Venous Leg Ulcer Management
Treatment Options and V.A.C.® Therapy

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Columbia University

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Important Information

- Prior to use of the V.A.C.® 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.® Therapy Device Instructions and V.A.C.® Therapy Clinical Guidelines.
- KCI recommends that clinicians participate in device in-service and training prior to use.
- The following slides include case studies based on the speaker’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.
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Ultimate Goal for Wound Healing: Closed Wound

Expeditious Wound Closure...

- Produce a cosmetically suitable, durable, reproducible outcome
- Create a minimal amount of pain, suffering, discomfort or negative impact on patient’s quality of life
- Avoid untoward complications
- Achieve an acceptable cost of care
The Scope of the Problem

One percent of all people in industrialized countries will suffer from a leg ulcer at some time. 1.5:1000 patient prevalence of active leg ulcers in Western Nations.


Objectives

- Review the epidemiology for venous stasis ulcers.
- Summarize pathogenesis of venous stasis ulcers.
- Discuss the clinical assessment of venous stasis ulcers.
- Review “standard of care” for venous stasis ulcer management.
- Review some advanced wound care options for venous stasis ulceration management.
- Focus upon the use of NPWT to treat venous stasis ulcers.
Epidemiology of Venous Stasis Ulcers

- Chronic leg ulcers affect up to 1% of the adult population in developed countries\(^1\)
- The prevalence increases with age to 4% to 5% of the population \(\geq 80\) years\(^{1,2}\)
- Venous disease is thought to account for 80% of all chronic leg ulcers\(^2\)
- The associated healthcare costs in the United States are estimated between $1.9 and $2.5 billion\(^3\)

# Incidence of Chronic Leg Ulcers

<table>
<thead>
<tr>
<th>Etiology</th>
<th>Approx. Incidence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venous insufficiency</td>
<td>60-80</td>
</tr>
<tr>
<td>Arterial insufficiency</td>
<td>20</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>10</td>
</tr>
<tr>
<td>Diabetes/neuropathic</td>
<td>5</td>
</tr>
<tr>
<td>Multifactorial</td>
<td>10-20</td>
</tr>
</tbody>
</table>

Venous

Nonvenous

- Least common
- Most common

Pathogenesis of Venous Stasis Ulceration

- **Anatomical Problem**
  - Obstructive pathology
  - Reflux pathology
    - Superficial
    - Deep
    - Perforator disease
  - Peripheral vascular disease (PVD)
- **Associated Factors**
  - Biomechanical abnormalities of foot and ankle
  - Arterial perfusion
  - Pulmonary hypertension

Micro Pathophysiology

- **Fibrin cuff theory**¹
  - Decreased oxygen transport
  - Fibrin leaks through endothelial pores creating a cuff

- **White blood cell trapping theory**²
  - Increased inflammatory mediators
  - Mast cell stimulation
  - Free radicals and proteolytic enzymes damage endothelium

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Effects of Edema Fluid

- Inactivates normal antistreptococcal properties of skin
- Inhibits mitogenic activity and DNA synthesis
- Has higher levels of inflammatory cytokines
- Higher levels of protease activity
- Reduces levels of growth factors

Risk Factors of Venous Stasis Ulceration

- Age > 80 yrs
- Foot deformity
- Female gender
- Prior leg injury
- Obesity
- Diabetes
- Previous hospitalization
- Hypothyroidism
- Varicose veins
- History of deep venous thrombosis
- Previous ulcer
- Venous insufficiency
- CRI
- CHF
- Falls
- Depression

Predictors of Poor Outcomes

- History of DVT
- Duration of ulcer
- Size and shape of the ulcer
- Male gender
- Bioburden
- Compliance with therapy
- Obesity
- Advanced protein C resistance/Factor V Leiden mutation

- History of CHF
- Previous total hip or total knee replacement
- History of previous venous ulcer
- Venous ulcer with high exudate volume
- HIV infection
- Advanced age

Clinical Assessment of Patients with Venous Leg Ulcers

- **Vascular Assessment:** Venous pathology, arterial perfusion
- **Neurologic Exam:** Pain control
- **Musculoskeletal Exam:** Joint Mobility, Deformities
- **Dermatologic Exam:** Integrity, Dermatitis, Skin friability
- **General Health, Risk factor modification**
- **Wound Evaluation:** Location, Size, Depth, Extent, Classification
- **Signs of Infection:** Odor, Exudate, Cellulitis, Fever

