V.A.C. Ulta™ Negative Pressure Wound Therapy System: Customizing Wound Healing

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Introduction
Over the years, wound treatment has progressed from dry gauze products to advanced moist wound therapies and further to active wound healing therapies. One such active therapy is V.A.C.™ Therapy, a clinically proven, advanced negative pressure wound therapy (NPWT) system that was cleared for commercialization in 1995. Since that time, a variety of NPWT systems and dressings has been developed in order to meet the needs of wound patients. In 2003, V.A.C. Instill™ Wound Therapy introduced to the US the principles of NPWT with instillation (NPWTi) that were developed by Fleischmann et al. NPWTi helps to further promote wound healing by combining the benefits of irrigation using topical wound solutions with the advantages of NPWT. The latest development in V.A.C.™ Therapy technology incorporates both NPWT and instillation features, including a new volumetric pump and dressings designed for instillation therapy, in one system: the V.A.C. Ulta™ Negative Pressure Wound Therapy System.

Introducing the V.A.C. Ulta™ Negative Pressure Wound Therapy System
The V.A.C. Ulta™ Therapy System (Figure 1) is an integrated wound management system that provides negative pressure for three therapy systems: 1) V.A.C.™ Therapy using V.A.C.® GranuFoam™ and V.A.C.® White-Foam Dressings, 2) V.A.C. VeraFlo™ Instillation Therapy using V.A.C. VeraFlo™ and V.A.C. VeraFlo Cleanse™ Dressings, and 3) ABThera™ Open Abdomen Negative Pressure Therapy using ABThera™ SensaT.R.A.C.™ Open Abdomen Dressing.

Figure 1. V.A.C. Ulta™ Negative Pressure Wound Therapy System
This discussion will focus on the improved instillation therapy, V.A.C. VeraFlo™ Therapy, which consists of NPWT coupled with automated, controlled delivery to and removal of topical wound treatment solutions from the wound bed. The user-selected soak phase and automated volumetric delivery differentiate V.A.C. VeraFlo™ Therapy from other commercially available instillation systems that provide instillation solutions only under continuous flow (without a soak time). V.A.C. VeraFlo™ Therapy is also unique in that it uses dressings specifically designed for instillation therapy with NPWT. The dressings are less hydrophobic than the current V.A.C.® GranuFoam™ Dressings and provide improved fluid distribution within the wound bed.

For more information on V.A.C.™ Therapy and the ABThera™ Open Abdomen Negative Pressure Therapy, please visit www.kci1.com.

Wound Management
Wounds differ not only in size and shape, but also in amount of exudate, edema, and presence of inflammatory mediators, pathogens, or physical contaminants. Additionally, all wounds can be categorized as unclean (ie, potentially contaminated with bioburden or infected). Wound severity and comorbidities of the host (eg, immunocompromised, malnourished, poor perfusion, smoking, chronic medical conditions, and advanced age) can further contribute to the probability of delayed wound healing. All of these factors influence the healing rate and should be considered in selecting optimal wound therapy for each patient.

There is widespread acceptance that wound cleansing is necessary in wound therapy; however, there are very few randomized controlled trials (RCTs) that compare cleansing techniques and solutions. Current wound treatment practice includes some or all of the following:

- Debridement
- Antibiotic treatment and local application of antiseptics or antimicrobials
- Delayed wound closure (when necessary)
- Use of drains
- Repeated wound cleansing with either manual or pulsed irrigation

Science Supporting V.A.C. VeraFlo™ Therapy
The V.A.C. Ulta™ Therapy System contains improved instillation technology with V.A.C. VeraFlo™ Therapy. Therefore, several analyses were conducted to evaluate different properties of this therapy. Table 1 describes benchtop, in vitro, in vivo, and ex vivo studies that demonstrate the properties of V.A.C. VeraFlo™ Therapy. Results of these preclinical studies have not yet been confirmed in human trials and are not to be considered as clinical claims.

Wound Management with V.A.C. VeraFlo™ Therapy
In addition to these wound treatment practices, V.A.C. VeraFlo™ Therapy can potentially be used for a variety of indicated wound types, such as acute, traumatic, and dehisced wounds, as well as pressure, diabetic foot, and venous ulcers. Because these are open wounds, it is not uncommon for them to become contaminated or infected. Therefore, these types of wounds may benefit from removal of infectious materials and controlled instillation of topical wound cleansers and/or topical antimicrobial/antiseptic solutions into the wound bed. Instillation therapy differs from irrigation/lavage, which is the practice of washing out a wound or body opening with a stream of liquid solution. In instillation therapy, instilled fluid is slowly introduced into the wound and remains in the wound bed for a defined period of time before being removed by applying negative pressure (Figure 2). Automated instillation helps with wound cleansing by loosening soluble contaminants in the wound bed, followed by subsequent removal of infectious material during NPWT. As a result, soluble bacterial burden can be decreased, contaminants removed and the wound cleansed without user interaction.

