The Use of a Novel Canister-free Negative-Pressure Device in Chronic Wounds: A Retrospective Analysis

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ABSTRACT

OBJECTIVE: Negative-pressure wound therapy (NPWT) is a mainstay in the treatment of acute and chronic wounds. Following the success of the Vacuum-Assisted Closure system (Kinetic Concepts Inc [KCI], an Acelity Company, San Antonio, Texas), many similar systems were developed with minor variations. However, these systems are best suited to wounds with soft-tissue defects. Moreover, the need for a canister to collect wound exudate adds to the size and weight of the device. A canister-free (CF) NPWT device was cleared by the FDA for the treatment of chronic wounds (Kalypto Medical, Mendota Heights, Minnesota). A retrospective study was designed to evaluate the effectiveness of the CF-NPWT device in promoting wound healing.

METHODS: The authors examined the records of 51 patients treated with the CF-NPWT device over a 21-month period. Study participants were treated in an outpatient setting, had at least 30 days of prior treatment, and carried insurance coverage through Medicare or Medicaid. The comparison of time to heal between groups was conducted using the log-rank, Breslow, and Tarone-Ware tests in conjunction with a Kaplan-Meier analysis.

RESULTS: In the study population, 65% of the wounds achieved complete closure. For unhealed wounds, the mean wound area reduction was 31.9%, and the mean wound depth reduction was 57.5%. The mean time to heal was 56.9 days (95% confidence interval, 46.4–67.4 days).

CONCLUSIONS: The results show that the CF-NPWT system meets or exceeds healing rates previously reported in the literature for canister-based systems. This CF device offers a more portable NPWT option, particularly effective in the treatment of shallow wounds.

KEYWORDS: chronic wound healing, negative-pressure wound therapy, retrospective study

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INTRODUCTION

Negative-pressure wound therapy (NPWT) has become an essential tool in the armamentarium of the wound care specialist. The technology has been shown to be effective in a variety of wound types, including surgical wounds, diabetic foot ulcers (DFUs),[2] venous leg ulcers (VLUs),[3] and pressure ulcers (PrUs).[4] The first commercialized device, Vacuum-Assisted Closure (V.A.C., Kinetic Concepts Inc [KCI], an Acelity Company, San Antonio, Texas), was introduced in the United States in the 1990s. The system consists of a hydrophobic foam–wound interface covered with an adhesive semiocclusive polyurethane film, a sealed canister to collect wound fluid, and a pump of varying physical sizes that generates negative pressure at the wound surface. There are several theories on the mechanism of action: first, the removal of fluid creates a favorable moisture balance at the level of the wound bed and removes harmful proteases; when suction is applied to the foam, it contracts and pulls the wound edges inward—this mechanical force stimulates the healing process; finally, in a process called microstrain, granulation is pulled up into the pores of the dressing. This has been shown to promote granulation tissue formation.[5]

The reported success of the V.A.C. system encouraged numerous other companies to introduce NPWT systems, and the majority of these devices followed a similar design strategy with minor variations. For example, some systems used gauze rather than foam, recommended a different pressure range, or included an air vent. However, all of these systems followed the basic V.A.C. design with a dressing, canister, and pump. This configuration is well suited to deep wounds with a soft-tissue defect. However, vulnologists frequently encounter superficial wounds that may benefit from NPWT, such as the active 18-year-old patient with a nonhealing elbow wound shown in Figure 1.

