Experience with Integrated Negative Pressure Wound Therapy System with Volumetric Automated Fluid Instillation in At-Risk Wounds

Allen Gabriel, MD, FACS
Department of Plastic Surgery
Peacehealth Southwest Medical Center
Vancouver, Washington
&
Loma Linda University Medical Center
Loma Linda, California

©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Important Information

• In most cases, unless otherwise indicated, these slides will reference indications and safety information generally applicable to V.A.C.® Therapy and V.A.C. VeraFlo™ Therapy.

• Before using V.A.C.® Therapy and V.A.C. VeraFlo™ Therapy, read all safety information which is provided with the therapy unit, as well as in dressing and canister cartons.

• Certain unique indications, contraindications, warnings, and precautions apply for products within KCI Negative Pressure Therapy Systems, including the V.A.C.Ulta™ NPWT system. Prior to use, read the instructions for use provided for the specific therapy unit or disposables for complete product information.

• Please refer to the V.A.C.® Therapy Clinical Guidelines, A Reference Source for Clinicians (available at www.kci1.com), for additional information when establishing patient-specific NPWT treatment protocols.

• Additional information and education on KCI Negative Pressure Therapy topics, including V.A.C.® Therapy, can be found on www.kci1.com. Clicking on the Education & Training link will provide information on these educational opportunities.

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

• Rx only.

3M and Cavilon are trademarks of 3M Company. Unless otherwise indicated, all other trademarks are proprietary to KCI Licensing, Inc., its affiliates and/or licensors.
Clinical Problem

Cases are more complicated
Clinical Problem

RAPID HEALING
Follow Principles
Goals of Wound Treatment

➢ Create an environment that is conducive to normal and timely healing
  – Immune system mounts immune response
  – Medical problems assessed and treated
Débridement

- Frequent débridements
  - Growth factors to function more effectively
  - Remove inhibitors of wound healing
Continuum

- **Contaminated**
  - Small number of bacteria
  - Non-adherent, non-replicating

- **Colonized**
  - Bacteria replicating
  - Adherent to surface, non-invasive

- **Critically Colonized**
  - Bacteria replicating
  - Beginning to invade
  - Subtle signs of infection

- **Infected**
  - Bacteria replicating
  - Deeply invasive
  - Classic signs and symptoms of infection

Patient and Wound Assessment: Biofilm

Microbial flora appear to change over time:

- **Acute wound**
  - Normal skin flora predominate

- **Sub-acute wound**
  - *S. aureus*, and beta-hemolytic *Streptococcus*

- **Chronic wound**
  - Gram negative rods will colonize wound (*MC Proteus, E. coli, and Klebsiella*)
Biofilm

- Anaerobes
- Poly-microbial
- Late contamination:
  - Pseudomonas
  - Acinetobacter
  - Stenotrophomonas
  - Enterococcus
  - Candida

Patient and Wound Assessment: Is the Wound Infected?

- A continuum exists between when pathogens colonize the wound and then start to cause damage.

- Two features are common to all infected chronic wounds:
  - Failure of the wound to heal
  - Progressive deterioration of the wound


©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Patient and Wound Assessment: Is the Wound Infected?

- Typical features of wound infections:
  - Increased exudate
  - Increased swelling
  - Increased erythema
  - Increased pain
  - Increased local temperature
  - Peri-wound cellulitis, ascending infection, change in appearance of granulation tissue (discoloration, highly friable)

Bacterial Burden

**Contamination**
- Presence of non-replicating bacteria on wound surface normal in chronic wounds

**Colonized**
- Replication of bacteria on wound surface without invasion of wound tissue & no host immune response

**Critically Colonized**
- Critical point between colonization & Infection

**Infection**
- Presence of replicating bacteria in wound tissue beneath the wound surface (viable tissue). Produce host response & tissue injury

Local Systemic

---

Biofilm

- Reversible adsorption of bacteria (sec.)
- Irreversible attachment of bacteria (sec.-min.)
- Growth & division of bacteria (hrs.-days)
- Exopolymer production & biofilm formation (hrs.-days)
- Attachment of other organisms to biofilm (days-months)
Protected Bacteria

