

# Comparative Effectiveness of Mechanically and Electrically Powered NPWT Devices: A Multicenter Randomized Controlled Trial

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## Introduction

Negative pressure wound therapy (NPWT) is now routinely used to treat a variety of acute and chronic wounds including diabetic foot ulcers, venous stasis ulcers, pressure ulcers, and trauma wounds. [1-4] The numerous benefits of NPWT include improved granulation tissue formation, decreased time to healing, and reduced overall cost of treatment compared to modern dressings. [5-9]

Although NPWT has been widely adopted in the marketplace today, the traditional electrically powered pumps such as the V.A.C.® Therapy System (K.C.I., San Antonio, TX) are fraught with significant limitations. Due to their weight and bulk, need for an electrical power source, complicated rental-based procurement process, negative impact on ambulatory patient quality of life, and high cost, such powered systems are not ideally suited for use in the outpatient setting.

This study evaluates a novel NPWT device that utilizes mechanical power instead. The SNaP® (Smart Negative Pressure) Wound Care System (Spiracur Inc, Sunnyvale, CA) is a single-use device that utilizes specialized springs to generate a pre-set continuous subatmospheric pressure level for NPWT delivery. [9, 10] This device is better suited for use in the ambulatory setting. Previous studies have shown that NPWT delivered by the SNaP® system has similar characteristics to the V.A.C. Therapy System in biomechanical testing and in an animal wound healing model. [11]

This study was developed to directly compare the SNaP Wound Care System to the V.A.C. 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 non-inferiority trial with pre-determined primary endpoints; results of a planned interim analysis from this study have previously been published. [13]



## Methods

Subjects were recruited from 17 sites in the US under presiding institutional review board approval. The study was registered at clinicaltrials.gov under number: NCT00951080. There was a one week run-in time that excluded wounds that healed more than 30% during this period. A 1:1 randomization was utilized. Subjects were evaluated on a weekly basis to complete wound closure (defined as complete re-epithelialization without drainage) or for up to 16 weeks of therapy. Dressing changes were performed following manufacturer recommended instructions and treatment was with -125 mm Hg. Wound sizes were evaluated using wound tracings captured by the Visitrak wound measurement system (Smith & Nephew).

Inclusion criteria included patients aged ≥ 18 years; lower extremity venous ulcer or diabetic ulcer with a surface area < 100 cm<sup>2</sup> but larger than 1 cm<sup>2</sup>, and < 10 cm in widest diameter. Wounds were to have been present for > 30 days despite appropriate wound care prior to admission. Admission criteria also required adequate blood perfusion defined as either transcutaneous oxygen measurements of the dorsum of the foot > 30 mm Hg, skin perfusion pressure > 30 mm Hg, or an ankle/brachial index (ABI) between 0.7 and 1.2. The wound was required to be in a location amenable 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 greater than 30% wound surface area reduction in size at 1 week after the screening visit.

