Differentiating Negative Pressure Wound Therapy Devices: An Illustrative Case Series

Editor:
Subhas Gupta, MD, CM, PhD, FRCSC, FACS

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Loma Linda Skin and Wound Care Technology Assessment Panel Members:

Subhas Gupta, MD, CM, PhD, FRCSC, FACS, is the chairman of the technology assessment panel and the editor of this supplement. Dr. Gupta is the Chairman and Program Director of the Division of Plastic Surgery at Loma Linda University and Loma Linda University Medical Center, Loma Linda, Calif. He is board certified in plastic surgery and a member of the American Society of Plastic Surgeons. His current research projects explore advanced technologies in wound care.

Barbara Bates-Jensen, PhD, RN, CWOCN, is Assistant Professor at UCLA School of Nursing and the Division of Geriatrics School of Medicine in Los Angeles, Calif. She is a past Vice President for the National Pressure Ulcer Advisory Panel and the co-editor of *Wound Care: A Collaborative Practice Manual for Health Care Professionals*, 3rd edition. Her research focuses on the quality of pressure ulcer care in nursing homes.

Allen Gabriel, MD, is from the division of plastic surgery at Loma Linda University, Loma Linda, Calif. Dr. Gabriel has conducted several studies on negative pressure wound therapy (NPWT) with focuses on infected and pediatric wounds as well as large surgical defects. He has multiple active research studies investigating the mechanism of action of NPWT and other advanced wound care modalities.

Allen Holloway, MD, RVT, is the Director of Burn Outpatient Services and Director of the Vascular Lab at Maricopa Medical Center in Phoenix, Ariz. He is board certified in internal medicine, is adjunct Professor of Bioengineering at Arizona State University, and is President-Elect of the Wound Healing Society with research interests in new technology and clinical aspects of wounds and burn care.

Jeffrey A. Niezgoda, MD, FACHM, FACEP, is board certified in emergency medicine and hyperbaric medicine. He serves as the Medical Director for the Centers for Comprehensive Wound Care and Hyperbaric Oxygen Therapy and Aurora Health Care and is President of Hyperbaric and Wound Care Associates, Milwaukee, Wisc. He is also an Associate Professor in the Department of Neurology at the Medical College of Wisconsin and Vice President of the American College of Hyperbaric Medicine.

Dot Weir, RN, CWON, CWS, is a board-certified wound and ostomy nurse as well as a certified wound specialist. She is the Clinical Coordinator for Wound Care at Osceola Regional Medical Center in Kissimmee, Fla. She is a member and past-president of the Association for the Advancement of Wound Care (AAWC), a member of the Wound, Ostomy and Continence Nurses Society, and Secretary of the Florida Association of Enterostomal Therapists.
Negative pressure wound therapy (NPWT) has become a popular method of treating a variety of acute and chronic wound types over the past decade. Until recently, there has been only one US Food and Drug Administration (FDA)-cleared commercial device for delivering NPWT, the Vacuum Assisted Closure™ device (V.A.C.® Therapy, KCI, San Antonio, Tex). A competing product called the Versatile 1™ (BlueSky Medical, Carlsbad, Calif) was approved in 2004. Since then, patients treated with the newer devices have presented to the authors' practices for additional management. Two recent cases with unexpected results (Case 3 and Case 4) prompted the Loma Linda Skin and Wound Care Technology Assessment Panel to evaluate the differences between V.A.C. Therapy and the Versatile 1 with respect to approved indications and peer-reviewed clinical efficacy reports and trials. Long-term NPWT users with broad experience in wound care and strong academic backgrounds were invited to participate as members of the panel. The panelists reviewed an extensive library of publications on NPWT as well as information requested from and provided by both manufacturers. Panelists also reviewed cases from their practices that exemplify contrasting efficacy of the technologies.