- Glycocalyx of bacteria
Protected Bacteria

- Irrigation or cleansing does not penetrate glycocalyx
- Mechanical/sharp debridement is necessary to expose the bacteria

Goal of surgical débridement

Excise the wound until it is:

- Normal
- Soft
- Well-vascularized
Reconstructive Goals

- Close wound
- Prevent infection
- Stable, robust coverage
- Minimize donor defect
- Maximize function

©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Successful Bridge between Débridement and Final Coverage

MANAGEMENT Is the Key to SUCCESS
Reconstructive Ladder

- Healing by secondary intention
- Direct tissue closure
  - primary
  - delayed
- Local tissue transfers
- Distant tissue transfers
- Free tissue transfer

High Tech Healing
- Tissue engineering
- Tissue expansion
- HBO
- Cytokine Therapy
- Xeno/Allograft skin
  - Negative Pressure Wound Therapy

©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Management

- NPWT
  - V.A.C. Ultra™ NPWT System.
Management

• NPWT
  – V.A.C.Ultimate™ NPWT System.
NPWT Instillation

- Instillation time
- Soak time
- Frequency
- NPWT
V.A.C. VeraFlo™ Therapy Can Help

**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.

©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Wound cleansing

- Crucial step in wound management and healing
Cleansing Solution

• Saline
  – Physiologically compatible
  – Non toxic (cell viability)
  – Non allergenic
  – Does not alter the flora
Irrigation modalities

• Low Pressure (4-15 psi)
  – Bulb syringe method
  – Gravity flow
• High Pressure (35-70 psi)
  – Manual Pump
  – Mechanical/pulsed lavage
Optimal Conditions for Cleansing

• No soft tissue/bone damage
• No aerosolization of bacteria
• No increase of the depth of contaminant and bacterial penetration into soft tissue
• No edema formation
Scientific Studies

• The following scientific studies were conducted using either bench, tissue, and living animal models to assess the impact of various cleaning methods.
• These results have not been confirmed in human studies.
Qualitative tissue damage grades for samples: Grade 1 = minimal damage to Grade 5 = severe damage. Samples treated with HPPL were consistently given higher grades.

Debridement of Cancellous Bone: A Comparison of Irrigation Methods.

©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
In vivo open noncontaminated diaphyseal femoral fracture model in rats

CONCLUSIONS:
The use of high-pressure pulsatile lavage in open noncontaminated diaphyseal femur fractures in rats has a significant negative impact on the mechanical strength of the fracture callous during the early phases (three weeks) of fracture healing.

FIGURE 4. Damage grades for samples: Grade 1 = minimal damage to Grade 5 = severe damage. Samples treated with HPPL were consistently given higher grades.
Comparison of tissue damage, cleansing and cross contamination potential during wound cleansing: Lavage vs. instillation

Low Pressure
(4-15 psi)

High Pressure
(35-70 psi)

Ex vivo study evaluating three methods of cleansing using raw porcine tissue


©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Comparison of tissue damage, cleansing and cross contamination potential during wound cleansing: Lavage vs. instillation

Ex vivo study evaluating three methods of cleansing using raw porcine tissue


©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Comparison of tissue damage, cleansing and cross contamination potential during wound cleansing: Lavage vs. instillation

NPWTi-treated < 3 psi

Model: Porcine wounds inoculated with fluorescent simulated wound debris and then treated with NPWTi or low pressure lavage


©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Comparison of tissue damage, cleansing and cross contamination potential during wound cleansing: Lavage vs. instillation

**Low Pressure (4-15 psi)**

Model: Porcine wounds inoculated with fluorescent simulated wound debris and then treated with NPWTi or low pressure lavage.


