DermaBlue™ Foam

DermaBlue™ Foam Transfer

Case Studies

for healthcare professionals

DermaRite®

Content adapted from the original publication to change the product name used in the study, from RTD Dressing to DermaBlue+ Foam. No data or conclusions have been altered in these materials.

Rev. 2019-08-12

Wound Dressing Comparison: Free Swell Absorptive Capacity Summary

EXECUTIVE SUMMARY

Thirteen DermaBlue+™ Foam* wound dressing samples from different lots were analyzed for free swell absorptive capacity. The free swell absorptive capacity results of these lots are averaged and presented in this report. The average free swell absorptive capacity of the DermaBlue+ Foam wound dressings analyzed is approximately 14.5 gram of solution per gram of dressing.

PURPOSE

This laboratory report summarizes the free swell absorptive capacity assays performed on thirteen lots DermaBlue+ Foam wound dressing from January to September 2017.

REPORT IDENTIFICATION

The original free swell absorptive capacity results were reported in the following reports:

1. ME-17-0125-01
2. ME-17-0628-01
3. ME-17-0509-01
4. ME-17-0911-01

MATERIALS

The scope includes the materials, equipment, methods, results[1] and associated data from performed experiments. The following samples were drawn from LOT numbers:

1. 1576
2. 1302
3. 5931298-Beginning
4. 5931298-Middle
5. 5931298-End
6. 5931622-Beginning
7. 5931622-Middle
8. 5931622-End
9. 5931298-5932629
10. 5931622-593259
11. 5931622-5932542
12. 5931622-5932742
13. 27016

DermaBlue+™ Foam - The DermaBlue+ Foam wound dressing samples were received on different days in 2017. Some of the DermaBlue+ Foam wound dressings were packaged in large Ziploc bags[1] and some were individually packaged and sterile-sealed. The DermaBlue+ Foam wound dressings received were of different sizes and thicknesses.

Incubator - A Shel Lab 51-9 incubator was used to pre-heat the test solution and also incubate the solution swollen DermaBlue+ Foam wound dressings.

METHODS

Test method was according to EN 13726-1 Section 3.31. The DermaBlue+ Foam wound dressings were cut into ~5 cm x ~5 cm sections[1] which were then weighed and placed in individual petri dishes of 95 mm in diameter, or appropriate containers when the assay required larger volumes of test solution (142 mM NaCl and 2.5 mM CaCl). The test solution was pre-heated to 37 ºC. Test solution equivalent to 40 times the mass (± 0.5 g) of each wound dressing section was added to each petri dish. Each sample was incubated at 37 ºC and relative humidity of 52-58 % RH, with air circulation, for 30 minutes. At the end of each incubation[1] the wound dressing sample was suspended with forceps by one corner or by one end for 30 seconds, then the weight was recorded. The same procedure was repeated for each wound dressing section. At least ten replicates were performed for each lot of DermaBlue+ Foam wound dressing.

RESULTS

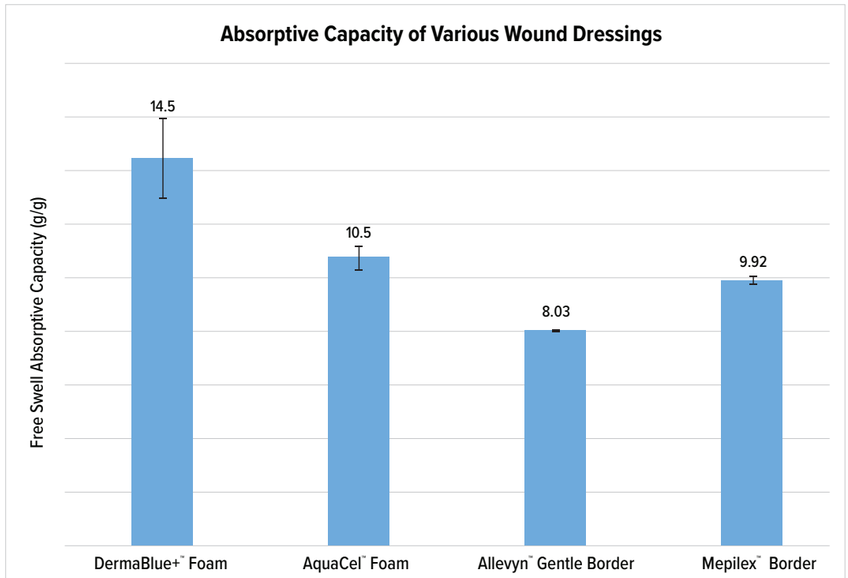


Figure 1. *Graphical presentation of absorptive capacity - comparison of different products*