V.A.C. VeraFlo™ Therapy combines the benefits of V.A.C.™ Therapy with automated solution distribution and removal.

- Cleanses the wound with instillation of topical wound cleansers in a consistent, controlled manner
- Treats the wound with the instillation of appropriate topical antimicrobial and antiseptic solutions and the removal of infectious material
- Heals the wound and prepares for primary or secondary closure

Figure 2. Schematic illustration of V.A.C. VeraFlo™ Therapy
**Table 1. Scientific studies supporting the use of V.A.C. VeraFlo™ Therapy**

<table>
<thead>
<tr>
<th>Property</th>
<th>Study Description</th>
<th>Results/Conclusions</th>
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</table>
| Reduction of Bacterial Aerosolization         | • In *in situ* wound irrigation evaluating instillation against lavage and the potential for cross contamination.  
  o Anatomical wound model was inoculated with simulated wound fluid containing inactivated common wound pathogens *Escherichia coli* and *Staphylococcus aureus*.  
  o Collection plates were placed 6 inches around the wound to capture droplets or splashing from the wound as it was cleaned.  
  o The following commercially available products were delivered at 4-15 psi for lavage: Sterile Wound Wash Saline® (Blairex Laboratories, Inc. COLUMBUS, OH), Carra-Klenz™ Wound and Skin Cleanser (Carrington Laboratories Inc., Irving, TX), and Ultra-Klenz™ Wound Cleanser (Carrington Laboratories, Inc., Irving,TX).  
  o Normal saline was used with V.A.C. VeraFlo™ Therapy (5 cycles, each cycle consisting of instillation of normal saline and 60 sec soak time followed by 20 minutes continuous negative pressure at -125 mmHg). | • Lavage wound cleansing caused significantly more aerosolization of the wound fluid and bacteria (p<0.05) compared to V.A.C. VeraFlo™ Therapy, and approximately one-half of the inoculated bacteria were captured outside of the wound bed on the collection plates.  
  • Using V.A.C. VeraFlo™ Therapy with normal saline, no bacterial droplets were detected on the collection plates.  
  • V.A.C. VeraFlo™ Therapy allows for a more controlled, contained wound irrigation compared to standard techniques, potentially reducing the likelihood of cross-contamination of patients, healthcare workers, and the surrounding environment. |
| Wound Cleansing and Tissue Damage             | • *In vivo* porcine model to evaluate cleansing ability of V.A.C. VeraFlo™ Therapy vs pulsed lavage.  
  Wounds were inoculated with fluorescent dextran particles and received either 10 cycles of V.A.C. VeraFlo™ Therapy (each cycle consisting of 40-second instillation of saline, 5-minute soak, and 5-minute NPWT over 2 hours) or pulsed lavage (1L of saline within 2 min).  
  • Resulting fluorescence decrease and tissue swelling were measured. | • Both pulsed lavage and V.A.C. VeraFlo™ Therapy showed a reduction in fluorescein-dextran (95% ± 1.5% vs. 99% ± 0.6%, respectively), indicating effective wound cleansing by both therapies.  
  • Changes in wound volume (+22% ± 8.3% V.A.C. VeraFlo™ Therapy vs. 4.5% ± 2.5% pulsed lavage) and wound depth (-19% ± 6.4% V.A.C. VeraFlo™ Therapy vs. 4.7% ± 2.1% pulsed lavage) showed that pulsed lavage-treated wounds exhibited significantly more swelling (p<0.05) than V.A.C. VeraFlo™ Therapy-treated wounds, indicating that pulsed lavage may damage tissue during cleansing.  
  • Histology results showed that pulsed lavage had a slightly higher edema score compared to V.A.C. VeraFlo™ Therapy.  