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Wounds Commonly Seen in Venous Stasis Patients

Medial Malleolar Wound

Larger Draining Ulcers
Clinical Assessment: Wound Examination

Classic Measurements

- Location
- Size
  - Length
  - Width
  - Depth
- Extent
  - Undermining
  - Tracts/Tunneling
- Amount of Exudate
- Level of Pain

Clinical Assessment: Wound Examination for Pain

Level of Pain

- **Analog Assessment**
  - Scale 0 – 10
  - Faces Scale - aids for cognitively impaired
  - Non-English languages

- **Communication Tools**
  - Thorough history
  - Trending
    - Location and onset
    - Intensity
    - Type of pain (eg. sharp)
    - Radiation - start and end
    - Nature: Constant/Cyclical
    - Exacerbation/Abatement

Classification: CEAP

Clinical classification
- C0: no visible or palpable signs of venous disease
- C1: telangiectasies or reticular veins
- C2: varicose veins
- C3: edema
- C4a: pigmentation or eczema
- C4b: lipodermatosclerosis or atrophie blanche
- C5: healed venous ulcer
- **C6: active venous ulcer**
- S: symptomatic, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other complaints attributable to venous dysfunction
- A: asymptomatic

CEAP Determination

Etiologic classification
- Ec: congenital
- Ep: primary
- Es: secondary (post-thrombotic)
- En: no venous cause identified

Anatomic classification
- As: superficial veins
- Ap: perforator veins
- Ad: deep veins
- An: no venous location identified

Pathophysiologic classification
- Basic CEAP
- Pr: reflux
- Po: obstruction
- Pr,o: reflux and obstruction
- Pn: no venous pathophysiology identifiable
### Venous Leg Ulcer Characteristics

<table>
<thead>
<tr>
<th>Also Known As...</th>
<th>Venous stasis ulcer, crural ulcer, ulcus cruris venosum, stasis leg ulcer, varicose ulcer, lower stasis ulcer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>Medial aspect of lower leg and ankle, superior to medial malleolus</td>
</tr>
<tr>
<td>Size</td>
<td>Small to large; circumferential</td>
</tr>
<tr>
<td>Depth</td>
<td>Shallow, full thickness</td>
</tr>
<tr>
<td>Wound Edges</td>
<td>Irregular</td>
</tr>
<tr>
<td>Wound Bed</td>
<td>Ruddy, fibrinous, loose slough or necrotic</td>
</tr>
<tr>
<td>Exudate</td>
<td>Copious, sometimes dripping, serous or bloody</td>
</tr>
<tr>
<td>Pain</td>
<td>Mild to moderate, decreased with elevation or compression</td>
</tr>
<tr>
<td>Surrounding Skin</td>
<td>Weepy, macerated, crusted, scaling</td>
</tr>
<tr>
<td>Odor</td>
<td>Sweet, offensive due to large amount of exudate</td>
</tr>
</tbody>
</table>

Clinical Assessment: Anatomic Considerations

• Lower extremity studies help determine if the patient has sufficient arterial inflow to heal an ulcer.

• Venous tests performed in the vascular laboratory are done for two primary reasons
  - first done to determine if reflux or obstruction is causing hypertension
  - then to identify the location of the reflux or obstruction

• Doppler ultrasound and color duplex scanners are used to obtain information about the venous system.
Etiology of Venous Insufficiency
Venous hypertension leads to venous insufficiency

Causes:
- Impaired valve function
- Thrombosis
- Impaired muscle function

Normal
Venous insufficiency
Normal
Venous obstruction
Muscle pump failure

Non-Invasive Evaluation: Ankle-Brachial Index (ABI)

<table>
<thead>
<tr>
<th>Ankle perfusion pressure (mmHg)</th>
<th>Brachial perfusion pressure (mmHg)</th>
</tr>
</thead>
</table>

**ABI Value Interpretation**
- > 1.2     Non-compressible (calcified)
- 0.9-1.2  Normal range
- 0.5-0.9  Mixed arterial/venous disease
- < 0.5    Critical stenosis
- < 0.2    Ischemic gangrene necrosis likely