Vacuum therapy has been used for the treatment of open wounds for nearly a century. Beginning in 1908 with Bier’s Hyperemic Treatment,¹ clinicians have applied vacuum suction to infections and all types of chronic, traumatic, and post-surgical wounds. More contemporary uses of vacuum suction were described in the 1970s in Russian literature²–⁶ and Fleischmann’s work⁷,⁸ followed by case studies described by Chariker,Jeter, and Tintle⁹ in 1989. In 1993, the FDA cleared “VAC therapy” for marketing.
purposes and use in wounds. The system included a sterile, open-cell foam dressing that was placed into a wound, sealed with an adhesive drape, and then exposed to subatmospheric pressure applied through attached tubing. Evidence of improved wound healing, increased granulation tissue formation, and decreased bacterial load was noted.10

Currently, the most common term for vacuum technology is NPWT. While there are presently several devices approved for NPWT, the two most frequently used are V.A.C. Therapy and the Versatile 1. Although originally given FDA clearance in 1993, the approved indications for V.A.C. Therapy have expanded considerably since its inception due to ongoing research and expanded clinical experience with the device (Table 1). V.A.C. Therapy is currently approved for use in preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and removing exudate and infectious material in the wound types listed in Table 1. In contrast, the Versatile 1 is approved for use as a wound suction device, and no specific wound types are included in the FDA indications for use.

The basic components of each device11,12 are a suction pump, tubing, sealing apparatus, and wound interface dressing (Table 2). Both pumps are capable of continuous and intermittent suction, although typical treatment ranges vary. The recommended daily therapy for V.A.C. Therapy is 22–24 hours of suction at 75–125 mmHg to prevent the wound exudate from becoming stagnant in the wound bed and potentially becoming a nidus for infection. The Versatile 1 clinical protocol recommends a continuous pressure of 60–80 mmHg and checking for dressing integrity every 6 hours or once per nursing shift but does not recommend a number of hours for treatment per day. Unpublished posters and manufacturer information on case studies using Versatile 1 describe maintaining suction on the wound for 6–8 hours per day and leaving the dressing undisturbed for the remainder of the 24 hours. The tubing and canister system of V.A.C. Therapy is preassembled and sealed to prevent contamination of the wound. The Versatile 1 tubing-canister system is user assembled, including connection of the filter. The adhesive drape is similar in both products. In addition, another version of V.A.C. Therapy, known as the V.A.C.® Instill® System, combines the function of the standard V.A.C. device with timed, intermittent delivery of an instilled topical solution. The major difference in the two devices is the wound interface. The Versatile 1 is used with gauze dressings. V.A.C. Therapy has two types of foam with varying pore sizes and densities. Evidence suggests that when the foam in the wound bed is exposed to pressure, microdeformational forces promote tissue changes, which increase granulation tissue formation.13 There is no evidence to date that demonstrates that gauze under pressure improves granulation tissue formation.

The safety and contamination control features for both products11,12,14 are detailed in Table 2. The V.A.C. devices include alarms that warn of breaches in the dressing integrity as well as machine malfunction. The Versatile 1 products also have alarms indicating machine malfunction, and the new VISTA™ Versatile 1 Portable provides users with protection against high vacuum. Contamination control is always a concern when using a vacuum device on an open wound. A critical difference between the products is that the V.A.C. canister and tubing are one piece, disposable, and have a gel pack in the canister—features that prevent evacuated wound fluid from re-entering the wound. The Versatile 1 tubing-canister-filter system must be assembled by the user, with a corresponding greater potential for contamination or malfunction if inappropriately connected or if dislodged.

