Negative Pressure Wound Therapy with Instillation: Next Step in the Evolution of Negative Pressure

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Financial Disclosures

- Kinetic Concepts, Inc
- Integra Life Sciences
- Innovative Therapies, Inc
Important Information

- Prior to use of the V.A.C.® Ulta Therapy System, it is important for the provider to consult the treating physician and read and understand all Instructions for Use, including Safety Information, Dressing Application Instructions, V.A.C.® Ulta Therapy Unit Instructions and V.A.C.® Therapy Clinical Guidelines.

- KCI recommends that clinicians participate in device in-service and training prior to use.

- This presentation contains case study slides based on the presenter’s individual clinical experience and research. 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 the patient’s circumstances and condition.

- Any opinions, findings and/or conclusions or recommendations expressed in this presentation are those of the presenter, not necessarily those of KCI.

- This information is intended for healthcare professionals only.

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Learning Objectives

• Review the V.A.C. Ulta™ Therapy System that provides both V.A.C. Therapy and V.A.C. VeraFlo Instillation Therapy
• Discuss the impact the V.A.C. Ulta™ Therapy System has on wound management
• Discuss cases treated with NPWTi
• Describe the benefits of NPWT and NPWTi in the management of complex wounds based on the preliminary Georgetown study of V.A.C. Ulta™ Therapy
• Consensus guidelines
What is V.A.C. VeraFlo™ Therapy?

- The V.A.C. Ulta Therapy Unit provides both V.A.C.® Therapy and V.A.C. VeraFlo™ Instillation Therapy
- V.A.C. VeraFlo™ Therapy is the controlled instillation of topical wound solutions coupled with negative pressure wound therapy.

In order to optimize the therapy, KCI developed new dressings (V.A.C. VeraFlo™ Dressing and V.A.C. VeraFlo Cleanse™ Dressing specifically designed for instillation.

*Seal Check™ Leak Detector
**Fill assist allows the user to monitor initial wound fill by manually starting and stopping instillation to determine correct instill volume after dressing is applied.
V.A.C. VeraFlo™ Therapy

- V.A.C. VeraFlo™ Instillation Therapy:
  - Delivers user selected topical wound solutions to the wound
  - After a user selected soak period, evacuates wound fluids under negative pressure
  - Closed system prevents “splash-back” or aerosol generation
  - Provides consistent, automatic, and controlled instillation therapy delivery
  - V.A.C.® Therapy can be provided between instillation cycles

- All in one therapy
It can help:

**Cleanse** the wound with instillation of topical wound cleansers in a consistent, controlled manner.

**Treat** the wound with the instillation of appropriate topical antimicrobial and antiseptic solutions and the removal of infectious material.

**Heal** the wound and prepare for primary or secondary closure.
Clinical Considerations
The V.A.C.Ultra™ Negative Pressure Wound Therapy System is an integrated wound management system that provides V.A.C.® Negative Pressure Wound therapy with an instillation option (VeraFlo™ Therapy).

Negative Pressure Wound Therapy *in the absence of instillation* 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 by removing exudate and infectious material.

The instillation option (VeraFlo Therapy) is indicated for patients who would benefit from vacuum-assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The V.A.C.Ultra™ Negative Pressure Wound Therapy System with and without instillation is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure, and venous insufficiency), flaps and grafts.
V.A.C. Ulta™ Therapy
System Contraindications

- Do not place foam dressings of the V.A.C. Ulta™ Therapy System (including V.A.C.® Therapy and V.A.C. VeraFlo™ Therapy Dressings) directly in contact with sensitive structures such as exposed blood vessels, anastomotic sites, organs, or nerves.
  - *(Note: Refer to Warnings section [of IFU] for additional information concerning Bleeding)*
- V.A.C.® Therapy and V.A.C. VeraFlo™ Therapy are contraindicated for patients with:
  - Malignancy in the wound
  - Untreated osteomyelitis
    - *(NOTE: Refer to Warnings section of IFU for Osteomyelitis information)*
  - Non-enteric and unexplored fistulas
  - Necrotic tissue with eschar present
    - *(Note: After debridement of necrotic tissue and complete removal of eschar, V.A.C.® Therapy may be used.)*
  - Sensitivity to silver (V.A.C. GranuFoam Silver® Dressing only)
Additional Contraindications for V.A.C. VeraFlo™ Therapy

• Do not use V.A.C.® Therapy Dressings with Octenisept™ (Schülke & Mayr GmbH)*, hydrogen peroxide or solutions that are alcohol-based or contain alcohol.

