

Case Series of Lower-Extremity Chronic Wounds Managed with an Antibacterial Foam Dressing Bound with Gentian Violet and Methylene Blue

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ABSTRACT

OBJECTIVE: To evaluate an antibacterial dressing for the management of lower-extremity chronic wounds with critical colonization.

DESIGN: A case series of $n = 15$ patients with lower-extremity chronic wounds were treated with an antibacterial foam dressing consisting of polyvinyl alcohol (PVA) foam bound with gentian violet and methylene blue (Hydrofera Blue; Hydrofera, LLC, Willimantic, Connecticut).

SETTING: An outpatient clinic in Ontario, Canada.

PATIENTS: The dressing was applied to diabetic foot ulcers ($n = 8$) and other venous/leg wound etiologies ($n = 7$). The study population was clinically challenging due to high mean body weight, extended wound durations, and high diabetes prevalence.

MAIN OUTCOME MEASURES: Wounds were assessed for clinical signs of superficial and deep/surrounding bacterial burden using the validated NERDS and STONEES mnemonic and with semiquantitative bacterial swabs. Changes in wound size, pain, and other clinical parameters were also recorded.

MAIN RESULTS: Improvements in surface critical colonization and pain score at the end of the study period were noted in some patients, especially in patients with diabetic foot ulcers. A decreasing wound size was observed in 8 of the 14 patients (57%) at week 4. One patient was excluded from wound size change analysis.

CONCLUSIONS: An antibacterial foam dressing consisting of PVA foam bound with gentian violet and methylene blue showed encouraging results in a clinically challenging study population. This dressing may be a suitable option for lower-extremity chronic wounds demonstrating an increased superficial bacterial burden. Further investigation focused on identifying the characteristics of patients who are most responsive to the dressing is warranted.

KEYWORDS: diabetic foot ulcer, wound healing, topical treatment, lower-extremity chronic wounds

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stresses the need to treat the “whole patient” before the “hole in the patient.” In other words, treat the cause and patient-centered concerns first and follow with the components of local wound care. The key local wound care components are debridement, critical colonization and abnormal surface inflammation, moisture balance, and the edge effect for healable chronic wounds that are stalled. An update to WBP can be found in the first article of this supplement.

All chronic wounds are contaminated and colonized by microorganisms, including bacteria. Within the chronic wound, a complex relationship exists between bacteria and the body's healing mechanisms. Bacteria in a chronic wound compete for nutrients and oxygen that are essential for healing. Evidence has documented compromised wound healing when bacterial burden crosses a critical colonization threshold and/or incorporates more than 4 pathological bacterial species.² Bendy et al³ first demonstrated healing was significantly thwarted at a bacterial load of 1.0×10^6 or greater colony-forming units per milliliter by analyzing chronic pressure ulcer wound fluids.

Chronic wounds should be clinically assessed in an evidence-based and systematic fashion. The mnemonics NERDS and STONEES¹ (see previous supplement article) outline criteria for assessment of the surface tissue compartment (critical colonization with 3 or more NERDS criteria)³ and for assessing the deep and surrounding tissue compartment. Bacterial swabs do not provide evidence for bacterial damage or for distinguishing between surface critical colonization and deep/surrounding compartment infection, but can be used to identify specific wound surface microbial species and their antimicrobial sensitivities.⁴

Heavy bacterial growth in the deep and surrounding tissue compartments usually requires the use of systemic antimicrobial agents (eg, oral antibiotics). In contrast, superficial wound infection (ie, critical colonization) may respond to topical antimicrobials. An ideal topical antimicrobial agent is one that is relatively nontoxic to the host while exerting activities against a broad spectrum of pathogens. Topical treatments may also facilitate moisture balance or autolytic debridement.¹

The authors evaluated an antibacterial foam dressing⁵ bound with gentian violet and methylene blue for the management of lower extremity wounds with critical colonization. The dressing's

Lower-extremity chronic wounds are debilitating, complex, and costly to treat. Common examples include diabetic foot ulcers and venous leg ulcers. Use of the wound bed preparation (WBP) paradigm is a recognized model for successful healing.¹ The WBP paradigm

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design and physical properties met many criteria as an ideal topical agent. This is the first case series study to evaluate this dressing in a peer-reviewed journal.

