POWER WEBINAR: Episode 2
Chronic Venous Leg Ulcers - Improving Outcomes and QoL for your Patients with BIOGUARD®
Chronic Wounds Statistics

- Chronic wounds affect approximately 5-8 million Americans with a cost upwards of $25 billion annually.

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Frykberg, RG, Diabetic Foot Ulcers: Pathogenesis and Management, American Family Physician, November 2002, 66(9), 1655-1662
Staggering Rates

Chronic wounds, including venous ulcers, result in 40 million inpatient surgeries and 31.5 million outpatient surgeries per year.


- Older people
- Women
- Obese
- History of deep vein thrombosis (blood clots)
- Leg trauma
- Jobs requiring prolonged standing

VLU Prevalence Varies by Gender & Age

<table>
<thead>
<tr>
<th>Gender differences</th>
<th>2-3x more prevalent in females</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prevalence increases with age</td>
</tr>
<tr>
<td></td>
<td>Peak prevalence: ages 60 to 80 years</td>
</tr>
<tr>
<td></td>
<td>72% patients have 1\textsuperscript{st} ulcer by 60 years of age</td>
</tr>
<tr>
<td>Age differences</td>
<td>Estimate: Prevalence of 1.7% in the ambulatory elderly (\geq 65 years) population</td>
</tr>
</tbody>
</table>

## Who Develops VLUs?

<table>
<thead>
<tr>
<th>Age Category (years)</th>
<th>Number of Subjects</th>
<th>Percent of Total</th>
<th>Percent with VLUs</th>
<th>Unadjusted Odd Ratios* (95% CI)</th>
<th>Fully Adjusted Odds Ratios* (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>65-69</td>
<td>27,812</td>
<td>37.4</td>
<td>1.5</td>
<td>ref cat</td>
<td>ref cat</td>
</tr>
<tr>
<td>70-74</td>
<td>16,254</td>
<td>21.9</td>
<td>2.7</td>
<td>1.90 (1.65,2.17)</td>
<td>1.83 (1.60,2.10)</td>
</tr>
<tr>
<td>75-79</td>
<td>13,148</td>
<td>17.7</td>
<td>4.2</td>
<td>2.95 (2.59,3.36)</td>
<td>2.66 (2.33,3.04)</td>
</tr>
<tr>
<td>80-84</td>
<td>9,758</td>
<td>13.1</td>
<td>5.5</td>
<td>3.90 (3.42,4.45)</td>
<td>3.27 (2.85,3.75)</td>
</tr>
<tr>
<td>85-89</td>
<td>5,122</td>
<td>6.9</td>
<td>6.1</td>
<td>4.36 (3.75,5.06)</td>
<td>3.46 (2.95,4.06)</td>
</tr>
<tr>
<td>&gt;90</td>
<td>2,252</td>
<td>3.0</td>
<td>5.2</td>
<td>3.65 (2.95,4.50)</td>
<td>2.68 (2.15,3.35)</td>
</tr>
</tbody>
</table>

The Reality of Venous Leg Ulcers

- Large painful ulcers
- Severe inflammation, odor and swelling
- Permanent skin changes
Impact on Quality of Life

- High rates of anxiety, depression
- Feelings of hopelessness
- Fear

- Severe pain
- Exudate, odor
- Sleep disturbance

- Increased isolation
- Loss of mobility
- Embarrassment

- Disability
- Dependence
- Difficulty with daily living
- Decreased work capacity

The impact of VLUs is worsened by long healing times and high recurrence rates.

Impact on Quality of Life

- 97.2% of patients reported functional restrictions
- 66.7% reported that their mood was affected
- Most felt the ulcers never seemed to heal, worried they would never be free of the condition

<table>
<thead>
<tr>
<th>Category</th>
<th>Patients (N = 38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep disturbances</td>
<td>66.6%</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>80.5%</td>
</tr>
<tr>
<td>Exude</td>
<td>77.8%</td>
</tr>
<tr>
<td>Itching</td>
<td>69.4%</td>
</tr>
<tr>
<td><strong>Functional limitations</strong></td>
<td></td>
</tr>
<tr>
<td>Daily living</td>
<td>58.3%</td>
</tr>
<tr>
<td>Increased dependency</td>
<td>50.0%</td>
</tr>
<tr>
<td>Social</td>
<td>30.6%</td>
</tr>
<tr>
<td><strong>Emotional/psychological</strong></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>44.4%</td>
</tr>
<tr>
<td>Loss of self-confidence</td>
<td>30.6%</td>
</tr>
</tbody>
</table>