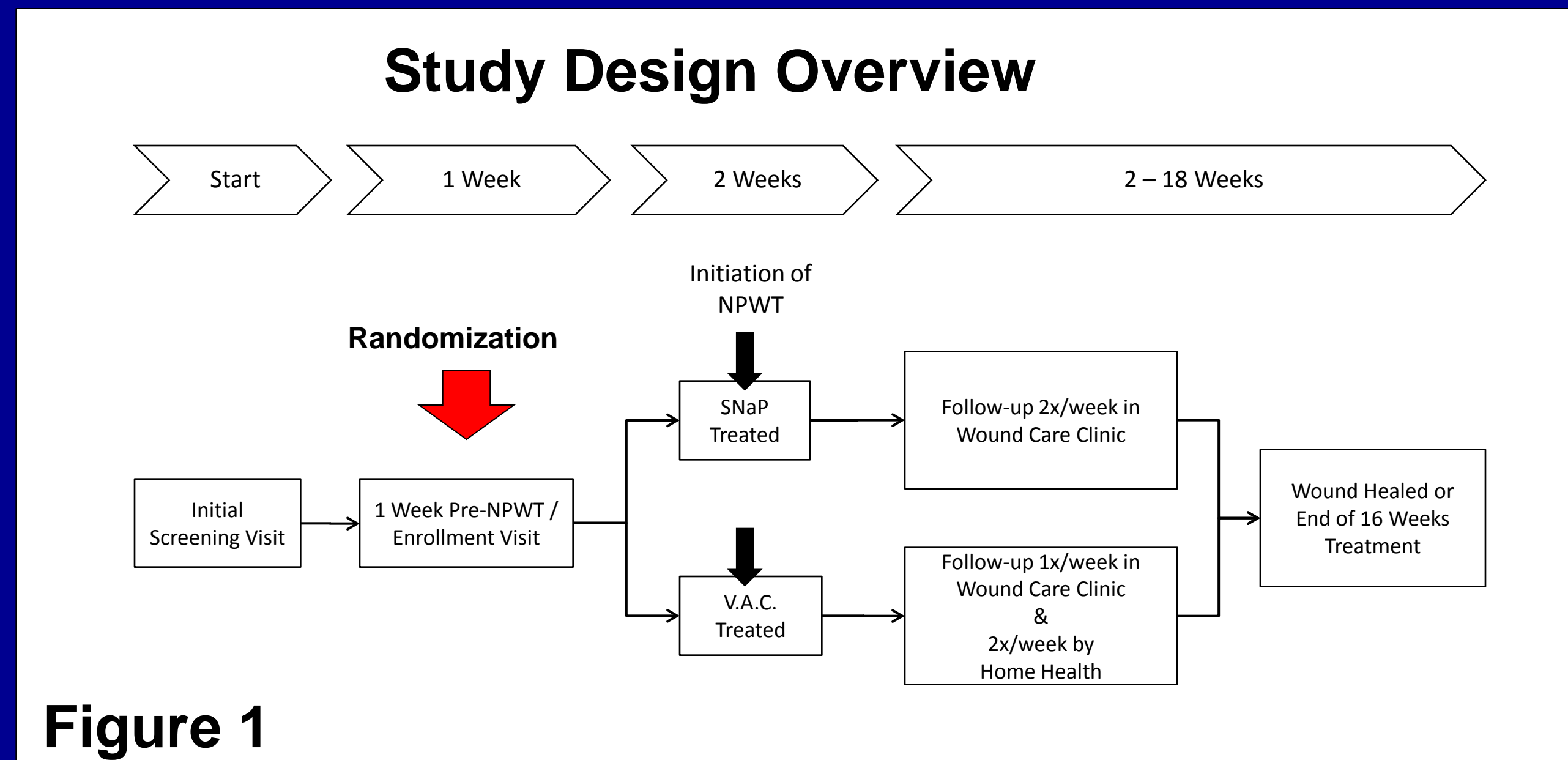


Figure 1

## Results

One hundred and thirty-two patients (N=132) were randomized to either the SNaP (N=64) or V.A.C. (N=68) treatment arms. Of these, eighty-three patients (N=41 SNaP, N=42 V.A.C.) completed the study with either healing or 16 weeks of therapy. All 132 subjects were included in the intent-to-treat (ITT) analysis. Fourteen subjects dropped from the study prior to initiating treatment (N=4 SNaP, N=10 V.A.C.). Of the 118 who received treatment, three subjects dropped after treatment initiation but prior to any follow-up assessments, resulting in 115 subjects (N=59 SNaP, N=56 V.A.C) with follow-up data available for analysis. Hence, 115 subjects were included in the ITT full analysis set (ITT-FAS).

### 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 V.A.C. System, and results are shown in Table 1. At sixteen weeks, the SNaP®-treated subjects demonstrated non-inferiority to the V.A.C.® -treated subjects (p = 0.0044). (Table 1).