Clinical Assessment: Vascular Examination

- Vascular Assessment Testing
  - Palpate the pulses
  - Ankle-Brachial Index (ABI) - 0.7-1.2
  - Toe-Brachial Index (TBI)
  - Transcutaneous Partial Oxygen Pressure (TcPO2)

- Medial arterial calcinosis extends to the lower extremity but rarely extends to the digits so TBIs may be more accurate than ABIs in some diabetic patients

- Always refer patients to a Vascular Surgeon for assessment when the patient has diminished or loss of pulses

- In general patients with an ABI < 0.8 are not candidates for compression therapy

O’Meara, Cullum NA, Nelso EA. Comparison for venous leg ulcers. Cochrane Database of Systematic Reviews 2009, Issue1. Art No.:CD000265. DOI:10.1002/14651858.CD000265.pub2
Clinical Assessment: Examine for Infection

Non classical signs of infection¹

<table>
<thead>
<tr>
<th>Percentage of patients</th>
<th>w/ Infected Wounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any clinical signs of infection</td>
<td>(100%)</td>
</tr>
<tr>
<td>Non-progression of the ulcer</td>
<td>(100%)</td>
</tr>
<tr>
<td>Increased exudate</td>
<td>(79.2%)</td>
</tr>
<tr>
<td>Spontaneous pain between dressing changes</td>
<td>(83.3%)</td>
</tr>
<tr>
<td>Increased temperature around ulcer</td>
<td>(16.7%)</td>
</tr>
<tr>
<td>Discoloration of Granulation tissue</td>
<td>(25%)</td>
</tr>
<tr>
<td>Friable granulation tissue</td>
<td>(20.8%)</td>
</tr>
<tr>
<td>Local peri-ulcer erythema</td>
<td>(75%)</td>
</tr>
<tr>
<td>Oedema</td>
<td>(91.7%)</td>
</tr>
<tr>
<td>Purulent exudate</td>
<td>(16.7%)</td>
</tr>
<tr>
<td>Malodour</td>
<td>(41.7%)</td>
</tr>
</tbody>
</table>

Clinical Infection

- 80 to 100% of leg ulcers may be colonized with bacteria\(^1,2,3\)
- Most studies support that increased bio-burden delays healing\(^2,4\)
- Both bacteria diversity and density play a role in this delaying process \(^5,6\)
- The most common organisms are *Pseudomonas aeroginosa, Staph Aureus* and hemolytic *Streptococci* \(^5\)

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Clinical Assessment: Musculoskeletal Examination

- Goniometry (angle of joint movement)
  - Assess ankle joint loss of mobility
  - Loss of calf muscle pump function
  - Loss of joint mobility of the toes
  - Low ankle motion is an independent predictor of failure of compression therapy

Venous Leg Ulcer Percent Healing Over Time

4 months

- 50% Healed
- 50% Not healed

2 years

- 80% Healed
- 20% Not healed

5 years

- 92% Healed
- 8% Not healed

Standard of Care: Overall Medical Management

- Perform a clinical assessment
- Ensuring adequate oxygenation/perfusion
  - Intervene if necessary\(^1\)
- Debride
- Control infection
- Consider interventional correction of underlying lesion
  - Vein surgery
  - Endovenous laser ablation
  - Radiofrequency ablation
  - Sclerotherapy
  - Subfascial endoscopic perforator surgery

Standard of Care

- Assess local wound care progression
  - Should be 0.5 mm / week
- Maximize pain control
- Promote wound healing, advance therapies as required
- Educate patient and family about the condition and treatments
Standard of Care: Local Wound Care and Compression

- **Cleansing**
  - Do not use pressure irrigation (except for excision)
  - Do not use whirlpool
  - Do not use toxic agents
  - Do not use heat lamps
  - Sharp Debridement

- **Edema Control**

- **Primary Wound Dressing** - should maintain a moist wound care environment

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Best Treatment

- Debride
- Topical antimicrobials
- Compression Therapy
  - Stockings, Unna’s Boot, Multilayer wrap
- Drug Therapy?
- Venous corrective procedures
- Wound closure procedures
Debridement Enhances Treatment of VLUs