MATERIALS AND METHODS

This study evaluated the effectiveness of an antibacterial foam dressing⁵ bound with gentian violet and methylene blue in the management of chronic lower-extremity wounds with critical colonization.

DEVELOPMENT AND PHYSICAL PROPERTIES OF THE ANTIBACTERIAL DRESSING

The 2 antimicrobial agents in the dressing, gentian violet and methylene blue, have a long history of clinical use, known biochemical mechanisms, and minimal toxicity in humans.^{5–9} The dressing was originally developed by Edward Shanbrom, MD, in collaboration with polyvinyl alcohol (PVA) foam manufacturer (Hydrofera, LLC, Willimantic, Connecticut). This in vitro study demonstrated that when pathogen-seeded blood and the antibacterial agents methylene blue and gentian violet were filtered through PVA foam, the pathogens were killed without harm to red blood cells or serum proteins.¹⁰ Further development led to the creation of a blue foam dressing containing gentian violet and methylene blue. The dressing's physical structure is interconnected open cell foam, which promotes fluid wicking and absorption. The dressing has Food and Drug Administration clearance and has been commercially available since 2003 for use on many types of wounds, with the exception of third-degree burns.¹¹

CLINICAL USE OF TOPICAL ANTIMICROBIAL DRESSINGS

Topical antimicrobial dressings are indicated for the treatment of chronic wounds with clinical signs of increased bacterial burden (local infection).^{1,12–14} Use of topical antimicrobials that release agents directly onto the wound bed may be associated with adverse symptoms, including localized sensations of burning or stinging observed in some patients with the application of silver-¹⁵ or iodine-based¹⁶ dressings. In the topical antimicrobial dressings in this study, the 2 antibacterial agents are affixed to PVA foam. The antibacterial action therefore takes place within the dressing, which may minimize tissue toxicity and associated discomfort. The 2 antibacterial agents within the dressing physically bind with harmful bacterial byproducts (such as endotoxins), an action that may also aid in patient comfort.¹⁷ As with all living cells, bacterial survival depends on tightly controlled redox stability that balances between reductive and oxidative processes (conceptually similar to pH balances) in order to function and thrive.¹² Gentian violet and methylene blue act to alter the redox environment and create an environment unsustainable to bacterial survival.⁶

Use of this antibacterial foam dressing has been documented in previous case studies^{18,19} and case series,^{20–23} with some signs of effectiveness noted against a variety of microbes, including both methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococci.²⁴ The dressing is also compatible with enzymatic debriding agents (eg, collagenase).²¹ The dressing is easily removed from the wound and skin surface and may be covered with appropriate secondary cover dressing, depending on the amount of exudate present. The dressing also maintains moisture

balance via an open cell structure that absorbs excess exudate. In summary, the gentian violet and methylene blue foam dressing:

- has a high filtering efficiency,
- exhibits extreme softness when moist
- limits surface microbial growth, and
- provides excellent wicking and fluid retention properties.

CASE SERIES

A nonrandomized longitudinal case series of patients with stalled but healable lower-extremity chronic wounds was undertaken. Patient inclusion criteria were as follows:

- adults aged 18 to 85 years,
- healable but stalled chronic wounds of at least 30 days in duration,
- adequate blood supply deemed by palpable pulse or toe pressure greater than 55 mm Hg or ankle-brachial index (ABI) greater than 0.65,
- able to tolerate appropriate compression therapy (leg ulcers), and
- plantar pressure redistribution for persons with diabetes and foot ulcers.