The V.A.C. device comes with explicit clinical guidelines for use, and detailed instructions for use are also provided with V.A.C. dressings. The Versatile 1 products include general guidelines for use that do not include instructions on duration of use per day or wound-specific application. The clinical support for

### Table 1. Currently approved indications of NPWT devices

<table>
<thead>
<tr>
<th>V.A.C. Therapy</th>
<th>Versatile 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>The V.A.C. Therapy System is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute, and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps, and grafts.</td>
<td>The Versatile 1 is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing or for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids, or infectious materials from a patient’s airway or respiratory support system either during surgery or at the patient’s bedside.</td>
</tr>
</tbody>
</table>
the devices is also quite different. V.A.C. Therapy has substantial field support with wound care expertise to help ensure products are used safely and effectively. In addition to field clinical support, there are published guidelines developed by interdisciplinary panels of experts in wound care for safe and effective use of V.A.C. Therapy for specific wound types, including chronic wounds, diabetic foot ulcers, pressure ulcers, chest and sternal wounds, and open abdominal wounds.15–19

Hundreds of reports have been published on the use of NPWT in peer-reviewed journals with the majority of studies providing information on NPWT with V.A.C. Therapy. As of November 2006, evidence specifically supporting V.A.C. Therapy includes at least 14 randomized, controlled clinical trials, 2 prospective controlled studies, 14 comparative retrospective studies, 39 retrospective studies, 69 case series, 98 individual case studies, 19 basic science articles, and 2 economic studies as well as multiple reviews and papers outlining therapy description. Evidence supporting use of the Versatile 1 as of the same date are limited to 1 case series, 6 individual case studies, most in the form of poster presentations, 3 therapy descriptions, and posters of wounds including abdominal fistulas, dehisced abdominal wounds, diabetic foot ulcers, and amputations.20–24

Studies using the V.A.C. device have addressed all wound types, including burns, diabetic foot ulcers, skin grafts and flaps, orthopedic trauma, medias-

### Table 2. Overview of NPWT devices*

<table>
<thead>
<tr>
<th>Suction</th>
<th>KCI</th>
<th>BlueSky</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Mode</td>
<td>Continuous and intermittent</td>
<td>Continuous and intermittent</td>
</tr>
<tr>
<td>• Typical treatment range 75–125 mmHg</td>
<td>22 hours/day</td>
<td>60–80 mmHg</td>
</tr>
<tr>
<td>• Recommended therapy 22 hours/day</td>
<td>Preassembled</td>
<td>6–8 hours/day</td>
</tr>
<tr>
<td><strong>Tubing</strong></td>
<td><strong>Pressure sensing</strong></td>
<td><strong>Canister/tubing</strong></td>
</tr>
<tr>
<td>• Canister/tubing</td>
<td>Preassembled</td>
<td>User assembled</td>
</tr>
<tr>
<td>• Pressure sensing</td>
<td>Feedback loop</td>
<td>Alarms if pressure is too high or too low</td>
</tr>
<tr>
<td><strong>Sealing</strong></td>
<td></td>
<td><strong>Drape</strong></td>
</tr>
<tr>
<td>• Drape</td>
<td>Adhesive drape</td>
<td>Adhesive drape</td>
</tr>
<tr>
<td>• Bridging†</td>
<td>Bridging available</td>
<td>Bridging unknown</td>
</tr>
<tr>
<td><strong>Dressing</strong></td>
<td></td>
<td><strong>Antimicrobial dressing available</strong></td>
</tr>
<tr>
<td>• Material†</td>
<td>Reticulated and nonadherent foam</td>
<td><strong>Antimicrobial gauze available</strong></td>
</tr>
<tr>
<td>• Infection control</td>
<td></td>
<td><strong>Multiple gauze dressing kits</strong></td>
</tr>
<tr>
<td>• Type</td>
<td>Antimicrobial dressing available</td>
<td>Available</td>
</tr>
<tr>
<td>• Instillation</td>
<td>Anatomic and application specific dressings</td>
<td><strong>Gauze with nonadherent contact layer available</strong></td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>Available</td>
<td><strong>Antimicrobial gauze available</strong></td>
</tr>
<tr>
<td>• Alarms</td>
<td></td>
<td><strong>Multiple gauze dressing kits</strong></td>
</tr>
<tr>
<td>• Guidelines for use</td>
<td></td>
<td>Available</td>
</tr>
<tr>
<td><strong>Contamination Control</strong></td>
<td></td>
<td><strong>Overflow, low and high vacuum, low battery</strong></td>
</tr>
<tr>
<td>• Canister</td>
<td>Canister full, tubing blocked, leak, therapy not activated, low battery</td>
<td><strong>Suggested for pressure settings, indications and contraindications; no guidelines for treatment hours per day</strong></td>
</tr>
<tr>
<td>• Filter</td>
<td>Explicit for pressure settings, treatment hours per day, indications and contraindications</td>
<td><strong>User assembled</strong></td>
</tr>
<tr>
<td>• Other</td>
<td>Preassembled, closed, disposable</td>
<td><strong>External bacteria/overflow filter</strong></td>
</tr>
<tr>
<td></td>
<td>Charcoal filter, hydrophobic filter inside canister</td>
<td>Isolyzer available</td>
</tr>
<tr>
<td></td>
<td>Isolyzer (absorbent gel pack inside canister)</td>
<td></td>
</tr>
</tbody>
</table>