• Do not deliver fluids to the thoracic cavity or abdominal cavity due to the potential risk to alter core body temperature and the potential for fluid retention within the thoracic cavity.

• Do not use V.A.C. VeraFlo™ Therapy unless the wound has been thoroughly explored due to the potential for inadvertent instillation of topical wound solutions to adjacent body cavities.

*Not available in the United States. Brand name referenced is not a trademark of KCI, its affiliates, or licensors.
Additional Safety Information

- Additional safety information exists and will be made available at the end of this presentation.

- The participants are encouraged to review this information which can be found on [www.kci1.com](http://www.kci1.com) and with the V.A.C.Ulta™ Therapy System.
## Indicated Wound Types

### Indicated Open Wound Types
- Chronic
- Acute, traumatic
- Dehisced
- Pressure ulcers
- Diabetic foot ulcers
- Venous ulcers

### Factors which may compromise healing
- Contamination or infection
- Susceptible host (poor immune system)
- Comorbidities, e.g., diabetes, smoking may impact patient ability to fight bacteria and heal
- Edema
- Resistant bacteria
- Poor hygiene or wound care

### Benefits of V.A.C. VeraFlo™ Therapy
- Instillation of topical wound cleansers and topical antimicrobial or antiseptic solutions
- Removal of infectious material
- Controlled protected environment for flushing & cleansing wounds
- Protection from external contamination sources

V.A.C. VeraFlo™ Therapy is appropriate for a variety of indicated open wound types. It is not uncommon for these wounds to be contaminated or infected. These wounds may benefit from controlled instillation of topical wound cleansers, topical antimicrobial or antiseptic solutions and removal of infectious material.
Wound Care for Contaminated and Infected Wounds is a Multi-step Process Including:

1. Patient and wound assessment

2. Debridement that removes necrotic and fibrinous tissue and decreases the bacterial load

3. Initiation of appropriate cleaning and antimicrobial therapy

4. Removal of exudates

5. Increasing granulation tissue in preparation for wound closure

Wound Care for Contaminated and Infected Wounds using VeraFlo™ Therapy

V.A.C. VeraFlo™ Therapy can:

1. Cleanse the wound through instillation of topical wound cleansers that can help soften and loosen wound debris

2. Deliver topical antiseptic/antimicrobial wound solutions that can help reduce the bacterial population

3. Remove solubilized wound debris and infectious materials, including planktonic bacteria, during the V.A.C.® Therapy Cycle

4. Promote granulation tissue formation and perfusion during the V.A.C.® Therapy Cycle, helping prepare the wound for closure

5. Provide contained and controlled wound irrigation without risk of bacterial aerosolization typically generated during manual cleansing
Clinical Literature Review

• Negative pressure wound therapy is a well-established adjunctive wound healing modality
• Negative pressure wound therapy with instillation has been reported in the literature for the use in infected or contaminated wounds.
• No robust studies examining the efficacy of negative pressure wound therapy with instillation on infected or contaminated wounds.
Introduction

Georgetown University Hospital Center for Wound Healing

Time

Phyletic Gradualism

Punctuated Equilibrium

Creationism
Introduction

Time

Progress

Negative Pressure Wound Therapy

Standard Wound Care

Negative Pressure Wound Therapy with Instillation
- Negative pressure wound therapy
  - 1511 indexed publications
- Negative pressure wound therapy with instillation
  - 11 small case series