Table 1 – Percent Decrease in Wound Area

	VAC (n = 56)	SNaP (n = 59)	P-value
	Median (%) [Min, Max]	Median (%) [Min, Max]	
16 weeks	-94.0 [-100.0, 500.0]	-85.7 [-100.0, 392.3]	0.0044*

\*p-value is for a test of a difference between treatment groups, statistically significance (p<0.05)  
\*\*p-value is for a test of non-inferiority with a 12.5% non-inferiority margin  
\*\*\*Statistically significant non-inferiority demonstrated (\*p<0.0482)

### The Proportion of Wounds Healed and Kaplan-Meier Analysis

The proportion of wounds healed at 4, 8, 12 and 16 weeks and the Kaplan-Meier estimates are shown in Figure 2. There was no significant difference (p = 0.97) in the proportion of subjects healed over time, indicating that the effect of the SNaP System was not significantly different than that of the V.A.C. System in promoting complete wound closure in the population studied.

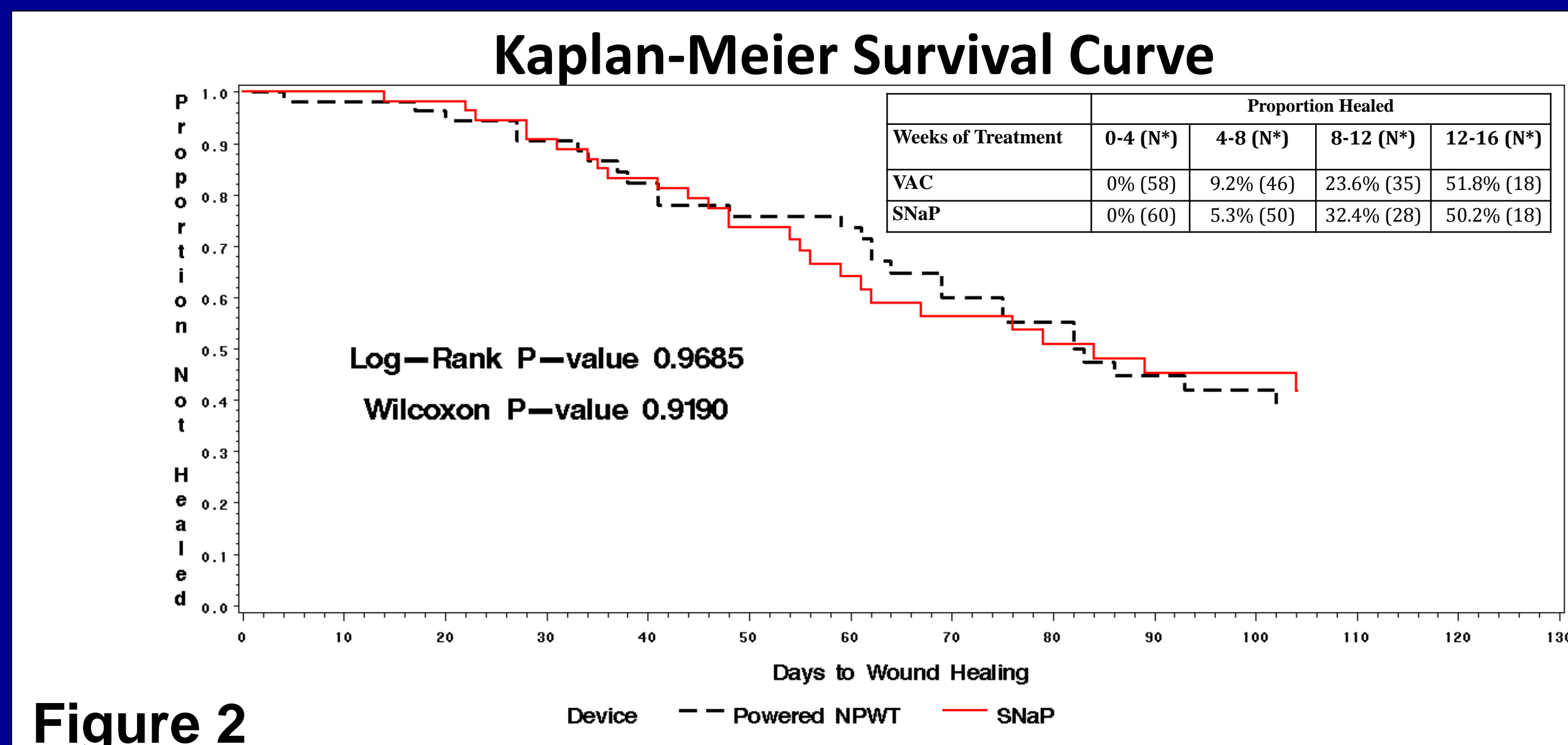


Figure 2

### 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 V.A.C. Therapy System was 18.26 minutes (SD +/- 9.37 minutes), while mean application time for the SNaP® System was 10.20 minutes (SD +/- 8.25 minutes). The mean application time for the SNaP® System was significantly shorter (\*p<0.0001) than that of the V.A.C. System at all time points (Figure 3).

Response data concerning user experience with their NPWT device was available on 104 (52 V.A.C.®-treated and 52 SNaP®-treated) subjects upon exit from the study, and 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. While 91.4% of the V.A.C.®-treated patients surveyed used the Acti-V.A.C.® System, the lightest and most portable V.A.C. Therapy System available at the time of patient enrollment, the remaining 8.6% were treated with the Freedom V.A.C.®, the second most portable V.A.C. Therapy System. Compared to V.A.C.®-treated patients, significantly (\*p<0.05) more SNaP®-treated patients never or rarely felt that people noticed their NPWT device in social situations, rated the SNaP® system as more comfortable to wear, and reported a better overall level of satisfaction with their NPWT device. Though there were no significant differences in reported pain and perceived effectiveness between the two devices, overall the SNaP® System demonstrated potentially significant advantages over the V.A.C. System.