*Information obtained from published data and manufacturer information
†Bridging 2 wounds in close proximity to one another: protect skin between the 2 wounds with a piece of V.A.C. drape or another skin barrier. Fill both wounds with foam, and then connect the 2 wounds with an additional piece of foam, like a bridge. All foam pieces must come into contact with each other. The tubing is placed in a central location to ensure exudate from 1 wound is not being drawn across the other wound. Bridging can also be used for dressing small wounds, such as those on the plantar surface or heel of the foot.11
‡For all devices, a variety of nonadherent dressings are used in practice.
tinitis, pressure ulcers, and open surgical and dehisced wounds. In addition, there are over 100 more published reports on other types of wounds and animal studies.25–35

Because all the FDA-cleared vacuum therapy devices are approved to provide NPWT, there is a perception that the therapies are equivalent. All NPWT is not equal, and clearly, more studies are needed comparing the different modalities. The following case series includes examples of wounds treated with both devices. In some instances, V.A.C. Therapy was instituted at an acute care facility, only to be changed over to the Versatile 1 when the patient was transitioned to long-term or home care. Wound deterioration was noted in these cases. Included in the case studies are pressure ulcers, abdominal wounds, diabetic foot ulcers, and burns.

**Case 1**

An 11-year-old boy presented to the emergency room with a lower-extremity soft tissue avulsion injury and open tibia/fibula fracture following a motor vehicle accident (Figure 1A). The patient was taken to the operating room for debridement and external fixation of a large soft tissue deficit with heavy contamination of exposed bone, muscle, and tendon. A silver-impregnated polyurethane foam dressing was applied directly over the wound without a nonadherent layer. V.A.C. Therapy was initiated at 125 mmHg on continuous mode. On Day 7, a split-thickness skin graft was applied and bolstered with silver-impregnated polyurethane foam dressing without a nonadherent layer, and V.A.C. Therapy was applied at 75 mmHg on continuous mode. The dressing was removed on Day 3, and there was 100% graft take and complete wound healing (Figure 1B).

**Case 2**

A 13-year-old boy presented to the emergency room following blunt abdominal trauma (Figure 2A). After being diagnosed with abdominal compartment syndrome, the patient underwent emergency decompression, and V.A.C. Therapy was initiated with an abdominal compartment syndrome dressing system. A perforated, nonadherent layer was folded in around the viscera, and a polyurethane foam dressing was placed over the nonadherent layer and covered with a semi gas-permeable drape. V.A.C. Therapy was initiated at 125 mmHg on continuous mode (Figure 2B). The goal of therapy was to actively remove third space fluid, control the potential visceral space, and maintain a closed wound system in preparation for delayed primary closure. The surgical team performed multiple dressing changes using sterile surgical technique. After the edema resolved, the abdomen was closed via delayed primary closure (Figure 2C). The patient had an uncomplicated recovery and was discharged home on post-trauma Day 22.