Effect of Debridement on Wound Healing at 12 Weeks

<table>
<thead>
<tr>
<th></th>
<th>ECM + SOC</th>
<th>SOC Alone</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients completely healed (intent-to-treat N = 120)</td>
<td>34/62 (55%)</td>
<td>20/58 (34%)</td>
<td>.0196</td>
</tr>
<tr>
<td>Patients debrided at baseline with complete healing</td>
<td>19/30 (63%)</td>
<td>8/27 (30%)</td>
<td>.0167</td>
</tr>
<tr>
<td>Overall probability of complete healing at 12 weeks (evaluable N = 96)</td>
<td>63%</td>
<td>40%</td>
<td>.0226</td>
</tr>
</tbody>
</table>


ECM = extracellular matrix graft; SOC = standard of care
Serial Debridements Effect on Healing Outcomes: VLU

68 Patients Serially Debrided
47% closure rate

298 Patients Not Serially Debrided
30% closure rate

\( p=0.007 \)

The management of bioburden: topical antibiotics and antimicrobials

- Debride $^{1-13}$
- 25 trials reviewed $^{14}$
  - 5 trials of systemic antibiotics; 10 trials of cadhexomer iodine, providine iodine (5 trials), peroxide based preparations (3 trials), ethacridine lactate (1 trial), mupirocin (1 trial), chlorhexidine (1 trial)
- Cadhexomer Iodine – statistically significant improved frequency of complete healing at six weeks $^{14}$

Compression Stockings

- Worn during the day
- Elastic stockings with adjustments in pressure
- Lower pressure stockings (20-30mm Hg) for edema and DVT prophylaxis
- Higher pressure (30-40+mm Hg) for ulcers and significant venous disease
- Operator dependent
  - Difficult to put on
  - Physical impediments/Co-morbidities
- 50% of patients were unable to put them on alone
- 30-65% noncompliance noted in clinical trials in venous centers

Efficacy of Compression Therapy

1. 22 trials comparing healing of venous ulcers using compression stockings
   - Compressive therapy more effective than non-compression
   - Higher pressure were more effective than lower
   - Multilayer compression was better than single layer bandaging

2. 466 patients with a healed ulcer
   - Continued use of compression stocking reduced reoccurrence within 3-5 year

3. ESCHAR study: 500 limb trial that compares surgery and compression vs. compression alone for ulcer treatment
   - Combination therapy had lower rates of reoccurrence of ulcer at year 4 (24% vs. 52%)

The Standard of Care

- 20% of ulcers remain unhealed after more than 50 weeks of appropriate compression

- Longstanding ulcers and large ulcers only have a 22% chance of healing at 24 weeks, vs 71% chance for smaller ulcers of more recent duration


Standard of Care: In Clinical Trials
Low Healing Rates

Complete closure with standard of care in randomized clinical trials

- Repifermin (KGF 2) trial (SOC) – 117 pts/Dynaflex – 61.5% closure rate at 20 weeks (40% at 12 weeks)\(^1\)
- Apligraf\(^\text{®}\) (SOC) – 48% closure at 6 months when multilayer compression wraps were applied.\(^2\)
- Oasis (SOC) – 34% at 3 months\(^3\)
- Profore\(^\text{™}\) (SOC) – 31% at 12 weeks\(^4\)
- Promogan\(^\text{™}\) (SOC) – 31% at 12 weeks\(^5\)

Drug Therapy

- Pentoxifylline
  - PDE\textsubscript{4} inhibitor that increases intracellular cAMP and stimulates protein kinase A activity
  - Reduces blood viscosity and decreases platelet aggregation and thrombus formation
  - No proven efficacy
More invasive

- **Sclerotherapy**
  - 0.2% sodium tetradecyl injected directly into spider angiomas and smaller superficial varicosities
    - Complications (<5%): allergic reaction, hypo/hyperpigmentation, local skin necrosis
- **Endovenous laser ablation of saphenous vein (EVLT)**
- **Surgical excision of veins (“Stripping”)**
## Procedural Efficacy

Table II. The pooled proportion of patients with anatomical successful outcome after different time intervals