Product	Absorptive Capacity (g/g)
DermaBlue Foam	14.5 ± 1.5
AquaCel Foam	10.75 ± 0.45
Allevyn Gentle Border	8.03 ± 0.01
Mepilex Border	9.92 ± 0.15

Table 1. *Absorptive capacity - comparison of different products*

Average free swell absorptive capacity of DermaBlue+ Foam Dressing	14.5

Table 2. *Average free swell absorptive capacity of DermaBlue+ Foam Dressing*

The free swell absorptive capacity of each lot of the DermaBlue+ Foam wound dressing is summarized in Table 1. The average results and the standard deviation from 10 replicates of each lot (except for Lot 1576, which 12 replicates were assayed) are shown in Table 2. The results are reported as gram of solution retained per gram of wound dressing (g/g).

DermaBlue Foam Wound Dressing Sample LOT	Series #	Free Swell Absorptive Capacity (g/g)
1576	None	14.9 ± 0.5
1302	None	13.0 ± 0.5
S931298	Beginning	15.3 ± 0.5
S931298	Middle	15.2 ± 0.5
S931298	End	16.6 ± 0.5
S931622	Beginning	16.1 ± 0.5
S931622	Middle	16.2 ± 0.5
S931622	End	15.0 ± 0.5
S931298	S932629	12.9 ± 0.5
S931622	S932741	12.5 ± 0.5
S931622	S932542	13.1 ± 0.5
S931622	S932589	12.0 ± 0.5
27016	None	15.1 ± 0.5

Table 3. *Absorptive capacity of DermaBlue+ Foam Wound Dressing.*

CONCLUSION

The tested average free swell absorptive capacity of DermaBlue+ Foam wound dressing is an impressive 14.5 g/g. The free swell absorptive capacity of DermaBlue+ Foam wound dressing is compared to the reported values of the wound dressing products from other manufacturers in Table 1 and Figure 1.

REFERENCES

1. *BS EN 13726-1:2002. Test methods of primary wound dressings. Part 1: Aspects of absorbency. Section 3.2.*
2. *Bishop, SM, et al. 2013. A comparison of the in vitro bio-physical performance characteristics of silicone foam dressings used in wound management. ConvaTec product bulletin.*

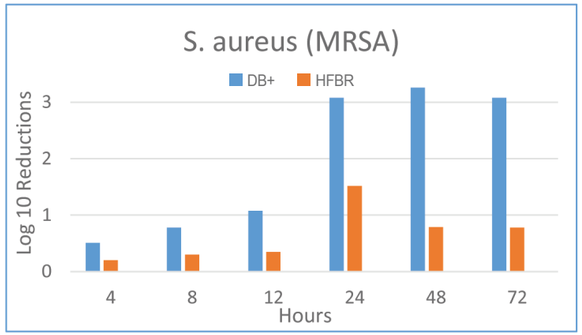
*At the time of this study DermaBlue+ Foam was sold under the name "RTD Wound Dressing".

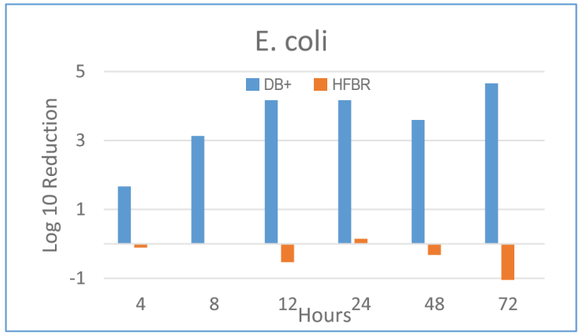
Rev. 2019-07-18

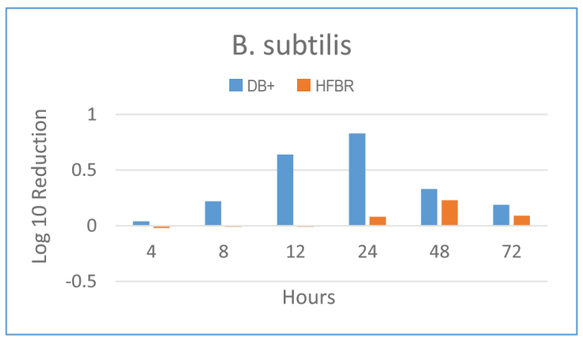
Content adapted from the original publication to change the product name used in the study, from RTD Dressing to DermaBlue+ Foam. No data or conclusions have been altered in these materials.

