The use of the NPWT device helped my wound to heal faster							
VAC®% (*N*)	0.0 (0)	8.3 (1)	16.7 (2)	33.3 (4)	41.7 (5)	0.4949	0.6548
SNaP®% (*N*)	7.7 (1)	0.0 (0)	30.8 (4)	15.4 (2)	46.2 (6)		
2. I would use the NPWT device again on another wound in the future							
VAC®% (*N*)	0.0 (0)	0.0 (0)	33.3 (4)	33.3 (4)	33.3 (4)	0.0668	0.0746
SNaP®% (*N*)	0.0 (0)	0.0 (0)	0.0 (0)	38.5 (5)	61.5 (8)		
	N	Sum of scores	Expected sum of scores	SD of sum		Wilcoxon test	*t* test
3. What was your overall level of satisfaction concerning the NPWT device used to treat your wound?							
VAC®% (*N*)	12	133.5	156.0	17.47		0.2202	0.6147
SNaP®% (*N*)	13	191.5	169.0	17.47			

*$p < 0.05$.
NPWT, negative pressure wound therapy; VAC®, Vacuum-Assisted Closure; SNaP®, Smart Negative Pressure.

Table 5. Patients with device-related adverse events

	VAC® (*n*=33)	SnaP® (*N*=32)
Infection	3.0% (1)	6.3% (2)
Maceration	12.1% (4)	9.4% (3)
Allergic reaction to dressing	3.0% (1)	3.1% (1)
Other	15.2% (5)	3.1% (1)

VAC®, Vacuum-Assisted Closure; SNaP®, Smart Negative Pressure.

Although no differences in wound-healing efficacy were shown, the SNaP® System did show significant advantages with regards to time required for dressing application and patient survey data. The SNaP® System was applied on average in less than half the time it takes to apply the VAC® System. It is important to note that time was measured till successful activation of NPWT was achieved; thus, the data more accurately describe ease of use for the system (both successful dressing application and operation of the negative pressure source) and not just dressing application alone. Furthermore, survey data found less detrimental impact on daily activities, overall mobility level, social interactions, and sleep. These factors can significantly affect patients' psychological well-being and may have effects on compliance and overall outcomes.[15–19]

In addition to comparing two systems of NPWT, the results of this study may also add insight into the role of foam and gauze and their relative effectiveness with NPWT. Should full results confirm the results of the interim analysis based on the demonstration of noninferiority between the gauze-based SNaP® System and the foam-based VAC® System, it would support, for at least a subset of chronic wounds, similar efficacy for both foam and gauze interfaces. Wounds enroled in this study were nonplantar extremity wounds, predominantly secondary to venous disease, and were therefore, *generally more superficial*. It is possible that the use of a foam interface may prove to have advantages for *deeper wounds with exposed structures*. However, a study comparing SNaP®-treated subjects to modern treatment protocols for highly refractory lower extremity ulcers demonstrated healing time improvements similar to studies using foam-based powered NPWT devices.[11] We look forward to completion of this study to further confirm or refute these interim findings.

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