<table>
<thead>
<tr>
<th>Type of Intervention</th>
<th>3 months</th>
<th>1 year</th>
<th>3 year</th>
<th>5 year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Success Rate %</td>
<td>95% CI</td>
<td>Success Rate %</td>
<td>95% CI</td>
</tr>
<tr>
<td>Surgery</td>
<td>80.4</td>
<td>72.3-86.5</td>
<td>79.7</td>
<td>71.8-85.8</td>
</tr>
<tr>
<td>UGFS</td>
<td>82.1</td>
<td>72.5-88.9</td>
<td>80.9</td>
<td>71.8-87.6</td>
</tr>
<tr>
<td>RFA</td>
<td>88.8</td>
<td>83.6-92.5</td>
<td>87.7</td>
<td>83.1-91.2</td>
</tr>
<tr>
<td>EVLA</td>
<td>92.9</td>
<td>90.2-94.8</td>
<td>93.3</td>
<td>91.1-95.0</td>
</tr>
</tbody>
</table>

\[ CI, \text{ Confidence Interval}; \text{EVLA, endovenous laser ablation}; \text{RFA, radiofrequency ablation}; \text{UGFS, ultrasound guided foam sclerotherapy.}\]

- Meta-analysis of 64 studies (12,320 legs)
  - Analyzed ablation via Duplex US
  - Follow up to 5 years
  - Success rate of EVLT highest after 5 years
  - Complications: DVT (<3%), local bruising and pain, paresthesias, foam emboli, stroke

The role of STSG in VLU

- Two armed, randomized, controlled trial
- V.A.C.® Therapy followed by STSG vs Institutional protocol followed by STSG
- Study period – ulcer closure or 12 weeks post STSG
  - Primary outcome – surgical closure, 90 day graft take
  - VLU’s > 25 cm²
- Result*
  7 Day graft take
  NPWT 100%; Bolster 84%
  3 month closure rate
  NPWT 100% graft survival; Bolster 68%

*This trial was terminated because of poor accrual and resistance to randomization to the non-NPWT group
The role of STSG in VLU

- Pinch skin grafts
  - Millard – 41 pts with pinch skin graft – 74% closure rate \(^{(1)}\)
  - Ahnlide also has positive experience \(^{(2)}\)

- Meshed skin grafts
  - Kirsner – 90% graft take, 70% complete healing \(^{(3)}\)

V.A.C.® Therapy Systems: NPWT Promotes Granulation Tissue Formation for Wound Healing

Integrated System of Negative Pressure Wound Therapy (NPWT) Promoting Wound Healing

V.A.C. ATS® System

V.A.C.VIA™ Therapy System

V.A.C. Freedom® System

InfoV.A.C.® System

V.A.C. Instill® System

ActiV.A.C.® System

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V.A.C.® Therapy Contraindications*

- Foam dressings of the V.A.C.® Therapy System directly in contact with exposed blood vessels, anastomotic sites, organs or nerves.
- Malignancy in the wound.
- Untreated osteomyelitis.

**Note:** Refer to the Warning section of the V.A.C.® Therapy Safety Information or the Clinical Guidelines for specific osteomyelitis information.

- Non-enteric and unexplored fistulas.
- Necrotic tissue with eschar present.
- Sensitivity to silver (V.A.C. GranuFoam Silver® Dressing only).

*Certain unique indications, contraindications, warnings, and precautions may apply for products within the V.A.C.® Therapy family of devices, such as for the V.A.C. Instill® System, V.A.C.® Abdominal Dressing and the ABThera™ OA NPT System. Please refer to the product instructions for use contained with the device or disposables.

*Refer to V.A.C.® Therapy Clinical Guidelines, a reference source for clinicians (available at [www.kci1.com](http://www.kci1.com)) or the V.A.C.® Therapy Safety Information (provided in V.A.C.® Dressing cartons) for detailed information on Warnings and Precautions.
V.A.C.® Therapy Warning Categories*

- Bleeding**
  - Protect vessels and organs
  - Infected blood vessels
  - Hemostasis, anticoagulants, and platelet aggregation inhibitors
  - Hemostatic agents applied at the wound site
  - Sharp edges
- Infected wounds
- Untreated osteomyelitis
- Protect tendons, ligaments and nerves
- Foam placement
- Foam removal
- Keep V.A.C.® Therapy On
- 1000 mL canister size
- Acrylic adhesive sensitivity
- Defibrillation
- Magnetic Resonance Imaging (MRI)
- Hyperbaric Oxygen Therapy (HBO)

*Certain unique indications, contraindications, warnings, and precautions may apply for products within the V.A.C.® Therapy family of devices, such as for the V.A.C. Instill® System, V.A.C.® Abdominal Dressing and the ABThera™ OA NPT System. Please refer to the product instructions for use contained with the device or disposables.