Patient exclusion criteria included the following:

- poor blood glucose control (hemoglobin A_{1c} ≥12%),
- renal insufficiency (creatinine levels >330 μmol/L),
- hepatic impairment (aspartate aminotransferase >120 U/L or alanine aminotransferase >360 U/L or bilirubin >40 μmol/L),
- immunosuppressive therapy in the previous 3 months,
- known allergic reactions to any dressing component,
- overt deep or surrounding compartment wound infection,
- pregnant or breastfeeding females,
- uncontrolled autoimmune disease,
- terminal cancer, and
- dietary issues causing a negative protein balance.

At baseline evaluation (week 0), demographic information and medical history were recorded for all patients in an outpatient setting in Ontario, Canada. This included age, sex, weight, known allergens, medications, vital signs, presence of palpable foot pulses, wound location, duration, and current status. Wounds with less than 30% healing over the previous 30-day period with adequate blood pressure supply were judged as *chronic and healable* and included in the study. A total of n = 15 patients with lower-extremity chronic wound etiologies were enrolled.

Patients were treated according to best practice recommendations,^{25–27} including the use of compression for venous leg ulcers and offloading devices for diabetic foot ulcers. Necrotic tissue was removed with a curette, scissors, or scalpel blade

Table 1.

STUDY POPULATION CHARACTERISTICS

	All Wounds	Diabetic Foot Ulcers	Leg Ulcers
All subjects, n (%)	15	8 (53)	7 (47)
Female, n (%)	2	0	2 (100)
Male, n (%)	13	8 (62)	5 (39)
Mean age, y	62 (48–77)	62 (53–72)	63 (48–77)
Mean weight, lbs	234 (110–301)	246 (186–301)	223 (110–300)
Diabetes diagnosis, n (%)	10 (67)	8 (100)	2 (40)
Mean wound duration, d	629 (120–2550)	313 (120–730)	957 (180–2550)

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Table 2.**CHANGES IN WOUND SIZE OBSERVED AT STUDY CLOSE (WEEK 4)**

Wound Type	Patients	Healing at End of Study		
		Decreasing in Size	Not Changing	Increasing in Size
Diabetic foot ulcer	8	5 (63%)	0	3 (37%)
Leg ulcers	6	3 (50%)	1 (17%)	2 (33%)
Total	14	8 (57%)	1 (7%)	5 (36%)

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when clinically indicated prior to the study. An antibacterial foam dressing consisting of PVA bound with gentian violet and methylene blue was applied in direct contact with the wound base and covered with appropriate secondary cover dressing. Dressings were then changed as many as 3 times per week for a period of 4 weeks. At dressing change, the study wounds were further debrided and cleansed with sterile normal saline or water as required.

Study visits were conducted by investigators (P.M.C., J.R.) who are specialist wound care nurses. At weeks 0, 2, and 4, they recorded a photograph of the wound, the NERDS and STONEES clinical signs, and self-reported patient pain level using a 0- to 10-point scale. Clinical signs were evaluated as present or absent. Wound depth was evaluated, but as all wounds were shallow (<0.5 cm), it was not factored into later analysis. Wound size was calculated by a

software program that analyzes photographs of wounds to calculate an accurate and precise wound size (Wound Tracker Professional version 1.3 NAH Technologies; Apple, Cupertino, California).²⁸ The wound size of 1 patient (patient 15) could not be analyzed by software because of its circumferential shape, poorly defined wound boundaries, and very large size (>150 cm²). This patient was thus excluded from the analysis of change in wound size. All patients had bacterial species and their antimicrobial sensitivities were evaluated by obtaining a bacterial swab sample of the wound base (healthy-appearing granulation after wound cleansing using the Levine technique²⁹) at weeks 0 and 4. Additional bacterial swabs of the wound base were taken at the discretion of the primary investigators.

Change in wound size was calculated as a trichotomous categorical variable (decreasing/no change/not decreasing) to limited skewing from the wide range in wound sizes of the patients. Change in wound size was determined by comparing wound size observed at weeks 2 and 4, which allowed for wound remodeling and to account for the slow-release formulation of the dressing. This case series was designed to evaluate everyday clinical usage in a difficult-to-heal population and not to evaluate statistical significance, given the small sample size and selection of challenging leg and foot ulcers.