<table>
<thead>
<tr>
<th>Author, date, publication type</th>
<th>Wound type</th>
<th>Instillation solution</th>
<th>Dwell time (minutes)</th>
<th>NPWT time (minutes)</th>
<th>Negative pressure setting (mmHg)</th>
<th>Instillate volume (mls)</th>
<th>Duration of application (days)</th>
</tr>
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<tbody>
<tr>
<td>Bernstein &amp; Tam (2005) Case series</td>
<td>Post traumatic osteomyelitis (n=30); control (n=54)</td>
<td>Lavasept (polyhexanide 0.04%)</td>
<td>10-15</td>
<td>?</td>
<td>300-600</td>
<td>3-10</td>
<td>24(6-60)</td>
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<tr>
<td>Timmers et al (2008) Case series</td>
<td>Acute infection (n=15); control (n=15)</td>
<td>Silver nitrate</td>
<td>30-45 secs instillation with 1 sec dwell</td>
<td>120</td>
<td>125</td>
<td>50-75</td>
<td>9.8(5-20)</td>
</tr>
<tr>
<td>Schintler et al (2009) Case series</td>
<td>Infectious peri-orthopedic implants (n=23)</td>
<td>Lavasept (polyhexanide 0.04%)</td>
<td>15</td>
<td>60</td>
<td>125</td>
<td>?</td>
<td>?</td>
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<tr>
<td>Leffler et al (2009) Case series</td>
<td>Chronic osteomyelitis (n=6) Infections peri-orthopedic implants (n=10)</td>
<td>Lavasept (polyhexanide 0.04%)</td>
<td>20</td>
<td>180-360</td>
<td>?</td>
<td>?</td>
<td>?</td>
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<tr>
<td>Raed et al (2010) Case series</td>
<td>Chronic venous wounds (n=5) Infections peri-orthopedic implants (n=32)</td>
<td>Lavasept (polyhexanide 0.04%)</td>
<td>5-30</td>
<td>70.3(30-270)</td>
<td>125-200</td>
<td>?</td>
<td>16.3(9-46)</td>
</tr>
</tbody>
</table>
Georgetown University Hospital Treatment Algorithm for Inpatient Care of the Infected Wound

1. Predebridement Cultures
2. Debridement/Irrigation
3. Postdebridement Cultures
4. NPWT
5. ± NPWT or NPWTi
6. ± Closure/Coverage

- Patients receive antibiotics per ID service at the time of admission
- Time elapsed between the 1st and 2nd OR visit within 2-4 days
- Coverage or closure is dictated by the prior post debridement culture results and clinical assessment
Case Studies
Case #1

- **59-year-old male**
  - Type II diabetes mellitus (DM), peripheral vascular disease (PVD), and peripheral neuropathy.
  - Presented with cellulitis, abscess, osteomyelitis of the proximal and distal phalanx of the right hallux

- **Hospital Course**
  - Initial I&D with filet of hallux, 4 days with NPWTi, closure
  - OR visit #1 debridement cultures positive staph
  - OR visit #2 debridement cultures no growth
Case #2

- 47-year-old male
  - Type II diabetes mellitus (DM), peripheral neuropathy, healed prior TMA
  - Presented with cellulitis, abscess, chronic wound sub 5th met with exposed bone

- Hospital Course
  - Initial I&D, 2 days with NPWTi, Integra
  - OR visit #1 debridement cultures positive pseudomonas
  - OR visit #2 debridement cultures no growth
Case #3

- 66-year-old male
  - Alcohol induced peripheral neuropathy and an ulcer of 1 year duration
  - Presented with cellulitis, abscess, osteomyelitis
- Hospital Course
  - Initial I&D, 2 days with NPWTi, closure
  - OR visit #1 debridement cultures positive coag neg staph, pseudomonas
  - OR visit #2 debridement cultures no growth
Case #4

- 52-year-old female
  - Poorly controlled DM
  - Hospital to hospital transfer with cellulitis, abscess, exposed tendon