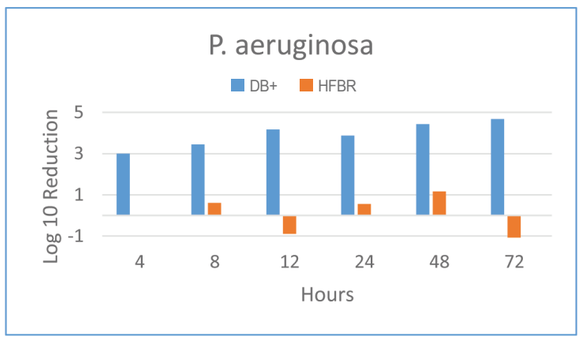
THE ADDITION OF SILVER TO METHYLENE BLUE AND GENTIAN VIOLET: ANTIMICROBIAL BENEFITS OF A POLYURETHANE FOAM WOUND CARE DRESSING

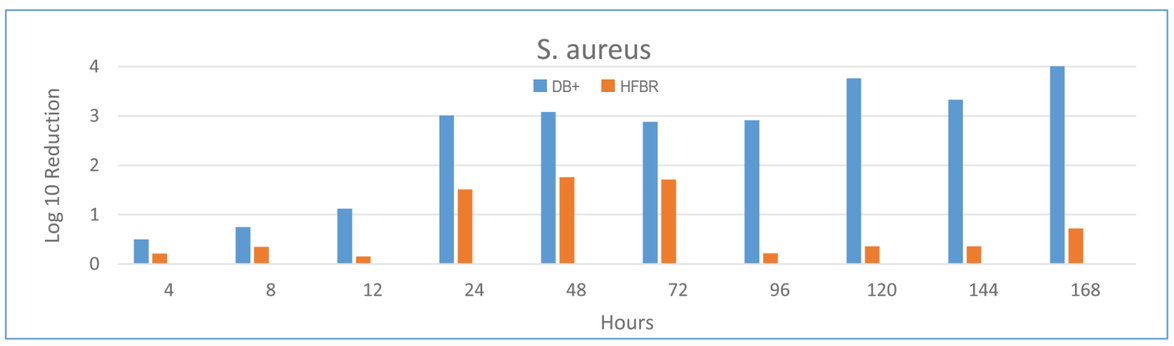
DR. JEAN ACHTERBERG, DC & LEILA ABBOUD, PT, MSC, MBA (KENERIC HEALTHCARE, IRVING TEXAS)











INTRODUCTION

Silver wound dressings have the advantage of having broad antimicrobial effectiveness against gram-negative and gram-positive bacteria[1] as well as a positive impact on wound healing[2]. Organic pigments such as methylene blue (MB) and gentian violet (GV) have also been used in wound care due to their antimicrobial, analgesic benefit and attraction for protein based chemicals. It is expected that the combination of MB, GV and silver would demonstrate greater antimicrobial activity than MB and GV alone.

The purpose of this study is to demonstrate the antimicrobial benefits of a polyurethane based foam dressing with silver, MB and GV (DermaBlue+™ Foam* (DB+)) versus the same with MB and GV alone (Hydrofera Blue® Ready (HFBR)).

METHOD

An independent laboratory performed the microbial testing. Three uniform, 48 mm x 48 mm sections of each dressing were inoculated with common wound bacteria; S. aureus (MRSA), S. aureus, P. aeruginosa, E.coli and B. subtilis.

The test articles were re-inoculated at 24 and 48 hours. The percent reduction were recorded at 0, 4, 8, 12, 24, 48, and 72 hours exposure periods. For one organism (S. aureus), test articles were re-inoculated every 24 hours and log reductions were measured every 24 hours for 7 days (168 hours).

Log reduction was calculated as the difference between the number of microorganisms recovered from the control dressing and test dressings, for each of the pathogens tested at each period. Sterile gauze was used as the control dressing.

DISCUSSION

This study compared the antimicrobial activity of two commercially available dye based antimicrobial foam dressings: HFBR contains MB and GV and DB+ contains MB, GV and silver (Ag+). Both dressings are made of a polyurethane foam base.