Infection = Number of organisms $\times$ Organisms' virulence
Host Immune Functioning

SUPERBUGS

Continued rise of antibiotic resistant organisms:

Methicillin-resistant Staphylococcus aureus (MRSA)
Vancomycin-resistant enterococci (VRE)
Carbapene-resistant enterobacteriaceae (CRE)
Emerging microbes - ↑ gram negatives

- Higher rates of morbidity and mortality
- More difficult to treat with antibiotics even without being drug resistant
  - Arterial insufficiency

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5810a4.htm
Contaminated environments

50% of surface and 40% of air sample of patient with colonized wounds positive for bacteria during dressing change

- 25% were gram (+) S aureus
- 12-44% of the patient’s room may be contaminated with MRSA

ORIGINAL ARTICLE
Bacterial contamination of the hospital environment during wound dressing change


20 μm
Direct and indirect transmission

- Contact between HCW and patient
- Patient to patient
- Environment to either
Indirect

Organisms present on the patient’s skin, or that have been shed onto inanimate objects (in close proximity to the patient), must be transferred to the hands of HCWs. These organisms must be capable of surviving for at least several minutes on the hands of personnel.

Hand washing or hand antisepsis by the worker must be inadequate or omitted.

Finally, the contaminated hands must come in direct contact with another patient, or with an inanimate object that will come into direct contact with the patient.
Opportunistic Pathogens

Traditional gauze is a breeding ground for bacteria

Figure 4a

Figure 5a
Transmission of Bacteria During Dressing Changes

During a typical change of gauze dressing on a moderately dry colonized wound, approximately 350 CFU of Staphylococcus aureus bacteria were released (aerosolized) per liter of air at two minutes after dressing change, increasing potential of cross contamination.

STAND GUARD

Against Opportunistic Pathogens Including MRSA

Broad-spectrum barrier protection you can rely on.
Helping to keep clean wounds clean!

ALL THE MAGIC HAPPENS WITHIN THE DRESSING

BIOGUARD® Barrier Dressings provide >5 log-kill **within the dressing substrate** against a broad spectrum of pathogens including **MRSA**

Its *patented* manufacturing process, intrinsically binds the active, PolyDADMAC to the substrate dressing

- Prevents bacteria from entering the wound area and inhibits its growth within the dressing

BIOGUARD® provides fast acting and long lasting barrier protection against opportunistic pathogens

BIOGUARD® is **non-leaching, non-resistant and non-toxic** for Healthy Healing

- Leaching antimicrobials can cause toxicity issues, delay wound healing and pose resistance issues
A Physical Mechanism of Action

Cationic biocides
- Work through a very physical mechanism of action
  - Quats attract bacterial cells
  - Bind rapidly to the cellular envelope to disrupt otherwise stable calcium ions
  - Chemically destroys the cell wall structures

PolyDADMAC - An advanced cationic biocide
- High charge density
  - The higher the charge density, the more likely the Quat’s effects will not be diluted in high levels of exudate or other bodily fluids
- High molecular weight
- Maintains it’s effectiveness even in the presence of bodily fluids of commonly used solutions
- Has no known resistance
A Closer Look at Cell Destruction