  • These data suggest that V.A.C. VeraFlo™ Therapy may have more effective wound cleansing, causing less tissue edema compared to pulsed lavage. |
| Dressing fluid distribution                    | • *V.A.C.® GranuFoam™* and V.A.C. VeraFlo™ Dressings were precut and placed between two transparent plates, which were compressed 65% to 5.3 mm thickness.  
  • Plates were immersed in a clear plastic reservoir containing 15 mm of saline and removed after 6-, 15-, or 30-minute exposure times.  
  • They were then weighed and the amount of saline wicked by each dressing was measured.  
  • Procedure was repeated 5 times and analyzed. | • Data showed that V.A.C. VeraFlo™ Dressing distributed more fluid into the foam than V.A.C.® GranuFoam™ Dressing.  
  • V.A.C. VeraFlo™ Dressing enabled more even fluid delivery during instillation and enhanced absorption by the foam.  
  • Fluid movement for *V.A.C.® GranuFoam™* Dressings reached equilibrium sooner than V.A.C. VeraFlo™ Dressings.  
  • These data suggest that the V.A.C. VeraFlo™ Dressing may have enhanced fluid distribution properties. |
| Periodic versus continuous instillation       | • *In vitro* model evaluating ability to distribute solution across a wound between instillation therapy and continuous irrigation.  
  • Agar wound model was either instilled continuously with solution while negative pressure was applied (30 mL/hr for 3.5 hours) or with instillation therapy (three 10-minute soak times followed by application of NPWT).  
  • Following instillation, model was evaluated for fluid distribution across the wound surface. | • With instillation therapy, solution covered 73% of the wound surface.  
  • With continuous irrigation, solution covered 30% of the wound surface.  
  • Instillation therapy allowed for better solution distribution across the wound surface, including into tunnels and undermined areas. |
| Disruption of ex vivo biofilm using instillation| • *Ex vivo* porcine skin explants biofilm model.  
  o Mature *Pseudomonas aeruginosa* biofilm (10^9-10^10 organisms) grown on porcine skin explants.  
  o V.A.C. VeraFlo™ Therapy was administered for 24 hours, with instillation delivered every 4 hours, followed by 10-minute soak time and negative pressure delivered at −125mmHg between instillation cycles.  
  o Various solutions were tested including 0.1% polyhexanide and Normal Saline.  
  o Biofilms were evaluated after therapy with colony counts (CFU/mL) and scanning electron microscopy (SEM). | • There was approximately a 3-log (99.8%) reduction in soluble bioburden using 0.1% polyhexanide with V.A.C. VeraFlo™ Therapy. |
| Granulation tissue formation                   | • *In vivo* porcine model (n=12) comparing V.A.C. VeraFlo™ Therapy using V.A.C. VeraFlo™ Dressing and V.A.C. Therapy using V.A.C.® GranuFoam™ Dressing.  
  o V.A.C. VeraFlo™ Therapy included instillation of 20 mL of normal saline with a 5-minute soak time followed by negative pressure at −125 mmHg for 2.5 hours continuously for 10 cycles daily.  
  o V.A.C.® Therapy was set at −125 mmHg continuous pressure. | • A significant increase in granulation thickness (43%, p<0.05) was observed with V.A.C. VeraFlo™ Therapy using V.A.C. VeraFlo™ Dressings compared to V.A.C.® Therapy using V.A.C.® GranuFoam™ Dressings (4.82 ± 0.42mm and 3.38 ± 0.55mm, respectively, p<0.05).  
  • Data showed that the V.A.C. VeraFlo™ Therapy using V.A.C. VeraFlo™ Dressing increased wound fill over traditional V.A.C.® Therapy using V.A.C.® GranuFoam™ Dressing. |