The dressing containing silver in addition to MB and GV (DB+) demonstrated significantly better antimicrobial activity and in all cases performed better than HFBR. The dressing containing MG and GV only (HFBR) demonstrated microbial growth after 12 hours with gram (-) bacteria; E. coli and P. aeruginosa. DB+ continued to demonstrate sustained effective microbial reduction through 7 days for S.aureus however the effectiveness of HFBR declined after 72 hours.

CONCLUSION

The DB+ dressing containing silver, MB and GV performed better than the dressing containing only MB and GV (HFBR) against S. aureus (MRSA), S.aureus, P. aeruginosa, E. coli and B. subtilis. It is expected that the addition of silver would have a beneficial impact on wound healing. More studies,such as comparative effectiveness would help to demonstrate the clinical benefit of the silver, MB and GV combination over MB and GV alone.

1) Myers BA. Wound Management. Upper Saddle River, NJ: Prentice Hall;3rdEdition 2011
2) Lo SF, Chang CJ, Hu WY, Hayter M, Chang YT. The effectiveness of silver-releasing dressings in the management of non-healing chronic wounds: a meta-analysis. Journal of Clinical Nursing. 2009 Mar; 18 (5):716-28.
DermaBlue+ Wound Dressing (Trademark of DermaRite Industries) Polyurethane, Silver Sodium Hydrogen Zirconium Phosphate (7 mg/gm), Methylene Blue (0.25 mg/gm) and Gentian Violet (0.25 mg/gm)
HFBR: Hydrofera Blue® Ready (Trademark of Hydrofera, LLC and sold by Hollister Wound Care, LLC) Polyurethane foam, Methylene Blue (0.35 mg/gm) and Gentian Violet (0.35 mg/gm)

***At the time of this study DermaBlue+ Foam was sold under the name "RTD Wound Dressing".**

Content adapted from the original publication to change the product name used in the study, from RTD Dressing to DermaBlue+ Foam. No data or conclusions have been altered in these materials.

Rev. 2019-07-18

Use Of DermaBlue+™ Foam Wound Dressing* In 168 LTC Patients

Steve Warren MD,FABFM,FABHPM,FABHPM, Medical Director; Diane Smith MSN GNP, Study Consultant

*At the time of this study, DermaBlue+ Foam was sold under the name "RTD Wound Dressing".

Introduction

Background

In this study the DermaBlue+ Foam wound dressing was used on 168 patients in 11 nursing homes in Utah. The majority of these wounds were chronic and non healing. The wounds were assessed and followed by the physician and wound care nurse of the facility. Approximately 10% of the patients were lost to death (2%) or return to home or transfer. The end number of patients was 152. Of these, the majority were white females.

DermaBlue+ Foam wound dressing is a highly absorbent, soft, wound conforming polyether/ polyurethane foam dressing infused with three antimicrobial agents. The three agents are Methylene Blue (up to 0.25mg/g), Gentian Violet (0.25mg/g) and Silver: Ag-Na-H-Zr-PO4 compound (up to 7mg/g). In this study the wounds were dressed with the DermaBlue+ Foam wound dressing and topped with a non occlusive dressing, such as Mefix. The patients were followed until wound closure was achieved. Mean time to closure for all wounds was 38 days or 5 weeks. The range being 2 weeks to 12 weeks. The study was active in the respective homes for 6 months.

The mean age of the patients was 72 years. Many of the wounds were heel and diabetic leg ulcers. All these patients had been residents of their respective nursing home and had tried other forms of treatment.

An unexpected benefit was that after the wounds were dressed with the DermaBlue+ Foam, many patients reported little or no pain at all.

Method

This was a descriptive study in which patients' data were entered by the treating physician.

Summary

Many of the wounds healed in this study are typical of the LTC and Palliative Care patient. This dressing proved to be effective, easy to use and had a side benefit of relieving pain. In these homes the DermaBlue+ Foam wound dressing has remained as a staple for wound healing.

This study was supported by a grant from GWM Products.