- Hospital Course
  - Initial I&D, 2 days with NPWTi, Repeat I&D, 3 days of NPWTi, filet of hallux, STSG
  - OR visit #1 post debridement cultures positive strep, pseudomonas
  - OR visit #2 post debridement cultures positive strep
  - OR visit #3 pre debridement cultures negative
Other Cases

Elbow

Achilles
Pilot Study Preliminary Data

Poster Presented at Symposium on Advanced Wound Care Spring 2013
6 Minute Dwell
3.5 Hours NPWT

20 Minute Dwell
2 Hours NPWT
Georgetown University Hospital Treatment Algorithm for Inpatient Care of the Infected Wound

- Patients receive antibiotics per ID service at the time of admission
- Time elapsed between the 1st and 2nd OR visit within 2-4 days
- Coverage or closure is dictated by the prior post debridement culture results and clinical assessment
### Demographics

<table>
<thead>
<tr>
<th></th>
<th>NPWT</th>
<th>NPWTi</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AGE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>58 (26 – 83)</td>
<td>60 (20 – 88)</td>
</tr>
<tr>
<td><strong>GENDER</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>M: 20</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>F: 15</td>
<td>18</td>
</tr>
<tr>
<td><strong>RACE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AA: 11</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>C: 20</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>H: 2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>A: 1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Other: 1</td>
<td>5</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td>42.2 (19.9 – 62.6)</td>
<td>31.5 (17.0 – 52.4)</td>
</tr>
</tbody>
</table>
Methods

- Retrospectively analyzed consecutive patients with historical control
- Data gathered from inpatient charts from a single institution (Georgetown University Hospital)
- 4 surgeons: 2 Plastic Surgeons, 2 Podiatric Surgeons
- All patients who received InfoV.A.C.® or V.A.C.Ultra™ Therapy for the same time period
Device

- **Negative Pressure**
  - V.A.C.Ultä™ System with V.A.C. VeraFlo™ (Kinetic Concepts, Inc.)
  - -125 mmHg, continuous
  - 3.5 hours/2 hours of NPWT (for NPWTi)

- **Instillation**
  - Prontosan®: Polyhexanide + Betaine (B.Braun Medical Inc.)
  - 6 or 20 minute soak (dwell) time
  - Volume: varies on wound size; when the sponge is visibly saturated
Methods

• Admission criteria
  – Signs and symptoms of infection (confirmed by WBC and/or qualitative cultures)

• Discharge criteria
  – Cleared infection (confirmed by WBC and/or qualitative cultures)

• Surgical Technique
  – Debridement
    • Use of scalpel, curette, hydrosurgical scalpel, rongeour
  – Irrigation
    • Pulsatile with 3 liters normal saline
Methods

• Independent Variables
  – OR visit #1 post-debridement qualitative cultures versus OR visit #2 pre-debridement cultures
  – Number of OR visits
  – Length of hospital stay
  – % closed prior to discharge
  – Number of days to closure (at the time of admission)

• Qualitative Bacterial Cultures
  – Cultures taken from deepest margin of the wound or infected site
  – Results converted to nominal data
    • No Growth = 1
    • Scant Growth = 2
    • Few Growth = 3
    • Moderate Growth = 4
    • Heavy Growth = 5
  – If polymicrobial then sum of the nominal data averaged for each patient
Wound Location

NPWT

June 2011, July 2011, & August 2011 (N = 35)

Sept 2011, Dec 2011, & Jan 2012 (N = 39)
Wound Location
## Results

6 Minute Dwell Time

NPWT= Negative Pressure Wound Therapy  
NPWTi= Negative Pressure Wound Therapy with Instillation