Bacterial Cells Collapse After Contact with BIOGUARD®

Before introduction of BIOGUARD®

After introduction of BIOGUARD®
### Broad-Spectrum Highly Effective Kill Rates

<table>
<thead>
<tr>
<th>BACTERIA</th>
<th>ATCC#</th>
<th>% REDUCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRSA</td>
<td>BAA-44</td>
<td>&gt;99.99999%</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>12600</td>
<td>&gt;99.9999%</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>15597</td>
<td>&gt;99.9999%</td>
</tr>
<tr>
<td><em>Klebsiella pneumoniae</em></td>
<td>13833</td>
<td>&gt;99.9999%</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>51447</td>
<td>&gt;99.9999%</td>
</tr>
<tr>
<td><em>Proteus vulgaris</em></td>
<td>13115</td>
<td>&gt;99.9999%</td>
</tr>
<tr>
<td><em>Serratia marcescens</em></td>
<td>13880</td>
<td>&gt;99.9999%</td>
</tr>
<tr>
<td><em>Enterococcus faecalis</em></td>
<td>19433</td>
<td>&gt;99.9999%</td>
</tr>
<tr>
<td><em>Enterobacter aerogenes</em></td>
<td>13048</td>
<td>&gt;99.9999%</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>13932</td>
<td>&gt;99.999%</td>
</tr>
<tr>
<td>VRE</td>
<td>700221</td>
<td>&gt;99.9994%</td>
</tr>
<tr>
<td>Bacteriophage</td>
<td>MS-2 (RNA virus)</td>
<td>&gt;99.994%</td>
</tr>
<tr>
<td>Bacteriophage</td>
<td>PRD1 (DNA virus)</td>
<td>&gt;99.87%</td>
</tr>
</tbody>
</table>

*Tested in 10% bovine serum (except viruses) after 18 hours of exposure*
Fast Acting & Long Lasting

Activity starts immediately, even in high challenge environments*

Percentage Reduction Within Indicated Time

<table>
<thead>
<tr>
<th>Time</th>
<th>Staph. aureus</th>
<th>E. coli</th>
<th>P. aeruginosa</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 min</td>
<td>99.98780 %</td>
<td>96.99842%</td>
<td>99.98205%</td>
</tr>
<tr>
<td>10 min</td>
<td>99.99415%</td>
<td>99.99763%</td>
<td>99.98564%</td>
</tr>
<tr>
<td>20 min</td>
<td>99.99268%</td>
<td>99.99938%</td>
<td>99.99397%</td>
</tr>
<tr>
<td>30 min</td>
<td>99.99878%</td>
<td>99.99972%</td>
<td>99.99746%</td>
</tr>
<tr>
<td>60 min</td>
<td>99.99999%</td>
<td>99.99946%</td>
<td>99.99936%</td>
</tr>
<tr>
<td>4 hrs</td>
<td>99.99999%</td>
<td>99.99981%</td>
<td>99.99996%</td>
</tr>
<tr>
<td>8 hrs</td>
<td>99.99999%</td>
<td>99.99997%</td>
<td>99.99996%</td>
</tr>
<tr>
<td>12 hrs</td>
<td>99.99999%</td>
<td>99.99997%</td>
<td>99.99996%</td>
</tr>
</tbody>
</table>

... and is extremely long lasting due to its permanent bond

* Tested in 10% bovine serum
BIOGUARD® Barrier Dressings

A full line of barrier protection for your patients’ care.
Clinical Applications

- Can help to reduce wound odor, frequency of dressing changes, and spread of bacteria from fouled dressings to the patient and clinical personnel.

- Can help inhibit cross-contamination:
  - Patient to patient
  - Patient to clinician,
  - Patient to the environment

- Offers a physical barrier to bacterial contamination in environments where you don’t have as much control
Clinical Applications

Gauze Bandages With A Bound Antimicrobial Polymer Suppress Bacterial Growth In Patients With Heavily Exudating Wounds

Lisa Youngblood1, Robert Nappo1*, Janet Popp1, Albina Mikhaylova2, Bernd Liesenfeld2, David Moore2, David Mozingo3, Tera Thigpin3, Gregory Schultz2,3, Shands at the University Shands of Florida, 2Quick-Med Technologies, 3University of Florida, The Symposium on Advanced Wound Care, Spring 2011

24 hours Standard Gauze

Large amount green drainage and odor

24 hours after BIOGUARD

Improved odor and less green drainage
Clinical Applications

Gauze Bandages With A Bound Antimicrobial Polymer Suppress Bacterial Growth In Patients With Heavily Exudating Wounds

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After 24 hours with BIOGUARD®

No odor and no green drainage
Case 1

Patient is a 68 y.o. male with a history of recurrent CVUs for over 15 years. He has had skin grafts and a multitude of topical treatments. On admission, initial treatment was a silver product and compression. BIOGUARD® non-adherent was initiated on 03/16/15 and his leg was wrapped with BIOGUARD® wrap and followed by a 2-layer compression wrap. Wound progressed nicely after initiation of BIOGUARD® from 5.9x3.1x0.3 and on 06/01/15 were: 3.2x2.7x0.1.
Case 2