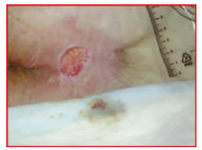
Results

Stasis Ulcer Healing Averages

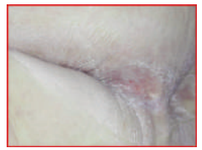
Average Percent of Wound Healed - 76.10%
Average Number of Days - 27.26

Diabetic Ulcer Healing Averages

Average Percent of Wound Healed - 67.91%
Average Number of Days - 21.94



August 17

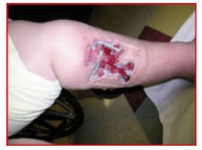


November 23

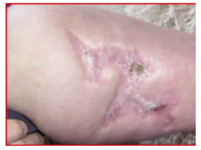
Wound Type	Location	Acute/Chronic	Stage	Gender	Age	Days to Healing	Wound Status
Pressure Ulcer	Coccyx	Chronic-incontinent of stool and urine	3	F	82	96	Healed

This Stage 3 Pressure Ulcer patient had the following issues of compromise:

- The patient is incontinent of stool and urine
- The wound could not be kept uninfected



April 18

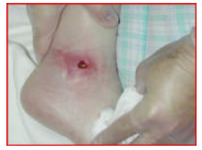


September 23

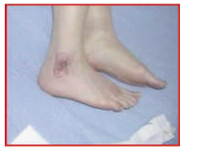
Wound Type	Location	Acute/Chronic	Stage	Gender	Age	Days to Healing	Wound Status
Pyoderma Gangrenosum	L Leg Medial	Chronic Autoimmune	4	F	61	162	In Process

This Pyoderma Gangrenosum patient had the following issues of compromise:

- Six wounds on her legs
- The University of Utah Medical Center could not suppress infection during 8 months of treatment
- The potential for sepsis made her a candidate for amputation



January 18

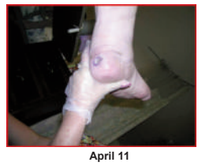


March 23

Wound Type	Location	Acute/Chronic	Stage	Gender	Age	Days to Healing	Wound Status
Pressure Ulcer	R Ankle Malleolus	Chronic	3	F	68	63	Healed

This Stage 3 Pressure Ulcer patient had the following issues of compromise:

- Severe advanced dementia
- Patient was never turned
- Ankle was never elevated
- Infection could not be suppressed with antibiotics



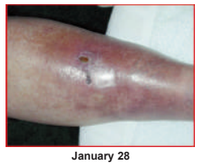
April 11

July 11

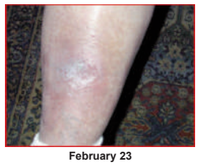
Wound Type	Location	Acute/Chronic	Stage	Gender	Age	Days to Healing	Wound Status
Pressure Ulcer	L Heel	Chronic	3	F	83	82	Healed

This Stage 3 Pressure Ulcer patient had the following issue of compromise:

- Had been treated with Aquacel® Ag for 5 months with no healing



January 28

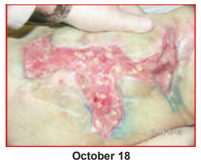


February 23

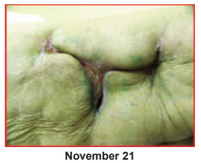
Wound Type	Location	Acute/Chronic	Stage	Gender	Age	Days to Healing	Wound Status
Diabetic Ulcers	L Shin	Chronic	2	M	60	26	Healed

This Stage 2 Diabetic Ulcer patient had the following issues of compromise:

- Under the care of an infectious disease specialist for one year
- Infection could not be suppressed with IV antibiotics
- IV's were discontinued during DermaBlue+ Foam protocol



October 18



November 21

Wound Type	Location	Acute/Chronic	Stage	Gender	Age	Days to Healing	Wound Status
Suspected Pyoderma	R Leg Posterior	Chronic	4	F	64	48	Healed

This stage 4 suspected Pyoderma Gangrenosum patient had the following issue of compromise :

- Hyperbaric & wound vac regimen for one year with no healing progress
- Pockets 5cm deep
- Carted a 50 pound wound vac around long enough to name it "George"

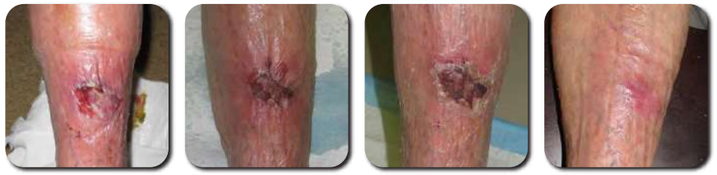
Management Of Lower Extremity Wounds In Clients With High Risk For Wound Infection