<table>
<thead>
<tr>
<th></th>
<th>NPWT N=35</th>
<th>NPWTi N=34</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>NUMBER OF OR VISITS</td>
<td>2.9 ± 1.5</td>
<td>2.4 ± 0.9</td>
<td>*0.04</td>
</tr>
<tr>
<td>LENGTH OF STAY (Days)</td>
<td>15.7 ± 10.8</td>
<td>11.9 ± 7.8</td>
<td>0.066</td>
</tr>
<tr>
<td>TIME TO FINAL</td>
<td>9.9 ± 6.3</td>
<td>7.8 ± 5.2</td>
<td>0.13</td>
</tr>
<tr>
<td>SURGICAL PROCEDURE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(From Admission in</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Days)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PERCENT CLOSED</td>
<td>57% (20)</td>
<td>94% (32)</td>
<td>*0.001</td>
</tr>
<tr>
<td>(Prior to Discharge)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PERCENT REMAINED</td>
<td>75% (15)</td>
<td>75% (24)</td>
<td>1.0</td>
</tr>
<tr>
<td>CLOSED (1 Month f/u)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DAYS to 1 Month f/u</td>
<td>33.91 ± 13.33</td>
<td>34.45 ± 10.29</td>
<td>0.85</td>
</tr>
<tr>
<td>% IMPROVED:</td>
<td>40% (14/35)</td>
<td>59% (20/34)</td>
<td>0.15</td>
</tr>
<tr>
<td>All Bacteria Included</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% IMPROVED:</td>
<td>64% (9/14)</td>
<td>90% (19/21)</td>
<td>0.09</td>
</tr>
<tr>
<td>Gram Negatives,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corynebacterium,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yeast Excluded</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Improved = no growth or decrease in bacterial amount  
Culture results were obtained from qualitative analysis  
Improved = no growth or decrease in bacteria amount

*p<0.05  
Statistical significance calculation utilizing T-test of means, 2-tailed distribution.  
Statistical significance calculation of % utilizing Fisher’s exact test, 2-tailed.
### Results

#### 20 Minute Dwell Time

NPWT = Negative Pressure Wound Therapy  
NPWTi = Negative Pressure Wound Therapy with Instillation

<table>
<thead>
<tr>
<th></th>
<th>NPWT N=39</th>
<th>NPWTi N=34</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NUMBER OF OR VISITS</strong></td>
<td>3.0 ± 0.9</td>
<td>2.6 ± 0.9</td>
<td>*0.04</td>
</tr>
<tr>
<td><strong>LENGTH OF STAY (Days)</strong></td>
<td>13.4 ± 4.8</td>
<td>11.4 ± 5.1</td>
<td>0.089</td>
</tr>
<tr>
<td><strong>TIME TO FINAL SURGICAL PROCEDURE (From Admission in days)</strong></td>
<td>9.8 ± 4.3</td>
<td>7.5 ± 3.1</td>
<td>*0.012</td>
</tr>
<tr>
<td><strong>PERCENT CLOSED (Prior to Discharge)</strong></td>
<td>67% (26)</td>
<td>80% (27)</td>
<td>0.29</td>
</tr>
<tr>
<td><strong>PERCENT REMAINED CLOSED (1 Month f/u)</strong></td>
<td>50% (13)</td>
<td>52% (14)</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>DAYS to 1 Month f/u</strong></td>
<td>30.79 ± 13.33</td>
<td>33.41 ± 9.04</td>
<td>0.23</td>
</tr>
<tr>
<td><strong>% IMPROVED: All Bacteria Included</strong></td>
<td>36% (14/39)</td>
<td>50% (17/34)</td>
<td>0.25</td>
</tr>
<tr>
<td><strong>% IMPROVED: Gram Negatives, Corynebacterium, Yeast Excluded</strong></td>
<td>62% (8/13)</td>
<td>65% (13/20)</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Culture results were obtained from qualitative analysis  
Improved= no growth or decrease in bacteria amount

*p<0.05  
Statistical significance calculation utilizing T-test of means, 2 tailed distribution.  
Statistical significance calculation of % utilizing Fisher’s exact test, 2 tailed.
Findings

• Comparing NPWT to NPWTi there was a statistically significant
  • Decrease in the number of OR visits (6 & 20 Minute Dwell),
  • % closed (6 Minute Dwell)
  • Time to final closure (20 Minute Dwell) using NPWTi as compared to NPWT.