©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Comparison of tissue damage, cleansing and cross contamination potential during wound cleansing: Lavage vs. instillation

Model: Porcine wounds inoculated with fluorescent simulated wound debris and then treated with NPWTi or low pressure lavage


©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Optimal Conditions for Cleansing

- No soft tissue/bone damage
- No aerosolization of bacteria
- No increase of the depth of contaminant and bacterial penetration into soft tissue
- No edema formation

< 3 psi offers adequate cleansing with no soft tissue damage
Comparison of tissue damage, cleansing and cross contamination potential during wound cleansing: Lavage vs. instillation

Benchtop wound model was:

- Inoculated with wound fluid and fluorescent bacteria particles (*E. coli* and *S. aureus*)
- Cleansed with low pressure manual lavage or NPWTi utilizing new reticulated open-cell foams (ROCF-V and ROCF-VC), and aerosolized bacteria were collected

Comparison of tissue damage, cleansing and cross contamination potential during wound cleansing: Lavage vs. instillation

- Low pressure lavage caused aerosolization of wound fluid bacteria more than 6 inches (15 cm) from model
- **NPWTi provided controlled, contained cleansing**
  - No wound fluid bacteria detected outside the wound model
  - Wound fluid bacteria found inside canister

Suggests NPWTi may help reduce likelihood of cross-contamination that can occur during manual cleansing


©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
High-pressure pulsatile lavage propagates bacteria into soft tissue

- Model: Fresh ovine muscle was harvested, contaminated with fluorescently stained *Staphylococcus aureus*, and subjected to lavage treatment.
- These results show that high-pressure pulsatile lavage causes deeper penetration of bacteria and results in greater bacterial retention in soft tissue when compared with low-pressure lavage.

Side-effects of high pressure irrigation

• Model: Standardized surgical wounds made in Yorkshire pigs were subjected to high pressure syringe and pulsatile irrigation.
• Resulted in tissue injury
  — impairing defense mechanism
  — making the wound more susceptible to infection

Optimal Conditions for Cleansing

- No soft tissue/bone damage
- No aerosolization of bacteria
- No increase of the depth of contaminant and bacterial penetration into soft tissue
- No edema formation

> 4 psi causes aerosolization and increased bacterial penetration
Comparison of tissue damage, cleansing and cross-contamination potential during wound cleansing: Lavage vs. instillation

- Model: Porcine wounds inoculated with fluorescent simulated wound debris and then treated with NPWTi or low pressure lavage
- Pulsed lavage caused swelling
- NPWTi did not cause swelling


©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
Edema and Inflammation

- Porcine wound healing model with 7 days of either NPWT or NPWTi
- Contralateral non-infected wounds

<table>
<thead>
<tr>
<th></th>
<th>NPWT/ ROCF-G</th>
<th>NPWTi/ ROCF-V</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granulation tissue thickness (mm)</td>
<td>3.38 ± 0.55</td>
<td>4.82 ± 0.42</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Edema score</td>
<td>1.17 ± 0.25</td>
<td>0.83 ± 0.18</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Inflammation score</td>
<td>1.54 ± 0.23</td>
<td>1.71 ± 0.18</td>
<td>&gt; 0.05</td>
</tr>
</tbody>
</table>

Porcine (pig) wound healing model with 7 days of therapy

Contralateral non-infected wounds

Wounds with V.A.C. VeraFlo™ Therapy with saline instillation had 43% more granulation tissue than V.A.C.® Therapy wounds

NPWT Instillation
Clinical Cases

NOTE: As with any case study, the results and outcomes experienced by the following patients should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient’s circumstances and condition.
Case 1
Case 1
Debridement
Case 1
Case 1
4 Days-V.A.C. VeraFlo™ Therapy
Polyhexanide
3 min soak time followed by 1 hour of NPWT at -125 mmHg
Case 1
Case 1
Case 1
NPWT Instillation

©2012 KCI Licensing, Inc. All rights reserved. DSL#12-0687.W (11/12)
NPWT Instillation

Canister Fluid:
Gram – /Gram + Bacteria
NPWT Instillation

Canister Fluid:
Necrotic Tissue Cells

Nuclear Dust (cell death)
Nuclear Dust (cell death)
Case 2
Case 2
4 Days-V.A.C. VeraFlo™ Therapy
Polyhexanide
3 min soak time followed by 1 hour of NPWT at -125 mmHg
3 months Post Chest wall Reconstruction with Latissimus Flap
Case 3

Necrotizing fasciitis

V.A.C. VeraFlo™ Therapy
Saline
1 sec soak time followed by 2 hours of NPWT at -125 mmHg
Case 3

V.A.C.® Therapy using GranuFoam Silver™ Dressing
after application of dermal regeneration template
Case 3

6 months Post Coverage
with Split Thickness Skin Graft and Dermal Substitute
Case 4