*Results of the preclinical studies have not yet been confirmed in human trials and are not to be considered as clinical claims.

**Clinical Evidence Supporting the Use of Instillation Therapy**

In recent years, instillation therapy has emerged as an alternative option for patient wounds that would benefit from vacuum-assisted closure and controlled delivery of topical cleansing solutions and suspensions, such as normal saline and wound cleansers, into the wound bed. Table 2 summarizes the literature on instillation therapy, which spans over 10 years of clinical research.
Table 2. Literature Review*

<table>
<thead>
<tr>
<th>Author</th>
<th>Patients</th>
<th>Solution Used</th>
<th>Instillation/NPWT Parameters</th>
<th>Results/Conclusions</th>
</tr>
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<tbody>
<tr>
<td>Bernstein and Tam 16</td>
<td>A series of 5 post-surgical diabetic patients whose foot wounds were treated with instillation therapy.</td>
<td>Solution composed of saline, polymyxin B, and bacitracin</td>
<td>6 hours of NPWT at −125 mmHg followed by instillation for 90 seconds and a soak time of 5 minutes.</td>
<td>Authors noted a decrease in hospital stay and amputation rate and that the addition of instilled solutions lowered wound fluid viscosity, facilitating more efficient removal into the canister.</td>
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<tr>
<td>Gabriel et al 17</td>
<td>15 patients with complex, infected wounds treated with instillation therapy compared to a retrospective historical control of 15 patients treated with moist gauze wound care (control).</td>
<td>Silver nitrate</td>
<td>Instillation therapy consisted of instillation for 30 seconds with a 1-second hold time followed by 2 hours of NPWT at −125 mmHg continuously.</td>
<td>Results showed that patients managed with instillation therapy required fewer days of treatment (p&lt;0.001), cleared the infection earlier (p&lt;0.001), achieved wound closure sooner (p&lt;0.001), and had fewer in-hospital days (p&lt;0.001) compared to the control group.</td>
</tr>
<tr>
<td>Timmers et al 18</td>
<td>A retrospective, case–control cohort study of 30 patients diagnosed with osteomyelitis of the pelvis or lower extremity and treated with debridement, systemic antibiotics and adjunctive instillation therapy.</td>
<td>Polyanthanide</td>
<td>Soak time was 10–15 minutes. 300 mmHg to 600 mmHg negative pressure range was used. Dressing changes occurred every 3–4 days with mean therapy duration of 19.0–22.4 days.</td>
<td>In instillation therapy group, recurrence infection rate was 3/30 (10%) compared to 55/93 (58.5%) for the control group (p&lt;0.0001).</td>
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<tr>
<td>Schintler et al 19</td>
<td>A series of 15 patients with skin and soft tissue infection (eg, necrotizing fasciitis) treated with instillation therapy.</td>
<td>Polyanthanide</td>
<td>Instillation time was dependent on wound size; dwell time was 20 minutes in all cases. Therapy duration ranged from 4–18 days with dressing changes every 2–4 days.</td>
<td>Results showed that infection was controlled and complete healing was achieved in all patients. Authors concluded that instillation therapy may be a viable option for infection control in complicated anatomical regions and in cases of incomplete debridement in complicated skin and soft tissue infections.</td>
</tr>
<tr>
<td>Raad et al 20</td>
<td>5 patients with venous stasis ulcers (&gt;200cm²) and with colonization greater than 10⁸ bacteria were studied.</td>
<td>12.5% Dakin’s solution</td>
<td>Patients were initially debrided and then treated with instillation therapy for 10 days with instillation for 10 minutes every hour. After 10 days and following negative quantitative cultures, patients received an STSG and 4 days of standard NPWT.</td>
<td>Results showed 100% graft take at 1-month follow up. Authors concluded that instillation therapy provided an effective therapy for managing patients with infected chronic venous stasis ulcers.</td>
</tr>
</tbody>
</table>

*Studies were performed with previous generations of negative pressure with instillation therapy, not V.A.C. Ultra™ Therapy with V.A.C. VeraFlo™ Therapy.

Solutions Compatible with V.A.C. VeraFlo™ Therapy

A number of solutions have been tested and are compatible with V.A.C. VeraFlo™ Therapy System components:
- Hypochlorite-based solutions (eg, Hypochlorous acid, sodium hypochlorite) such as ½ strength Dakin’s solution and Dermacyn®
- Silver nitrate (0.5%)
- Sulfur-based solutions (eg, sulfonamides), such as mafenide acetate and Sulfamyl®
- Biguanides (eg, polyhexanide) such as Prontosan® and Lavasept®
- Cationic solutions (eg, octenidine and benzalkonium chloride) such as Octenilin® and Zephiran®
- Isotonic solutions, such as normal saline and lactated Ringer’s solutions

Contraindications

V.A.C.® Therapy and V.A.C. VeraFlo™ Therapy are contraindicated for patients with: malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, necrotic tissue with eschar present, or sensitivity to silver. Dressings should never be placed directly in contact with exposed blood vessels, anastomotic sites, organs, or nerves. Solutions, such as Octenisept® (Schülke&Mayr GmbH), hydrogen peroxide, or alcohol-based solutions should not be used with dressings. Also, fluids should not be delivered to the thoracic or abdominal cavity due to the potential risk of altering the core body temperature and the potential for fluid retention within the cavity. V.A.C. VeraFlo™ Therapy should not be used unless the wound has been thoroughly explored due to the possibility of inadvertently instilling topical wound solutions into adjacent body cavities.

It is important to always read and follow all instructions and safety information prior to use for any NPWT device. Detailed safety information can be found with the device and disposables, as well as on KCI’s e-labeling link [http://www.kci1.com/KCI1/elabeling].