• Trend for decrease in the length of hospital stay and higher % improvement in bacterial cultures using NPWTi as compared to NPWT.
Study Limitations

- Not prospective or randomized
- Use of historical controls
- No outcomes data after discharge
- Large number of excluded patients due to missing or not captured data points
- The use of qualitative cultures
- Nonstandardized volume of instillate used
- Length of hospital stay variables unaccounted for
Consensus Guidelines

Note: the following guidelines are those of the Consensus Panel and not of KCI

Manuscript accepted in March 2013 for publication in the journal Plastic and Reconstructive Surgery
<table>
<thead>
<tr>
<th>Panelists</th>
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</thead>
</table>
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Associate Professor, Department of Plastic Surgery  
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Washington, DC, USA |
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Chief Senior Consultant, Orthopedic and Plastic Surgery  
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Berlin, Germany |
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Associate Professor, Department of Plastic Surgery  
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| Karen K Evans, MD  
Assistant Professor, Department of Plastic Surgery  
Georgetown University Hospital  
Washington, DC, USA |
| Tom Wolvos, MD, MS  
Chief, Division of General Surgery  
Scottsdale Osborne Healthcare Medical Center  
Scottsdale, AZ, USA |
## Panelists

<table>
<thead>
<tr>
<th>Panelist</th>
<th>Title and Affiliation</th>
</tr>
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<tbody>
<tr>
<td>Dennis Orgill, MD, PhD</td>
<td>Professor, Department of Surgery, Harvard Medical School</td>
</tr>
<tr>
<td>Allen Gabriel, MD</td>
<td>Chief, Department of Plastic and Maxillofacial Surgery</td>
</tr>
<tr>
<td>William Ennis, DO, MBA</td>
<td>Professor, Clinical Surgery, University of Illinois at Chicago</td>
</tr>
<tr>
<td>John Lantis, MD</td>
<td>Associate Clinical Professor, Department of Surgery, Columbia University</td>
</tr>
<tr>
<td>Gregory Schultz, PhD</td>
<td>Professor, Wound Research, University of Florida</td>
</tr>
<tr>
<td>Chris Lessing, PhD</td>
<td>Senior Scientist, Applied Science Group in Research &amp; Development, Kinetic Concepts Inc</td>
</tr>
</tbody>
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Boston, MA, USA

Vancouver, WA, USA

Chicago, IL, USA

Gainesville, FL, USA

San Antonio, TX, USA
Consensus Process

Selection of Panelists

Consensus Panel Meeting

Surveys Sent to Panelists

Survey Responses Tallied & Comments Evaluated

Draft of Manuscript Circulated for Comments

Manuscript Submission
## Consensus Agreement

### Modified Willy & Steller

<table>
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<tr>
<th>Rank</th>
<th>Agreement</th>
<th>% Agreement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Strong Consensus</td>
<td>&gt;95% or participants agree</td>
<td>Statement should be included</td>
</tr>
<tr>
<td>2</td>
<td>Consensus</td>
<td>&gt;75-95% of participants agree</td>
<td>Statement should be included</td>
</tr>
<tr>
<td>3</td>
<td>Majority Approval</td>
<td>&gt;50-75% of participants agree to</td>
<td>Statement should be included</td>
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<tr>
<td>4</td>
<td>No Consensus</td>
<td>&lt;50% of participants agree</td>
<td>Statement should not be included</td>
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### Modified Delphi Method

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<th>Agreement</th>
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<td>Essential, Important</td>
<td>&gt;80% of panel in agreement, Statement should be included</td>
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<td>2</td>
<td>Don’t Know/Depends</td>
<td>Statement should be excluded</td>
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<tr>
<td>3</td>
<td>Unimportant</td>
<td>Statement should be excluded</td>
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<tr>
<td>4</td>
<td>Should Not Be Included</td>
<td>Statement should be excluded</td>
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Consensus Statement #1

Negative pressure wound therapy with instillation can be used as an adjunct therapy after being appropriately treated and evaluated in the following wound types:

1) acutely and chronically infected wounds
2) contaminated wounds
3) diabetic wounds
4) traumatic wounds
5) decubitus wounds
6) wounds with exposed bone
7) wounds with underlying osteomyelitis
8) infected wounds in the presence of orthopedic hardware
9) painful wounds
10) as a bridge between staged/delayed amputation.