ETHICAL APPROVAL

All potential subjects were informed of their rights to discontinue their participation in the study at any time without affecting their usual and

Figure 1.

UPON REMOVAL, LOOSE SLOUGH AND DEVITALIZED TISSUE WERE OBSERVED ON THE WOUND CONTACT SURFACE OF THE DRESSING

**Figure 2.**

CHRONIC VENOUS ULCER WITH SECONDARY TRAUMA AND CRITICAL COLONIZATION AT WEEKS 0 AND 4



Week 0



Week 4

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Figure 3.**DIABETIC FOOT ULCER WITH STALLED HEALING AFTER SKIN GRAFT AT STUDY WEEKS 0 AND 4**

Week 0



Week 4

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routine wound treatment protocols. Study subjects signed a written consent form explaining these rights. Ethical approval for this study was given by Institutional Review Board Services (Aurora, Canada) protocol hBBD001. This study conformed with the principles of Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans³⁰ and the World Medical Association's Declaration of Helsinki.³¹

RESULTS

A total of 15 individuals were recruited: 13 males and 2 females. The study population was clinically challenging in multiple respects (Table 1). Two thirds ($n = 10$, 67%) had a diagnosis of diabetes mellitus. High mean weight (234 lb), older age (62 years), and extended wound duration (629 days) were also observed.

Wounds ranged in size from less than 1 cm² to more than 150 cm² at week 0. The largest wound was removed from analysis as its size, poorly defined wound boundaries, and circumferential shape made it impossible for its surface area to be calculated by software. The most common wound type observed were the diabetic neuropathic foot ulcer ($n = 8$) and venous leg ulcer ($n = 5$). At week 4, a decreasing wound size was observed in 8 of 14 patients (57%), no change in 1 patient (7%), and an increasing size in 5 patients (36%)

(Table 2). One patient with a diabetic foot ulcer experienced complete wound closure by week 4. Autolytic debridement was observed in some wounds, with the presence of slough on the removed dressing surface as illustrated in Figure 1. Caution should be used in interpreting these results because of the small sample size.

CASE 1

A 59-year-old man with type 2 diabetes mellitus presented with a chronic venous ulcer aggravated by secondary trauma and critical colonization (Figure 2). There is a history of left femoral artery occlusion treated by angioplasty and femoral popliteal saphenous vein bypass. The diagnosis of necrobiosis lipoidica diabetorum was made, and this is consistent with multiple previous ulcerations over the shin area.³² At week 0, the left shin ulcer had been present for 3 years and measured 17.9 × 3.0 cm, with 95% slough covering the wound base. Vascular testing revealed a left ABI of 0.53 and left toe pressure of 60 mm Hg. The bacterial swabbing indicated the presence of *S aureus* and group G streptococcus. At week 4, the wound measured 8.0 × 3.3 cm. Bacterial swab at this time showed the presence of commensal flora (part of the normal skin flora). The patient reported a decrease in pain during the study and no pain with removal of the dressing.

CASE 2

A 67-year-old retired man with type 2 diabetes mellitus and hypertension presented with a neuropathic ulcer that developed after grafting (Figure 3). Vascular testing revealed a left ABI of 1.10 and a left toe pressure of 81 mm Hg. At week 0, the wound measured 1.0 × 0.3 cm with minimal depth. Bacterial swab taken at week 1 of the study showed commensal flora. At week 4, the ulcer was closed.

In general, the dressing was well tolerated, with no study patients expressing dressing-related discomfort (eg, burning, stinging, or other pain) at dressing changes. None of the patients with diabetic foot ulcers experienced an increase in pain over the course of the trial; 3 (38%) reported a decrease in pain. Positive changes were noticed in NERDS and STONEES clinical criteria (Table 3), which are useful in the evaluation of bacterial burden in chronic wounds. The results were noteworthy for study participants being treated for diabetic foot ulcers, with $n = 5$ (63%) displaying fewer clinical signs of both superficial critical colonization and deep/surrounding infection after 4 weeks. Caution should be used in interpreting these results because of the very small sample size.