Patients often voice complaints about the size and weight of the NPWT system. The wound collection canister determines the minimal size and weight of the device. A canister-free (CF) device, however, does not have this restriction. The US FDA cleared an NPWT device with a CF design to promote the healing of acute and chronic wounds (NPD 1000 NPWT system; Kalypto Medical, Mendota Heights, Minnesota). The authors noted that this model was the first approved NPWT with a canister-free design available at the time of their study. The CF-NPWT system favors wounds that are more superficial. The dressing is easy to apply and convenient to wear (Figures 2 and 3). The absorbent

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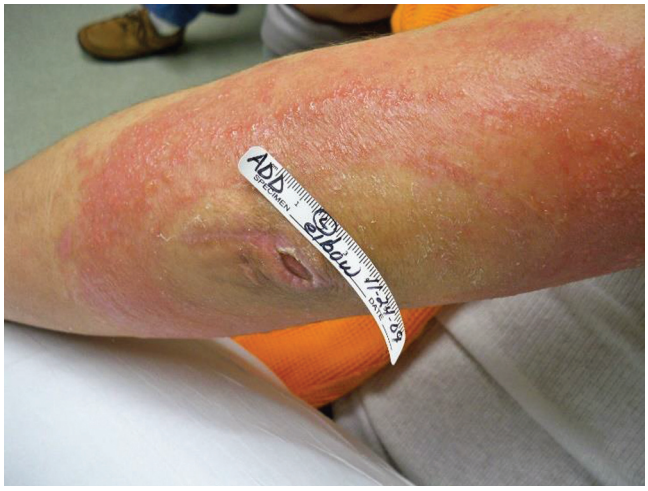
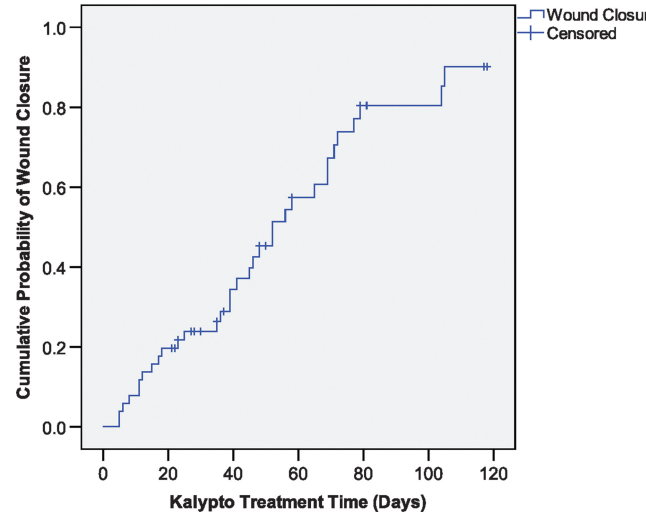
Figure 1.
NONHEALING ELBOW WOUND



pad dressing absorbs exudate, while allowing for the administration of negative pressure to the wound bed. Canister function is assumed by the dressing. The CF system results in the engineering of

Figure 2.
NPD 1000 NEGATIVE-PRESSURE WOUND THERAPY SYSTEM

Figure 3.
TIME TO HEAL ALL WOUNDS (KAPLAN-MEIER PLOT)



a more compact pump, which is the size of an average garage door opener, and is powered by AA batteries (Figure 2). Kalypto marketed this novel pump and dressing from the beginning of 2009 until September of 2011. (The authors noted that Smith & Nephew [St. Petersburg, Florida] later acquired Kalypto and added the CF NPWT to its products.)

MATERIALS AND METHODS

Like all powered NPWT systems, the studied device has an electromechanical pump that is programmable across a variety of pressure ranges from −40 to −125 mm Hg. The pocket-sized pump is capable of delivering the pressure continuously or intermittently to the wound bed and is powered by AA batteries. The system does not require a canister: it simultaneously absorbs fluid and delivers negative pressure to the wound bed. Studies at the author's clinic have demonstrated that the dressing can deliver negative pressure even when completely saturated with fluid.[6] The wound contact layer is a minimally adherent silver product (Silverlon; Argentum Medical, Chicago, Illinois). The nonwoven absorbent pad consists of hydrophilic fibers made of a polymer that molecularly bonds fluid, thereby "locking" the wound exudate in the dressing. Because the wound contact layer is minimally adherent, it can lay over the normal skin at the margin of the wound without causing maceration. Moreover, keratinocytes can theoretically migrate under the dressing, allowing complete epithelialization to occur during the course of NPWT.

