

NPWT vs Standard Care: Which is the Better Treatment for Complex Wounds?

Two systems are used in the United States, and the interest may be growing internationally.

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A recent development in wound care – negative pressure wound therapy (NPWT) – is surfacing as a possible therapy for diabetic wounds secondary to amputation.¹

NPWT systems create a moist environment for wound healing. The technology consists of a pump that applies intermittent or continuous subatmospheric pressure to the wound; a canister that removes wound exudates and excess fluid; and a dressing that isolates the wound. The two most common NPWT systems in the United States are the Vacuum Assisted Closure (VAC) Therapy System (KCI USA, San Antonio) and the Versatile 1 Wound Vacuum System (V1, Blue Sky Medical, Carlsbad, Calif).²

In the United States, both systems are covered under Centers for Medicare and Medicaid Services (CMS) reimbursement coding (HCPCS code E2402) for use in NPWT. However, they are significantly different, according to David G. Armstrong, DPM, PhD, who spoke with *DIABETIC MICROVASCULAR COMPLICATIONS TODAY* in an interview. The VAC system is a wound-healing device and the V1 is a drainage system. “Most people have not heard of or used the Blue Sky device. I have, and these two devices could not be more different,” he said.

FDA APPROVAL

In 1995, the VAC system was first to be approved by the Food and Drug Administration (FDA) for NPWT (Figure 1). On its Web site, KCI claims that the VAC device promotes wound closure and tissue growth by applying negative

pressure via dressings on the wound cavity or over a flap or graft.³ One benefit of the VAC is the material of the dressing, Dr. Armstrong said, because it promotes a protective environment for wound healing. Pressure is localized to the wound site and margins.

According to the company, the VAC Therapy System can be used on patients who benefit from subatmospheric pressure and the removal of infectious material and fluids from the wound. It is indicated for use in patients with diabetic ulcers, chronic open wounds, pressure ulcers, acute and traumatic wounds, flaps and grafts, dehisced wounds and partial-thickness burns. Patients with untreated osteomyelitis, wound malignancy, nonenteric and unexplored fistula or necrotic tissue with eschar should not receive NPWT.

The Versatile 1 drainage system uses a piston and suction system to apply localized negative pressure to the wound.⁴ While there are no peer-reviewed published data to support the device's efficacy, the system carries a claim for wound healing and wound drainage. According to a 2004 company news release, the V1 is FDA approved for marketing, with the indication that the device “may promote wound healing.” It was added to the CMS reimbursement category in October 2005. The V1 system may also be used for other suction needs, according to the company. It was recently displayed at Medica Germany (The 37th World Forum for Medicine International Trade Fair with Congress, Dusseldorf, Germany) to increase international interest.

Photo courtesy of KCI USA



Figure 1. The VAC family of devices, from KCI USA.

Complex lower extremity wounds, which may be some of the most difficult to treat wounds, require substantial care and attention in order to heal. The size and extent of a complex wound is devastating; it is usually large and deep with bone and tendon exposure.⁵⁻⁷ Despite the benefits of standard wound care (ie, debridement and pressure offloading), many patients with diabetic foot wounds persist with high complication rates and poor healing response.⁸ Previous wound care technology has also left patients with poor outcomes.

Reporting in *The Lancet*,¹ Armstrong and Lavery hypothesized that NPWT with the VAC system would produce a better healing response than seen with standard care. Previous studies have investigated VAC-NPWT with positive results,⁹⁻¹³ and there have been between 150 and 200 peer-reviewed manuscripts on the use of VAC. Dr. Armstrong said that data supporting the use of the V1 drainage system is not as diverse or plentiful.

In a 16-week, randomized, controlled trial, 1,162 patients from 18 US diabetic foot/wound centers were treated with either NPWT by means of the VAC Therapy System (n=77, dressings were changed every 48 hours and treated until wound closure or the end of the study) or standard care (n=85, moist wound therapy with dressing changes daily). The primary endpoint was complete wound closure and secondary endpoints included the rate of wound healing, foot salvage and treatment-related complications.

CLINICAL TRIAL

All patients had diabetes, were aged ≥ 18 years and had a foot wound that resulted from amputation, as categorized to the University of Texas grade scale (2 or 3). Wounds were assessed with digital images taken at baseline and at weeks 1, 2, 4, 6, 8, 12 and 16. Of the patients who reached complete wound closure, those who received NPWT did

so in a shorter time (median time to closure 56 days vs 77 days, $P=.005$) and at greater frequency (56% vs 39%, 0.1702, 95% asymptomatic CI, 0.0184-0.322).

Eleven percent of patients in the standard-care group and 3% in the NPWT group had a second amputation. This was not a significant difference, Drs. Armstrong and Lavery reported. However, "it suggested a benefit in favor of NPWT ($P=.060$) ... indicating that patients treated with NPWT were only a quarter as likely as control patients to need a second amputation."

Granulation tissue was also assessed; at baseline 19 NPWT patients and 15 standard-care patients had 0% to 10% granulation. Median time for granulation to reach 76% to 100% was 42 days versus 84 days, respectively. Drs. Armstrong and Lavery concluded that one reason for the lower amputation rate in the treatment group was due to faster granulation time in the NPWT group.

NPWT is a newer option for wound therapy that may produce positive results for the treatment of diabetic wounds. Its use for complex wounds is compelling, as seen from results with the VAC system. Use caution, however, when selecting the appropriate device, Dr. Armstrong said. ■

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