- All wounds should be appropriately treated and evaluated.
- Should not be used as a sole modality to treat infection.
Consensus Statement #2

Negative pressure wound therapy with instillation does not replace debridement of the acutely infected, chronically infected, or contaminated wound.

- NPWT with instillation is not a debridement modality.
- NPWT with instillation can be used as a bridge between debridements.
- Instillation can serve to prepare the wound bed for closure or grafting.
The following are appropriate instillation solutions that can be used with negative pressure wound therapy with instillation*

1) Lavasept® (polyhexanide 0.04%)**
2) Prontosan® (polyhexanide 0.1%+ Betaine),
3) Microcyn®/Dermacyn®.

- Other Solutions: 0.25% and 1% dilute acetic acid, dilute iodine, and 1.25% sodium hypochlorite (Dakin’s solution), antibiotics alone as well as cocktails utilizing antibiotics mixed with local anesthetics (1%, 2% lidocaine plain), normal saline, Silver nitrate solution

- Important to evaluate the unique properties of the instillation solution including its potential toxicity, activity, availability, and cost.

*Tested for compatibility with the V.A.C. VeraFlo™ Therapy Unit
**Not available in US
Consensus Statement #4

An appropriate range of installation dwell time is 10-20 minutes.

- A balance must be struck between the length of dwell time and the length of time in which negative pressure is applied.
- No evidence that evaluates the length of dwell and its relationship to antimicrobial dressing activity when a solution is used in combination with NPWT.
An appropriate volume of instillation solution used is 20-100 mLs or until the foam is visibly saturated.

- Ideal volume of instillation solution is elusive due to wounds size variation complicated by tunneling and irregular dimensions.
- Too much solution may cause difficulty in maintaining a seal with the occlusive dressing and could cause maceration of the surrounding tissue.
- Too little solution will not allow enough solution to bathe the entire wound surface.
An appropriate negative pressure time phase is 1-2.5 hours.

- The combination with NPWT with installation of a solution may have an additive cleansing effect.
- For large wounds, short negative pressure times can lead to frequent exchanging of the solution emptying container and placement of the new solution container, which may lead to compliance issues.
An appropriate negative pressure wound therapy with instillation pressure setting is -125 mmHg and -150 mmHg.

- Morykwas, et al suggested that both pressures lower or higher than 125 mmHg result in a significant decrease in formulation of granulation tissue.
- Timmers, et al report the use of negative pressures ranging from 300-600 mmHg when utilizing NPWT with instillation.
Consensus Statement #8

An appropriate setting for negative pressure is continuous not intermittent.

- Some degree of intermittency inherent to NPWT with installation.
- More frequent release of suction during intermittent negative pressure, thereby increasing the chance of loss of a seal with the occlusive dressing.
Consensus Statement #9

The exact minimum and maximum duration of negative pressure wound therapy with instillation is variable.

• No absolute minimum or maximum duration for the use of NPWT with installation.
• Duration of NPWT with instillation therapy is dependent on factors such as wound quality and the surgical plan.
• Indefinite use of NPWT with instillation is not clinically or economically prudent.
Consensus Statement Limitations

- Expert opinion is low on the hierarchy of evidence
- A true Delphi Method was not utilized
- Relatively small number of experts on the panel
- Paucity of evidence to support statements
- The consensus statements only provide preliminary guidelines
- As the body of evidence grows, these guidelines will require modification
Conclusions

• NPWTi shows promise as an adjunctive wound cleanser as shown by decreasing bacterial amounts, OR visits, length of hospital stay.
• Georgetown University Hospital is leading a randomized, controlled, prospective, multicenter study objectively examining the efficacy of negative pressure wound therapy with instillation.
Safety Information for V.A.C. VeraFlo™ Therapy
For complete safety information for V.A.C. VeraFlo™ Therapy, please refer to labeling provided with the V.A.C.Ultra™ Therapy Unit, dressing and component cartons.