**Case 3**

The patient was a 57-year-old Hispanic woman with a history of type II diabetes, hypertension, end-stage renal disease, and a below-knee amputation of the right leg. The patient reported a history of a fall onto her left leg with...
subsequent hematoma requiring evacuation and debridement 3 weeks prior to presenting to the outpatient wound center secondary to lack of progress of healing. The patient had been in a local skilled nursing facility under treatment with the Versatile 1 for 16 days (Figure 3A). The dressing, which consisted of an oil emulsion dressing in the wound bed, a Jackson-Pratt drain, gauze, and a transparent film dressing, was removed (Figure 3B and 3C). Initial evaluation of the wound revealed little viable tissue evident and a relatively dry wound bed consisting primarily of moist yellow and dry dark slough (Figure 3D). The wound bed was debrided (Figure 3E), revealing 14 mm of undermining on the medial edge of the wound. The recommendation was made to change the patient’s NPWT to V.A.C., and the facility agreed. Subsequent visits revealed more than acceptable resolution of the undermining and improvement in the wound bed. The V.A.C. was discontinued after 5 weeks, and the wound healed completely shortly after V.A.C. discontinuation.

Case 4
A 72-year-old man with a history of exploratory laparotomy presented with a dehisced surgical wound. At the time of his initial wound care consultation, the patient underwent sharp debridement (Figure 4A) and was placed on the Versatile 1. The patient returned for follow-up after one week (Figure 4B). The malodorous soiled gauze (Figure 4C) and the drain (Figure 4D) were removed. At the time of the next weekly follow-up visit, the patient was noted to have an area of fluctuance at the inferior wound margin. Exploration of this area revealed a periwound subdermal abscess (Figure 4E). The abscess was drained and the necrotic wound was again sharply debrided. Versatile 1 was discontinued because of the deterioration, and the patient was placed on NPWT using V.A.C. Therapy. A comparative view of the wound after 2 weeks of treatment with each NPWT device is shown in Figure 5. Excellent healing occurred after several weeks of V.A.C. Therapy.

Case 5
A 48-year-old man with diabetes and history of right diabetic foot ulcer presented with a nonhealing dorsal foot wound. He was taken to the operating room for wound debridement. The patient was started on V.A.C. Therapy, and after the first dressing change on postoperative Day 3, he was transitioned to home V.A.C. The patient, however, was started on Versatile 1 by the home care team, unknown to the treating physician. The patient presented in follow-up 10 days after discharge with a sealed moist gauze in the wound bed. After removal of the gauze and drain, necrotic tissue was noted. He was admitted, the wound was debrided, and

Figure 3. Case 3: diabetic lower-extremity wound treated with Versatile 1 and salvaged with V.A.C. Therapy.
he was placed on V.A.C. Therapy for 10 days until the wound was ready for split-thickness skin grafting. He was successfully skin grafted and discharged home with a closed wound.

Case 6
A 50-year-old woman was hospitalized with bilateral cellulitis of the feet 2 weeks after suffering bilateral partial-thickness contact burns on the soles of her feet. Over the course of 2 weeks, the patient underwent multiple tangential excisions and debridements with fasciotomies of the right first, second, fourth, and fifth metatarsals, leaving deep open wounds. She was also diagnosed with diabetes, which was well controlled. After the final debridement, V.A.C. Therapy was started, and she was discharged to home. Unknown to her caregivers at the hospital, she was changed from the KCI V.A.C. to a BlueSky Versatile 1 device immediately following discharge. At her clinic appointment 5 days later, the BlueSky device was in place on the plantar aspect of both feet with a gauze sponge, Jackson-Pratt drain, and a film dressing covering. The wounds were heavily macerated and filled with thick, opaque, foul smelling liquid. Both were clinically infected, and she was readmitted to the hospital for intravenous antibiotics and wound care. After aggressive treatment with whirlpool and debridement, the wounds improved, and she was again discharged with a V.A.C. device. Over the next 2½ months, she developed healthy granulation tissue in the wound, and the V.A.C. was eventually changed over to moist surface dressings. Complete healing of both feet occurred within the next month, and she returned to normal ambulation.