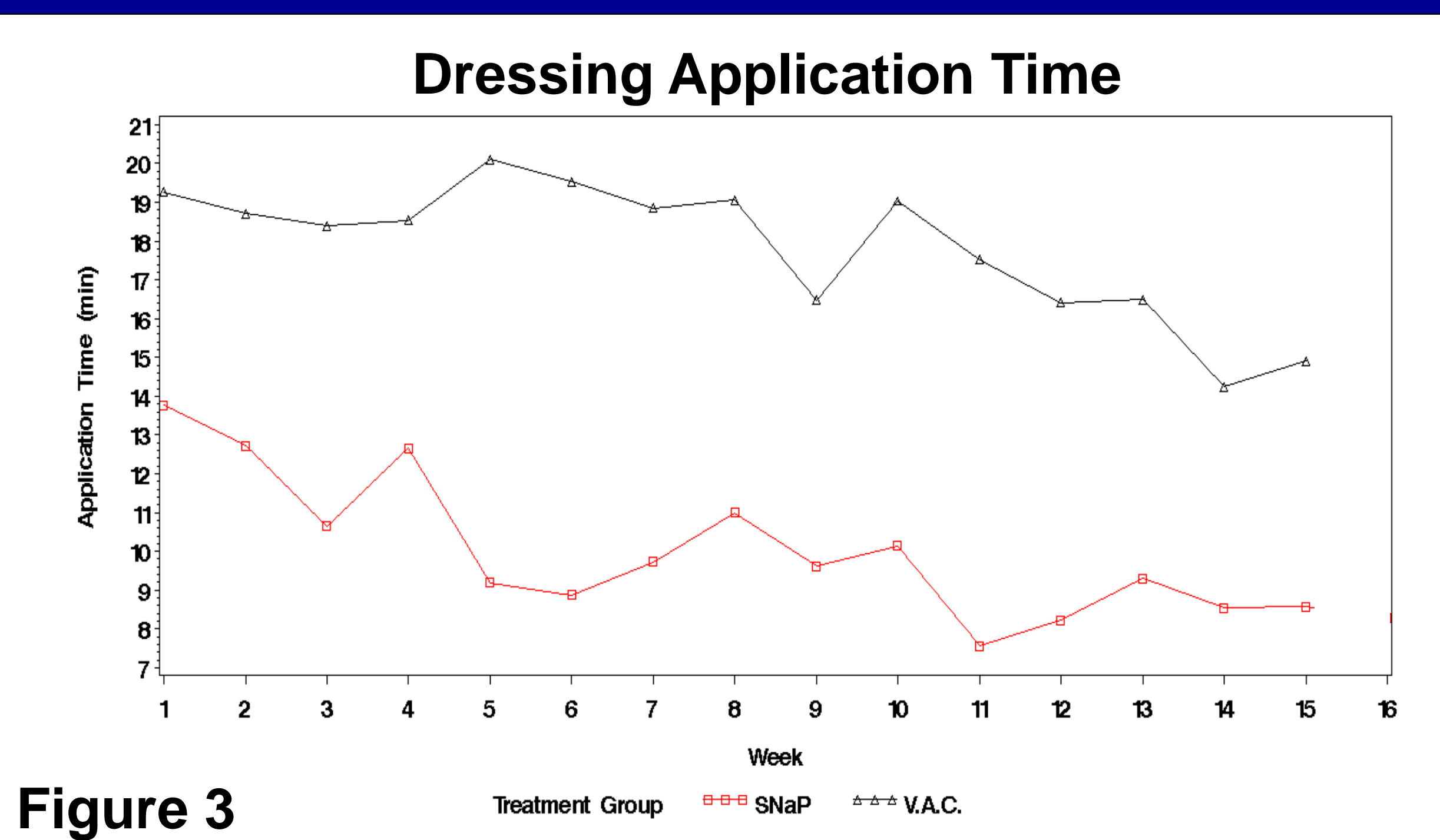


Figure 3

## Results

### Adverse Events and Incidence of Infection

The proportion of patients experiencing one or more device-related adverse events (AE) was similar between the V.A.C. and SNaP treatment groups (Table 2). Percent of subjects with clinically determined infection was 7.4 % versus 3.1 %, maceration was 19.1 % versus 15.6 %, allergic reaction to dressing material was 7.4 % versus 6.3 %, pain requiring dressing removal was 5.9 % versus 1.6 %, and blistering was 5.9 % versus 4.7 % for SNaP and V.A.C. groups, respectively. Other device-related AE's (including formation of new ulcer, wound size increase, skin tear and wound bed necrosis) were 4.7 % versus 8.8 % for SNaP and V.A.C. groups, respectively.

Table 2 –Patients with Device-related Adverse Events.

Adverse Event	Subjects with AE	VAC (N=68)	SNaP (N=64)
Infection	7	7.4% (5)	3.1% (2)
Maceration	23	19.1% (13)	15.6% (10)
Allergic Reaction to Dressing	9	7.4% (5)	6.3% (4)
Pain	5	5.9% (4)	1.6% (1)
Blisters	7	5.9% (4)	4.7% (3)
Other	9	8.8% (6)	4.7% (3)

## Conclusion

At least four randomized-controlled trials exist demonstrating the use of the V.A.C. Therapy System is superior to standard care for diabetic foot and venous leg ulcers.[5, 6, 7, 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 (AHRQ) 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. The data demonstrate very similar results in terms of healing between those wounds treated with the SNaP and V.A.C. systems, with analysis of the primary endpoint of wound size reduction demonstrating non-inferiority between treatment groups at 16 weeks of therapy. However, the SNaP System did demonstrate significant advantages with regards to time required for dressing application, and patient survey data found less detrimental impact on daily activities, overall mobility level, social interactions, and sleep. These factors can significantly affect patient's psychological well-being and may have effects on compliance and overall outcomes. These data support similar wound healing outcomes between the SNaP System and the VAC system in the population studied.

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