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**Additional information on V.A.C.® Therapy on the Vascular Surgical Wounds of Lower Extremity can be found on: [http://www.kci1.com](http://www.kci1.com). Click on Education & Training. Under “Educational Opportunities“, click Lower Extremity Wound Training.
V.A.C.® Therapy Precaution Categories*

- Standard Precautions
- Continuous vs. Intermittent V.A.C.® Therapy
- Patient Size and Weight
- Spinal Cord Injury
- Bradycardia
- Enteric Fistulas
- Protect Periwound Skin
- Circumferential Dressing Application
- V.A.C.® Therapy Unit Pressure Excursions

Additional Precautions for V.A.C. GranuFoam Silver® Dressing:

- Topical Agents or Solutions
- Protective Layer
- Electrodes or Conductive Gel
- Diagnostic Imaging
- Dressing Components

*Certain unique indications, contraindications, warnings, and precautions may apply for products within the V.A.C.® Therapy family of devices, such as for the V.A.C. Instill® System, V.A.C.® Abdominal Dressing and the ABThera™ OA NPT System. Please refer to the product instructions for use contained with the device or disposables.

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Training Module:
V.A.C.® Therapy on the Vascular Surgical Wounds of Lower Extremity

In accordance with its commitment to provide advanced practical education to the users of V.A.C.® Therapy, KCI has developed a special training program on V.A.C.® Therapy on the Vascular Surgical Wounds of Lower Extremity.

If you are a clinician using V.A.C.® Therapy on these types of wounds, access the training module on the KCI website, www.kci1.com: Click on Education & Training. Under “Educational Opportunities”, click Lower Extremity Wound Training.
(Therapeutic Regulated Accurate Care)
**V.A.C.® Therapy System: Family of Reticulated Open-Cell Foam Foam Dressings**

The Essential Component for Effective NPWT

<table>
<thead>
<tr>
<th>V.A.C.® GranuFoam® Dressing - Black</th>
<th>V.A.C.® GranuFoam® Dressing - Black</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Hydrophobic</td>
<td>Reticulated polyurethane ether foam</td>
</tr>
<tr>
<td>• Open pore nature (400-600 microns) provides uniform distribution of negative pressure at the wound site</td>
<td></td>
</tr>
<tr>
<td>• Aids wound contraction</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>V.A.C.® WhiteFoam Dressing - White</th>
<th>V.A.C.® WhiteFoam Dressing - White</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Hydrophilic, pre-moistened with sterile water</td>
<td>Open Cell Polyvinyl alcohol foam</td>
</tr>
<tr>
<td>• Denser foam with greater pore size distribution</td>
<td></td>
</tr>
<tr>
<td>• Requires higher pressure 125-175 mmHg to provide adequate negative pressure therapy distribution</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>V.A.C. GranuFoam Silver® Dressing - Silver</th>
<th>V.A.C. GranuFoam Silver® Dressing - Silver</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Hydrophobic</td>
<td>Silver-bonded</td>
</tr>
<tr>
<td>• Direct and complete contact with wound bed delivers silver</td>
<td>Reticulated polyurethane ether foam</td>
</tr>
<tr>
<td>• Open pore nature (400-600 microns) provides uniform distribution of negative pressure at the wound site</td>
<td></td>
</tr>
</tbody>
</table>

**Artist rendering**

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V.A.C.® Therapy Creates an Environment That Promotes Wound Healing

Video Demonstration

Prepares the wound bed for closure
- Promotes granulation tissue formation
- Promotes perfusion
- Maintains a moist wound environment
- Removes exudate and infectious material
- Reduces edema
- Draws wound edges together
V.A.C.® Therapy Prepares the Wound Bed for Closure

Macrostrain: The visible alteration that occurs when negative pressure contracts the foam dressing and draws the wound edges together.