Clinical Case Studies

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on patient circumstances and conditions.

Case Study 1

A 69-year-old female patient with a history of arterial hypertension presented with an open fracture of the left lateral malleolus (Figure 1A). An initial large surgical debridement was performed, followed by V.A.C. VeraFlo™ Therapy with a V.A.C. VeraFlo™ Dressing for 9 days. Saline (0.9% NaCl) was instilled until the foam was filled, followed by a soak time of 10 minutes (Figure 1B). Instillation was repeated every 6 hours followed by continuous negative pressure at −125 mmHg. Dressing changes occurred on Days 3 (Figure 1C) and 6, with final removal on Day 9. A thin hydrocolloid dressing was applied around the wound edges for extra skin protection (Figure 1D). After 9 days of therapy, there was rapid development of homogenous granulation tissue (Figure 1E) and a clean appearance of the wound. A split thickness skin graft (STSG) was applied on Day 10 (Figure 1F), and by Day 18, wound was completely closed (Figure 1G).

Figure 1.

- Day 0: A. Presentation of an open fracture of the lateral malleolus of the left ankle
- Day 0: B. Application of V.A.C. VeraFlo™ Therapy with saline
- Day 3: C. Wound after first dressing change
- Day 9: D. A thin hydrocolloid dressing applied around the wound edges for extra skin protection
- Day 10: E. Rapid development of homogenous granulation tissue with a clean appearance of the wound
- Day 18: F. Application of STSG
- G. Wound was completely closed
Case Study 2
A 66-year-old male with a history of alcohol-induced peripheral neuropathy and an ulcer of 1-year duration presented with cellulitis, abscess, osteomyelitis, and a chronic ulcer on the lateral 5th metatarsal base secondary to cavovarus foot type (Figure 2A). He was admitted to the hospital and was placed on intravenous antibiotics. The patient was taken to the operating room (OR) for initial incision and drainage (debridement) (Figure 2B) as well as for cultures. The culture method involved swabbing the deepest margins of the wound and then creating 4 streaks on an agar medium. Qualitative cultures were determined through growth on the medium. The post-debridement culture results were “few (ie, 1 streak of growth) coagulase negative Staphylococcus, rare (<1 complete streak of growth) Pseudomonas aeruginosa, and rare (<1 complete streak of growth) Corynebacterium.” V.A.C. VeraFlo® Therapy was initiated using V.A.C. VeraFlo® Dressing. Prontosan® was instilled until the foam was filled, followed by a soak time of 10 minutes. Instillation was repeated every 3.5 hours, followed by continuous negative pressure at -125 mmHg for 3 days (Figures 2C and 2D). The patient was then returned to the OR for a second debridement. The pre-debridement culture results from the second OR visit were “no growth (ie, no growth on all 4 streaks).” The wound was closed with an antibiotic spacer (ie, cement impregnated with vancomycin and gentamicin) (Figure 2E). Patient was discharged home with prophylactic antibiotics and subsequently followed up in clinic. No incision dehiscence or wound complications were noted on subsequent visits.

Figure 2.

A. Cellulitis/abscess on the lateral aspect of the right foot
B. Debrided wound
C. Application of V.A.C. VeraFlo® Dressing and V.A.C.® Advanced Drape
D. Application of V.A.C. VeraFlo® Therapy with Prontosan®
E. Wound closed with antibiotic spacer

Conclusion
The V.A.C.Ulta™ Therapy System is designed to provide therapeutic options that can be customized for different wound care needs. When used in conjunction with good wound healing management (eg, debridement and antibiotics), instillation therapy allows physicians to manage a variety of wound types effectively. More importantly, V.A.C. VeraFlo™ Therapy can help: 1) cleanse the wound with instillation of topical wound cleansers; 2) treat the wound with the instillation of appropriate topical antimicrobial and anti-septic solutions, and removal of infectious materials during the negative pressure cycle; and 3) heal the wound and prepare for secondary closure. V.A.C. VeraFlo™ Therapy also provides a controlled environment that is protected from external contamination sources. Thus, the V.A.C.Ulta™ Therapy System incorporates the proven benefits of V.A.C.™ Therapy with the added advantages of V.A.C. VeraFlo™ Therapy for the treatment of acute and chronic wounds.

Reference List
(1) Gupta S. The impact of evolving V.A.C.™ Therapy technology on outcomes in wound care. Int Wound J. 9(Suppl 1), iii-47. 8-1-2012.

Learn more at vaculta.com/veraflo or call 800.275.4524

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