Initial presentation

Day 4-V.A.C. VeraFlo™ Therapy
Saline
1 sec soak time followed by 2 hours of NPWT at -125 mmHg
Case 4

Application of NPWT

After dressing removal
Case 4

36 days
Post Delayed
Primary Closure
Case 5
6 months Post
Gastrocnemius Flap
Wound Management Summary

MANAGEMENT

- **Systemic**
  - Blood flow
    - Antibodies
    - Nutrition/Oxygen

- **Topical**
  - Tissue growth
  - Bioburden
NPWT Instillation

- Future is bright and exciting
- New technologies have the potential to:
  - Enhance healing
  - Facilitate patient discharge
  - Downstaging resections?
Safety Information for V.A.C. VeraFlo™ Therapy

Full IFU can be downloaded at:
http://www.kci1.com/cs/Satellite?c=Page&childpagename=KCI1%2FKCILayout&cid=1229636259704&pagename=KCI1Wrapper
V.A.C.Ulta™ Therapy System Indication for Use

• The V.A.C.Ulta™ Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound therapy with an instillation option.

• 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 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.Ulta™ 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 to 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

• **V.A.C. VeraFlo™ Therapy:**

• **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.

• **Bioengineered Tissue:** V.A.C. VeraFlo™ Therapy is not intended for use with cellular or acellular bioengineered tissues.
V.A.C. VeraFlo™ Therapy Warnings (cont.)

- **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.

- **Magnetic Resonance Imaging (MRI)** – V.A.C.® Dressings: V.A.C.® Dressings and V.A.C. VeraFlo™ Therapy Dressings can typically remain on the patient with minimal risk in an MR environment, assuming that use of the V.A.C.Ulta™ Therapy System is not interrupted for more than two hours.

  **NOTE**: If using V.A.C. VeraFlo™ Therapy, ensure that irrigation fluid or treatment solutions are fully removed from the dressing prior to stopping negative pressure wound therapy.
V.A.C. VeraFlo™ Therapy Warnings (cont.)

• **Hyperbaric Oxygen Therapy (HBO):** Do not take the V.A.C.Ulta™ Therapy Unit into a hyperbaric oxygen chamber. The V.A.C.Ulta™ Therapy Unit is not designed for this environment and should be considered a fire hazard.

• After disconnecting the V.A.C.Ulta™ Therapy Unit, either
  • (i) replace the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing with another HBO compatible material during the hyperbaric treatment, or
  • (ii) cover the unclamped end of the V.A.C.® Tubing with moist cotton gauze and completely cover the V.A.C.® Dressing or V.A.C. VeraFlo™ Therapy Dressing (including tubing) with a moist towel throughout the treatment in the chamber. For HBO therapy, the V.A.C.® Tubing or V.A.C. VeraFlo™ Therapy Tubing must not be clamped.

• Never leave a V.A.C.® Dressing in place without active V.A.C.® Therapy for more than two hours; please refer to the Keep V.A.C.® Therapy On section.

• **NOTE:** If using V.A.C. VeraFlo™ Therapy, ensure that irrigation fluid or treatment solutions are fully removed from the dressing prior to stopping negative pressure wound therapy.
V.A.C. VeraFlo™ Therapy
Precautions

• **V.A.C. VeraFlo™ Therapy:**

• **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.
V.A.C. VeraFlo™ Therapy
Precautions (cont.)

• 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.

• **Canister Changes:** Monitor fluid level in canisters frequently during use of V.A.C. VeraFlo™ Therapy. Frequent canister changes may be necessary depending on volume of fluid instilled and wound exudates. At a minimum, the canister should be changed weekly and disposed of according to institutional protocol.

• **Enteric Fistulas:** To prevent wound contamination, V.A.C. VeraFlo™ Therapy should not be used in the presence of enteric fistulas.
Summary & Key Points

• V.A.C. VeraFlo™ Therapy can be used for a variety of wounds
  – **Cleanses** the wound with instillation of topical wound cleansers
  – **Treats** the wound with the instillation of appropriate topical and antimicrobial solutions and the removal of infectious materials with topical antimicrobial and antiseptic solutions
  – **Heals** the wound and prepares for primary or secondary closure
Thank You.