- Decreases wound margins
- Removes exudate and infectious material
- Reduces edema

Maintaining a Moist Wound Environment: The occlusive V.A.C.® Drape helps provide a moist wound environment and protects the wound from external contamination.
V.A.C.® Therapy Promotes Granulation Tissue Formation and Perfusion by Means of Microstrain

**Microstrain:** The deformation that occurs at the cellular level when mechanical forces are applied.

- Stimulates cell proliferation
- Fibroblast migration

**V.A.C.® GranuFoam™**
The open-cell, reticulated characteristics of V.A.C.® GranuFoam™ Dressings allow for conformation to the wound surface for maximum tissue interaction.

**Gauze Fibers**
The large size of gauze fibers may contribute to less microstrain magnitude and distribution.
V.A.C.® Therapy: Mechanisms of Action (MOA)
Combined Effects of Macrostrain and Microstrain

**Macrostrain**
Visible alteration occurs when negative pressure contracts the foam, drawing the wound edges together and removing fluid
- Decreases wound margins
- Removes exudate
- Reduces edema
- Removes infectious material

**Microstrain**
Tissue micro-deformation at the cellular level under negative pressure leading to cell stretch
- Cell proliferation
- Fibroblast migration
- Results in granulation tissue formation and perfusion.

Microstrain Helps Enhance Cellular Bio-responses*

Microstrain can be translated to the interior of the cell through integrins (cell surface receptors linked to extracellular matrix)

Microstrain induces generation of secondary messengers involved in proliferation.

*Finite Element Model


Chen, et al., JBC. 274:18393-400, 1999
Sequential Combinations: Designed to Expedite Typical Sequenced Wound Healing to Full Closure

- Bioburden Reduction
- Wound contraction
- Granulation filling
- Epithelialization

Surgical Debridement or Amputation

NPWT

Acellular Human Dermis

Split-thickness Graft

Ready for Closure

Bilayer Skin Equivalent

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V.A.C.® Therapy Clinical Efficacy Demonstrated in VLU – STSG Trial

Study Population: Subjects with VLU ready to undergo debridement

- Total- 10
- V.A.C.® Therapy- 5 patients
- Bolster STSG Wound Care Control- 5 patients

Primary Endpoint: Percentage of Complete Wound Closure

This trial was terminated because of poor accrual and resistance to randomization to the non-NPWT group

- 7 Day graft take
  - NPWT 100%; Bolster 84%

- 3 month closure rate
  - NPWT 100% graft survival; Bolster 68%

Lantis JC, et al. V.A.C.® Therapy Appears to Facilitate STSG Take when applied to Venous Leg Ulcer. 2nd World Union of Wound Healing Societies’ Meeting, Paris, France, July 9, 2004
**V.A.C.® Therapy Clinical Efficacy Demonstrated in Skin Grafting**

<table>
<thead>
<tr>
<th>Author</th>
<th>N</th>
<th>Wound Type</th>
<th>% Take</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blackburn ¹</td>
<td>3</td>
<td>Large Complex</td>
<td>95</td>
<td>Case series</td>
</tr>
<tr>
<td>Scherer ²</td>
<td>61</td>
<td>Heterogenous</td>
<td>Only 3% regraft</td>
<td>Control group 19% regraft</td>
</tr>
<tr>
<td>Kober ³</td>
<td>54</td>
<td>Venous</td>
<td>93%</td>
<td>100% in DM, and old pts</td>
</tr>
<tr>
<td>Vidrine ⁴</td>
<td>45</td>
<td>Radial forearm flap</td>
<td>92%</td>
<td>81% with traditional bolster</td>
</tr>
<tr>
<td>Lantis ⁵</td>
<td>18</td>
<td>Venous</td>
<td>94%</td>
<td></td>
</tr>
</tbody>
</table>

3) Korber A, Franckson T Gabbe S, Dissemond J. Vaccum assisted closure device improves the take of mesh grafts in chronic leg ulcers. Dermatology 2008;216(3):250-6

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Experience with V.A.C.® Therapy - Fast Wound Bed Preparation

V.A.C.® Therapy System Compared to Control:
- Yielded higher proportion of wounds ready to close at 10 days than compression therapy alone
- More robust granulation tissue response at 10 days