Case 7
A 42-year-old man with long-term paraplegia was admitted to the hospital for surgical management of an ischial ulcer and debridement of a sacral pressure ulcer. Three days following surgery, the patient was discharged to an extended care facility on NPWT with V.A.C. Therapy for the sacral wound. However, the patient’s device was switched to Versatile 1, and he presented to the emergency room with fever and chills 3 weeks post-discharge. Examination of the wound showed periwound cellulitis with gauze and drain in place. Upon removal of the...
In addition, careful attention should be paid to the development of worsening infection, necrotic tissue, and uncontrolled bleeding with the use of NPWT.

Discussion

The term NPWT is pervasive in the wound healing literature and market. Clinicians choosing to use NPWT should know the difference among the devices, including differences in indications and appropriate wound types for use. Negative pressure wound therapy devices have different wound interface materials, safety features, and recommended applications. V.A.C. Therapy has been studied extensively in all wound types. The Versatile 1 has not been studied as rigorously, and its appropriateness for all wound conditions is unknown.

The cases presented provide support that there are differences in NPWT (Table 3). Case 4 demonstrates observational case-controlled clinical differences between the devices, including discrepancy in granulation tissue formation and wound complications.

Several of the presented case studies illustrate experiences when Versatile 1 was substituted for V.A.C. Therapy in the long-term care setting. By necessity, patients must transfer out of the acute care setting while still on advanced wound care therapy, resulting in changes in caregivers and, therefore, often changes in wound treatment. Because of insurance reimbursements and facility protocols, a less expensive therapy (cost per treatment day, not cost to closure analysis) is occasionally used despite the prescribing physician’s preference. Because not all of these devices are considered to be NPWT, some facilities use devices interchangeably, without consideration of the evidence behind individual device types and the potential consequences. In turn, a lack of communication with the prescribing clinician and lack of proper oversight of the therapy can produce major wound complications with significant morbidity.

In order to avoid wound deterioration, the panel recommends that clinicians know the difference among the NPWT devices including appropriate use of individual NPWT devices. The following questions should be considered prior to commencement of NPWT.

Summary Questions

1. How often should patients on NPWT be evaluated and on what criteria should treatment be based?

Patients on NPWT should be evaluated at each dressing change by a clinician experienced with wound therapy and at least every other week by a wound care specialist. Careful wound measurements should be recorded weekly to follow wound progress. If wound measurements have not improved at least 10% per week or have worsened, the therapy may not be appropriate. It has also been recommended that a 50% improvement in wound size over 4 weeks is a good indication that the therapy is working and that the wound will heal. In addition, careful attention should be paid to the development of worsening infection, necrotic tissue, and uncontrolled bleeding with the use of NPWT.

2. What is the evidence support for treatment hours per day?

Evidence supports the use of negative pressure for 22 hours per day. There appears to be no evidence to support use for shorter periods of time. Recent research indicates that the ability of a dressing to conform to the contours of a wound is important to reduce areas of noncontact where bacteria may proliferate. Continuous NPWT maintains conformability of the interface to the wound bed, minimizing potential glycocalyx. The porous nature of a foam in a negative pressure environment also allows for compression and conformity to the entire wound surface.

3. When should NPWT be stopped?

When the treatment goal is met or any of the conditions in question 1 are present, NPWT should be stopped. In some cases, NPWT can be used until wound closure, although in most cases, it is used until the wound is filled with good granulation tissue and ready for skin graft or flap or standard wound therapy.