Labeling may also be found at the e-labeling web site on KCI1.com.

What follows are key safety points for application of V.A.C. VeraFlo™ Therapy.
Do not place foam dressings of the V.A.C. Ultra™ Therapy System (including V.A.C.® Therapy and V.A.C. VeraFlo™ Therapy Dressings) directly in contact with sensitive structures such as exposed blood vessels, anastomotic sites, organs, or nerves.

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
- Sensitivity to silver (V.A.C. GranuFoam Silver ® Dressing only)
Additional Contraindications for V.A.C. VeraFlo™ Therapy

- Do not use V.A.C.® Therapy Dressings with Octenisept™ (Schülke & Mayr GmbH)*, hydrogen peroxide or solutions that are alcohol-based or contain alcohol.

- Do not deliver fluids to the thoracic cavity or abdominal cavity due to the potential risk to alter core body temperature and the potential for fluid retention within the thoracic cavity.

- Do not use V.A.C. VeraFlo™ Therapy unless the wound has been thoroughly explored due to the potential for inadvertent instillation of topical wound solutions to adjacent body cavities.

*Not available in the United States. Brand name referenced is not a trademark of KCI, its affiliates, or licensors.
Warnings

- **Topical Wound Solutions**: Topical wound solutions or suspensions may enter internal body cavities if the wound is open to such cavities. They should not be infused into wounds with unexplored tunnels or unexplored undermining as they may enter into unintended cavities.

- **Pauses in Negative Pressure**: Application of V.A.C. VeraFlo™ Therapy will result in pauses of negative pressure wound therapy, which is not recommended on wounds requiring continuous V.A.C.® Therapy. Do not use V.A.C. VeraFlo™ Therapy over unstable structures, such as unstable chest wall or non-intact fascia, on patients at increased risk of bleeding, highly exudating wounds, on flaps, grafts or wounds with acute enteric fistulae.
Warnings (cont.)

- **Bioengineered Tissue:** V.A.C. VeraFlo™ Therapy is **not intended** for use with cellular or acellular bioengineered tissues.

- **Hemostasis:** Patients with difficult or fragile wound hemostasis are at increased risk of bleeding associated with V.A.C. VeraFlo™ Therapy due to the potential for disruption of clots or dilution of clotting factors. **Do not use V.A.C. VeraFlo™ Therapy where hemostatic agents have been used in the wound bed.**
Precautions

- **Suitable Solutions:** V.A.C. VeraFlo™ Therapy is intended for use with V.A.C. VeraFlo™ Therapy disposables and topical wound treatment solutions and suspensions. **Only use solutions or suspensions that are:**
  - **Indicated for topical wound treatment according to solution manufacturer’s instructions for use.** Some topical agents may not be intended for extended tissue contact. If in doubt about the appropriateness of using a particular solution for V.A.C. VeraFlo™ Therapy, contact the solution’s manufacturer about its suitability for saturated topical wound exposure.
Suitable Solutions (continued). Only use solutions or suspensions that are:

- Compatible with V.A.C.® Dressings and disposable components. Contact your KCI representative for a list of solutions shown to be compatible with V.A.C.® Dressings and disposable components.

  NOTE: Hypochlorous acid solutions applied frequently at high concentrations can lead to significant material degradation. Consider utilizing concentrations and exposure durations as low as clinically relevant.

  NOTE: The V.A.C. GranuFoam Silver® Dressing is not intended to be used with V.A.C. VeraFlo™ Therapy because instillation solutions may negatively affect the benefits of the V.A.C. GranuFoam Silver® Dressing.