Moist Wound Therapy Control:
- Resulted in a greater proportion of patients undergoing secondary amputation
- Longer duration of wound presence

Wound Bed Preparation

6-18

6-25
Studies supporting the use of V.A.C.® Therapy for VLU

- 60 hospitalized patients randomized to:
  - 30 V.A.C.® Therapy
    - Used for both wound bed preparation and as bolster for STSG
  - 30 MWT
- Wound bed prep time 58.8% shorter
- Median time to complete healing was reduced by 35.6%

Studies supporting the use of V.A.C.® Therapy for VLU

- V.A.C.® Therapy cut treatment costs by 28.8%
- V.A.C.® Therapy cut nursing time by 39.9%

Novel Applications of
V.A.C. Instill® Wound Therapy

• PATIENTS:
  - Five patients with venous stasis ulcers greater than 200 cm²
  - Colonized with greater than $10^5$ bacteria
  - Treated with the V.A.C. Instill® Therapy for 10 days with 12.5% Dakins solution, instilled for 10 minutes every hour.
  - Two patients had multi drug resistant pseudomonas, three with MRSA.

• RESULTS:
  - All 5 had negative quantitative cultures, prior skin grafting 10 days after initiation of V.A.C. Instill® Therapy.

• Discussion:
  - Adequate delivery of bactericidal agents to the infected tissue can be very difficult, especially while promoting tissue growth. By providing a single delivery system for a bactericidal agent for a short period of time followed by a growth stimulating therapy the VAC instill provides a unique combination that appears to maximize wound bed preparation.

V.A.C. Instill® Wound Therapy: Prepping a Pseudomonas Infected Leg for Primary Closure

Debride in OR

10 DAYS later with V.A.C. Instill®

STSG in OR

30 Days later

Outcomes of STSG and V.A.C.® Therapy for Treatment of Complex Lower Extremity Wounds

Ross R, Lantis J, Gendics c, Mendes D, Benvenisty A, Todd G. Outcomes of complex lower extremity wounds treated with split thickness skin grafts and vacuum assisted closure. SAWC 2007, San Diego, CA, April 2007
V.A.C.® Therapy and STSG – Reported Potential Benefits

- Maintain moist wound environment\(^1,2\) therefore maintaining osmotic gradients
- Equal application of force allowing for uniform apposition with the wound bed, decreasing potential for shear
- Possible increased angiogenesis by microdeformation\(^3\)

Chronic Lower Extremity Wound (Mixed lower extremity wound, status post revascularization, prior to debridement)
Wound debridement in the operating room with pulse irrigation and placement of V.A.C.® Therapy
Immediately post debridement
Application of 0.015 inch STSG meshed 1.5:1
Application of non-adherent layer over STSG
Application of V.A.C.® GranuFoam™ Dressing

V.A.C.® GranuFoam™ Dressing must be applied over a non-adherent material.
Foam intact – ready for initiation of -125mmHG for five days
Wound after 5 days of V.A.C.® Therapy
Staple removal at 12 days post op
Post – operative 30 days
## Optimal Use of V.A.C.® Therapy in VLU May Be Early in Treatment

### Algorithm

#### Difficult to heal/chronic wounds

**Venous**: duration ≥1 year + size >20 cm²
BMI > 30, Poor compression response in first month, minimal islands of granulation at 30 days.

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiate debridement</td>
<td>Initiate debridement</td>
</tr>
<tr>
<td>Bioburden control</td>
<td>Bioburden Control</td>
</tr>
<tr>
<td>Contemplate NPWT</td>
<td>Compression</td>
</tr>
<tr>
<td>Under compression therapy</td>
<td>Substantial reduction in wound area by 2-4 weeks?</td>
</tr>
<tr>
<td>Consider venous intervention</td>
<td></td>
</tr>
</tbody>
</table>

Once wound bed prepped – add closure strategy – STSG, skin substitute, ECM replacement

**YES**  
Continue standard care

**NO**  
- Re-evaluate etiological factors
- Add NPWT
- Consider venous intervention

*References on next slide.*
Questions?
References for:
Optimal Use of V.A.C.® Therapy in VLU  May Be Early in Treatment Algorithm