Clinical outcomes of 51 patients treated with the CF-NPWT system between January 1, 2009, and September 27, 2010, were

Table 1.

BASELINE DEMOGRAPHIC AND CLINICAL CHARACTERISTICS AND OUTCOMES FOR TOTAL STUDY POPULATION

Demographic Data	Total Study Population (N = 51)
Gender	
Male	47.1% (n = 24)
Female	53.0% (n = 27)
Age, y	
Mean (SD)	66.1 (17.5)
Median	65
Range	28–96
Diabetic foot ulcer	25.5% (n = 13)
Foot	10
Toe	2
Heel	1
Venous leg ulcer	22.0% (n = 11)
Leg	8
Ankle/foot	3
Pressure ulcer	11.8% (n = 6)
Heel	2
Leg	1
Thigh	1
Back	1
Sacrum	1
Surgical wound	29.4% (n = 15)
Foot	7
Leg	3
Sacrum	1
Abdomen	1
Arm	3
Other wound type	11.8% (n = 6)
Chronic	1
Arterial ulcer	1
Below-knee amputation	1
Traumatic wounds	3
Baseline wound area, cm^2	
Mean (SD)	20.6 (50.9)
Median	6.0
Range	0.3–345.0
Baseline wound depth (cm)	
Mean (SD)	1.0 (1.0)
Median	0.6
Range	0.1–5.0
Treatment time, d	
Mean (SD)	44.6 (29.08)
Median	39.0
Range	5.0–118.0
Wounds healed	64.7% (n = 33)
Wounds unhealed	35.3% (n = 18)
Mean (SD) wound area reduction, %	31.9 (46.3)
Median	34.5
Range	−73.0 to 99.0
Mean (SD) wound depth reduction, %	57.5 (36.6)
Median	69.0
Range	0.0–97.0

analyzed in a retrospective fashion. The data source was patient treatment records maintained by durable medical equipment (DME) companies for insurance documentation (NPWT has been a covered outpatient Part B DME benefit in the United States for almost 2 decades). The authors reviewed deidentified patient files from DME dealers that carried the CF-NPWT system in their product line.

The study population included all patients served by the participating medical equipment dealers who met the study requirements: the patients had to have insurance coverage through the Centers for Medicare & Medicaid Services or a state-based Medicaid program. In addition, documentation of at least 30 days of treatment in an outpatient setting prior to initiating CF-NPWT was required. The study group was divided almost equally by gender (female = 27, male = 24). The mean patient age was comparable to other large NPWT studies.[1]

All statistical analyses were performed using SPSS PASW 19 (SPSS Inc, Chicago, Illinois). Comparison of time to heal between groups was conducted using the log rank, Breslow, and Tarone-Ware tests in conjunction with a Kaplan-Meier analysis. A χ^2 test was used to compare the healing rates of wounds closed among the different wound etiologies. Analysis of reduction of wound area from baseline to last measurement by 1-way analysis of variance was not practical as the subgroup sample size was too small.

RESULTS

Table 1 provides the baseline demographics, clinical characteristics, and outcomes for the study population. Wounds evaluated included DFUs, VLUs, PrUs, surgical wounds, and other wound types (Table 2). Healed was defined as a wound with complete closure. Both baseline wound area and baseline wound depth had a nonnormal distribution, with respective medians of 6.0 cm^2 and 0.6 cm.

In the study population, 65% of wounds treated achieved complete closure (Table 1). Although the percentage of wounds healed by the end of the CF-NPWT treatment period varied by wound type—surgical wounds (80% healed), DFUs (69% healed), and other wound types (67%)—these differences were not significant.

For unhealed wounds, the mean wound area reduction was 31.9%, and the mean wound depth reduction was 57.5% (Table 1). The mean time to heal was 56.9 days (95% confidence interval [CI], 46.4–67.4 days) (Table 3, Figure 3). Median time to heal was 52 days (95% CI, 39.4–64.6 days). Statistical significance

Table 2.