DISCUSSION

As outlined in WBP, any local wound treatment will be unsuccessful until the cause of the wound has been corrected and patient-centered concerns assessed in order to optimize adherence to

Table 3.**CHANGES IN NUMBER OF NERDS AND STONEES SIGNS OBSERVED AT STUDY CLOSE (WEEK 4)**

Ulcer Type	n	NERDS (Superficial Bacterial Burden) Signs Observed			STONEES (Deep Bacterial Burden) Signs Observed		
		Decrease	No Change	Increase	Decrease	No Change	Increase
Diabetic foot ulcer	8	5 (63%)	3 (38%)	0	5 (63%)	2 (25%)	1 (13%)
Leg ulcers	7	2 (29%)	1 (14%)	4 (57%)	2 (29%)	2 (29%)	3 (43%)
Total	15	7 (47%)	4 (27%)	4 (27%)	7 (47%)	4 (27%)	4 (47%)

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Table 4.**TREATMENT OF THE SUPERFICIAL COMPARTMENT: THE SIBBALD CUBE**

Component	Low Proteases	High Proteases
>3 NERDS criteria	Gentian violet and methylene blue foam dressing	Anti-inflammatory + antibacterial dressing
<3 NERDS criteria	Moisture balance dressing	Anti-inflammatory dressing

[©]Sibbald 2013, modified from [©]Sibbald 2011.

treatment.¹ The results of this study suggest that an antibacterial dressing made of PVA foam bound with gentian violet and methylene blue can be clinically effective at managing stalled lower-extremity chronic wounds. This was true among some patients with difficult-to-heal wounds who had been unresponsive to previous treatment. Diabetic foot ulcers in particular exhibited promising results regarding changes in wound size, reduction of NERDS and STONEES signs, and decreased pain scores at study closure. With regard to impact on bacterial burden, NERDS and STONEES criteria do indicate a positive antimicrobial action in some patients.

Relevant to this study is the concept of the Sibbald Cube, first introduced in WBP 2011.¹ The superficial compartment can have increased or normal components of bacterial damage or persistent inflammation. This compartment is only 1 to 3 mm thick and can be treated topically, as outlined in Table 4.

The study dressing is designed to manage critical colonization and may have also served as an appropriate moisture balance dressing. It is unlikely this dressing would manage any stalled wounds that had increased proteases, unless by an indirect mechanism by decreasing bacteria, which may have been associated with increased proteases. The result in this study is similar to a previous case series with a more expensive nanocrystalline silver dressing, where 21 of 29 stalled wounds improved, but there was no difference in quantitative biopsies that would be reflective of the deep and surrounding compartment bacterial load.³³ The nonresponsive subjects in this study need to be re-evaluated for the ability to heal, increased protease levels, and abnormalities of the deep and surrounding compartment.

Limitations of this study included the lack of a control group and a small sample size. Larger-scale trials are needed to detect statistically significant changes and whether differences in response to treatment exist between wound types.

CONCLUSIONS

Results of this study indicate that an antibacterial foam dressing consisting of PVA bound with gentian violet and methylene blue can be a suitable option for lower-extremity chronic wounds that are demonstrating an increased superficial bacterial burden. The results also suggest the dressing may be appropriate for the management of diabetic foot ulcers and may be limited in the management of chronic stalled leg ulcers. This may perhaps be because leg wounds are more likely to require an anti-inflammatory component (eg, silver) when stalled. However, caution must be exercised in this interpretation as patients with diabetic foot ulcers in the case series presented had significantly lower wound durations than those with leg wounds. Further study utilizing greater patient numbers and a control group is required to determine the

clinical effectiveness of this dressing and refine the patient characteristics that would benefit the most from its use. ●

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