Patient is a 52 y.o. male with a history of DVT and subsequent CVU formation. His previous treatment was Silvadene cream and he was treated with p.o. antibiotics for an infection. BIOGUARD® and compression were initiated on 04/27/15 demonstrating healthy progression. Measurements on 4/27/15 were: 2.5 x 3.8 x 0.1. Measurements on 06/01/15 were: 0.5x0.5x0.1.
Case 3

Patient is a 93 y.o female who developed cellulitis and edema to left lower extremity. In an effort to prevent a hospital admission, PCP was notified and agreed to initiation of by mouth antibiotics and topical wound care treatment. Patient admitted to hitting her leg on her walker and stated her leg had been weeping fluid. The associated wound was fairly superficial measuring 1.5x 2.4 cm without any appreciable depth. As soon as the wound was discovered, BIOGUARD was initiated and has been helpful in reducing erythema as well as healing of the wound overall.

7-2-15 | 1.5 x 2.4 cm.        7-5-15 | 1.4 x 2.3 cm.        7-13-15 | 1.3 x 0.9       7-17-15 | 1.0 x 0.8 cm
Case 4

History: This is a 58 Y.O. Patient who was found at his home on top of his bicycle on 02-28-14 by his father who had not heard from the patient a couple of days. He was taken to the hospital on 02-28-14 and wounds were found after a full body assessment. Patient was in acute renal failure and had Leukocytosis.

Patient was transferred from the hospital to nursing home on 03-12-14. Wound was treated with Santyl daily. Wound was found to have gangrene in the chest. Patient was on IV Vancomycin Rocephin. PCP referred patient to Woundtech for advanced wound care treatment in August 2014. Treatment continues however in January 2014 patient was transferred to a facility that did not permit photos which is why here is a break in the dates of the photos. In June 2015, Patient agreed to a photo for this case series.

Initially, Calcium Alginate with silver was implemented and in November of 2014, BIOGUARD® was started. As the wound became somewhat dry, a plain hydrogel was also utilized with the BIOGUARD®.

8-27-14 | 4.0 x 5.0 x0.2
10-20-14 | 4.0 x3.8 x0.2
11-06-14 | 3.3 x 2.2 x 0.2
12-19-14 | 2.8 x 1.6 x0.1
6-12-15 | 0.2x 0.2 x 0.1
Product Usage

Large Roll Gauze
- Large cavity packing or wrapping
- Ambulatory wound areas (orthopedics)
- Lower extremity
- Dermatology

Conforming Bandage
- Ambulatory wound areas (orthopedics)
- Protection for 1st and 2nd degree burns
- 2” and 3” perfect for pediatric or small digit areas (hands and feet)

Packing Strips
- Cavity wounds
- Plastic surgery
- ENT
- Pediatric Care
- Infection related to ear tube surgery

BARRIER DRESSING BIOGUARD®
Product Usage

Island Post-Op
- Orthopedics
- C-sections
- Abdominal wounds
- Head and neck

Non-Adherent
- Sensitive skin conditions
- Ideal for post-op where non-adherent is desired
  (Can wrap with BIOGUARD Conforming or Large Roll Gauze)

Ready-Cut Gauze Burn
- Ideal for burn units
  - Donor sites
  - Superficial to deep partial thickness burns
In Summary

Chronic Venous Leg Ulcers - Improving Outcomes and QoL for your Patients with BIOGUARD®

- VLUs can be challenging to manage – especially in the home environment where you cannot control what the wound is being exposed to - and severely impact a patient’s QoL.
- The impact of VLUs is worsened by infection, long healing times and high recurrence rates.
- Use of barrier dressings that can help to minimize the risk of bacterial contamination and keep that clean wound clean is paramount!
- BIOGUARD® Barrier Dressings provide >5 log-kill including MRSA within the dressing substrate without toxicity to healthy tissue.
Thank you! Questions & Answers

Loren Hayes
DNP, MS, ARNP, GNP-BC, GCNS-BC, CWCN-AP, CFCN, CWS, FACCWS, VP Clinical Operations
Wound Technology Network

For more information on BIOGUARD® and to view the MOA video visit our website www.dermasciences.com