TREATMENT OUTCOMES BY WOUND TYPE (ETIOLOGY)

	Wound Type, n (%)					
Healed	DFU	VLU	PrU	Surgical	Other	Total
Yes	4 (30.8)	5 (45.5)	4 (66.7)	3 (20.0)	2 (33.3)	18
No	9 (69.2)	6 (54.5)	2 (33.3)	12 (80.0)	4 (66.7)	33
Total	13	11	6	15	6	51

Abbreviations: DFU, diabetic foot ulcer; PrU, pressure ulcer; VLU, venous leg ulcer.

Table 3.

COMPARISON OF TIME TO HEAL (DAYS) BY WOUND TYPE (ETIOLOGY)

	95% Confidence Interval				95% Confidence Interval	
Wound Type	Estimate Mean	Lower Bound	Upper Bound	Estimate Median	Lower Bound	Upper Bound
DFU	72.6	53.6	91.5	69.0	41.5	96.5
VLU	60.0	47.4	72.6	69.0	40.7	97.3
PrU	48.50	29.9	67.1	39.0	__[a]	__[a]
Surgical	41.5	21.9	61.2	25.0	3.5	46.5
Other	34.5	16.1	52.9	35.0	8.1	61.9
Overall	56.9	46.4	67.4	52.0	39.4	64.6

Abbreviations: DFU, diabetic foot ulcer; PrU, pressure ulcer; VLU, venous leg ulcer.
[a]Cannot be estimated.

of the comparison of time to heal by wound type (Table 3) varied: log rank, not significant; Breslow, $P = .27$; Tarone-Ware, $P = .44$. In general, DFUs healed the slowest (mean, 72.6 days [95% CI, 53.6–91.5 days]; median, 69.0 days [95% CI, 41.5–96.5]), followed by VLUs, PrUs, surgical wounds, and other etiologies.

DISCUSSION

This retrospective study examined a novel CF-NPWT device that differs from historical designs for negative-pressure systems in that it captures wound exudate in an absorbent dressing, rather than a collection canister. The results suggest that wound healing is promoted by CF-NPWT. Moreover, the device was well tolerated in this primarily Medicare population. The CF-NPWT is a portable system. The authors expect that active patients may enjoy the freedom permitted by the size of the system. In addition, the configuration of the dressing allows the clinician to expand the types of wounds being treated with negative pressure. Superficial venous ulcers, for example, can now be treated more readily with CF-NPWT. The system is not appropriate for wounds with a depth greater than 5 cm (50 mm).

One of the purported advantages of the CF-NPWT is that it can be used to complete wound epithelialization. In this study, 65% of the wounds treated with CF-NPWT achieved complete closure in an average of approximately 57 days. Clinicians participating in the study reported that the use of the absorbent dressing allowed the device to be worn until complete healing is achieved.

One of the limitations of the study was that it was a retrospective analysis rather than prospective. Future work will explore this system in prospective, controlled studies, seeking to determine the "optimal" clinical algorithm for this technology.

Finally, it is the first author's (T.S.) experience that this type of device can be maintained and the dressings changed by the patient or home caregiver. This is a subject for future study.

REFERENCES

1. Yang CC, Chang DS, Webb LX. Vacuum-assisted closure for fasciotomy wounds following compartment syndrome of the leg. J Surg Orthop Adv 2006;15;19-23.
2. Armstrong DG, Lavery LA; Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. Lancet 2005;366:1704-10.
3. Vuerstaek JDD, Vainas T, Wuite J, Nelemans P, Neumann MH, Veraart CJM. State-of-the-art treatment of chronic leg ulcers: a randomized controlled trial comparing Vacuum-Assisted Closure (V.A.C.) with modern wound dressings. J Vasc Surg 2006;44:1029-37.
4. Wanner MB, Schwarzl F, Strub B, Zaech GA, Pierer G. Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. Scand J Plast Reconstr Surg Hand Surg 2003;37:28-33.
5. Orgill DP, Manders EK, Sumpio BE, et al. The mechanisms of action of vacuum assisted closure: more to learn. Surgery 2009;146:40-51.