4. What are the advantages of the device interfaces available?

Scientific evidence supports that microstrain results when an open cell, reticulated foam dressing is used in conjunction with negative pressure. There is no evidence to support that this occurs with gauze under pressure. Also, the hydrophobic nature of the V.A.C. foam allows exudate and infectious materials to be readily removed, while gauze absorbs this same fluid, keeping it in contact with the wound bed, particularly if NPWT suction is not used for extended periods daily.

5. How do you minimize wound bed contamination from the device?

The NPWT device should be equipped with an adequate filtration device and should be a closed drainage system with little risk of being dislodged. There should be consistent suction at all times.
Choosing the right NPWT device should be based on careful consideration of the specific FDA indications for use (Table 1), the amount of clinical evidence, and availability of clinical support.

### Recommendations

The Loma Linda Skin and Wound Care Technology Assessment Panel makes the following recommendations:

- Appropriate wound bed preparation is always paramount
- Review and follow indications for NPWT devices and be sure they are appropriate for wound type and patient condition
- Indications are not the same for all NPWT devices
- Careful oversight of patients’ care as they transition to different inpatient or outpatient settings is necessary
- Monitor the wound consistently and weekly to assess wound progression toward goal of therapy.

### Conclusion

Over the last decade, NPWT has been established as a well defined wound care option in treating complex acute and chronic wounds and, in many instances, has become the standard of care. However, different devices claim to deliver NPWT. They do not have the same efficacy and indications. Given the differences between the technologies, each system was reviewed in the context of evidence-based medicine. There is a substantial body of peer-reviewed evidence supporting the use of KCI’s V.A.C. in numerous wound types, but the panel was unable to conclude that the BlueSky Versatile 1 had evidence supporting its use in wound management. Additionally, the panel’s case series highlights cases in which the V.A.C. was required for salvage of Versatile 1-treated wounds that had deteriorated. The panel expects to see the unveiling of additional products delivering NPWT, and it shall be left to the individual practitioner to use his or her clinical judgment and review the evidence in order to provide patients with the most efficacious and safe modality available on the market.

### References


### Table 3. Case series summarized by indications

<table>
<thead>
<tr>
<th>Wound Type</th>
<th>Case Number</th>
<th>NPWT Modality</th>
<th>Outcome</th>
<th>Indication-Specific Evidence Supporting NPWT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic (diabetic lower extremity)</td>
<td>3, 5</td>
<td>Versatile 1</td>
<td>Stalled healing; second debridement and V.A.C. for salvage</td>
<td>References 15, 16, 25, 26, 30</td>
</tr>
<tr>
<td>Acute (traumatic)</td>
<td>1, 2</td>
<td>V.A.C. Therapy</td>
<td>Successful tertiary closure and flap closure</td>
<td>References 19, 30, 34</td>
</tr>
<tr>
<td>Subacute and dehisced</td>
<td>4</td>
<td>Versatile 1</td>
<td>Infection; abscess drainage and V.A.C. for salvage</td>
<td>References 18, 28, 29, 30, 33</td>
</tr>
<tr>
<td>Partial-thickness burns</td>
<td>6</td>
<td>Versatile 1</td>
<td>Increased necrotic tissue; debridement and V.A.C. for salvage</td>
<td>References 30, 32</td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td>7</td>
<td>Versatile 1</td>
<td>Infection; urgent operative debridement and V.A.C. for salvage</td>
<td>References 17, 30, 31</td>
</tr>
<tr>
<td>Flaps and grafts</td>
<td>1</td>
<td>V.A.C. Therapy</td>
<td>Successful flap and complete graft take</td>
<td>References 30, 32</td>
</tr>
</tbody>
</table>

6. How does one choose the appropriate NPWT device?

Choosing the right NPWT device should be based on careful consideration of the specific FDA indications for use (Table 1), the amount of clinical evidence, and availability of clinical support.