Furqan Alex Khan, APRN ACNS-BC MSN, ALI A. PITAFI MD
www.ProHealthcare.us

Rev: 2020-05-12

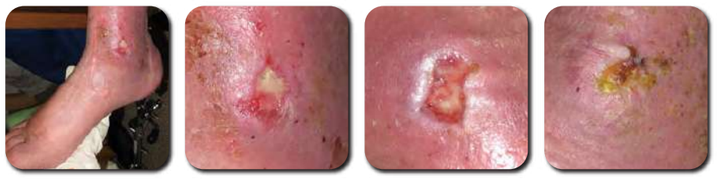
Case 1

Trauma Wound | Left Shin | 3.2 x 4.5 x 0.2 cm
Patient Age: 88 | Gender: F
Healing Time: 6.5 Weeks



Case 2

Neuropathic Ulcer | Right Ankle | 2.1x 1.8 x 0.3 cm
Patient Age: 78 | Gender: M
Healing Time: 15.5 Weeks



PROBLEM

Infection of the lower extremity wounds is one of the most frequent problem identified in the homebound clients. In addition, wound infection not only alters the wound healing process but can lead to adverse outcomes, and mortality. Lower extremity ulcers are a major cause of morbidity in elderly clients and often colonized by many different microorganisms, including fungi. Some studies have identified the presence of *Candida albicans*, *Candida parapsilosis*, and *Candida ciferrii* in lower extremities wounds. Current clinical practice does not involve culturing of the wounds to identify presence of fungi; nor wounds are commonly treated with topical antifungal wound dressings. Further, wound cultures are commonly collected for aerobic and anaerobic bacterial identification and treated with oral antibiotics. Gentian violet is known to be antimycotic, antibacterial, and anthelmintic. It is potent against fungi like *Candida*, which causes various yeast infections, as well as bacteria including *Streptococcus*, *Pseudomonas*, and *Staphylococcus*, and even methicillin–resistant *Staphylococcus aureus*.

METHOD

Four (4) patients with the wounds of the lower extremity were identified who were receiving home health care for the management of their wounds. All four (4) patients have wounds with different etiology and were high risk for developing wound infection due to their complex comorbid medical conditions and their poor living conditions. All patients were treated with Polyurethane foam containing gentian violet, methylene blue, and silver. Wounds were cleansed with sterile water and 4x4 gauze each time and dressing was changed (3) times each week.

RESULTS

Use of Polyurethane foam dressing with Methylene Blue, Gentian Violet, and Silver Sodium Zirconium Phosphate in all four (4) reviewed cases resulted in complete re–epithelialization of all wounds in less than 16 weeks. Patient made full recovery without any hospital admission. Sharp wound debridement was utilized to remove the non–viable tissue and Polyurethane foam dressing with Methylene Blue, Gentian Violet, and Silver Sodium Zirconium Phosphate dressing was utilized to create optimal wound healing environment by preventing wound infection, optimal moisture management and minimal pain with the dressing changes.

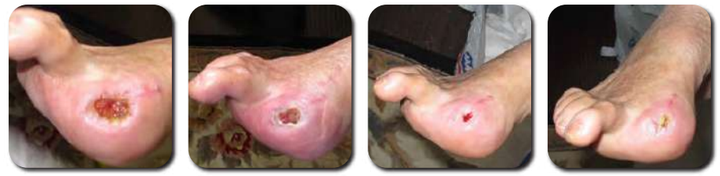
CONCLUSION

Use of Polyurethane foam with gentian violet, methylene blue, and silver was found to be effective in managing clients with lower extremities wounds.

Bibliography:
S.Hsieh, E.Maranda, T.Saleh, M.Flores, J.Jimenez (2016). The Purple Dye That Heals. JAMA Dermatology April 2016.
C.Friedman, E.Bass, J.Steinberg (2006). Key Considerations For utilizing Silver Dressings. Podiatry Today May 2006.

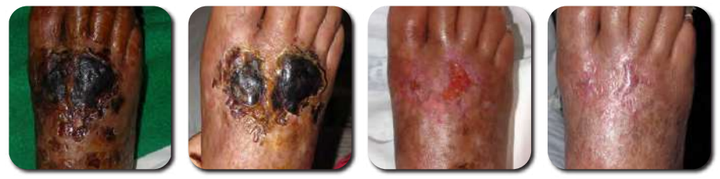
Case 3

Surgical Wound | Right Great Toe | 2.8 x 2.0 x 0.3 cm
Patient Age: 74 | Gender: M
Healing Time: 10.2 Weeks



Case 4

Arterial Wound | Right Foot | Multiple Areas of Ulceration
Patient Age: 72 | Gender: F
Healing Time: 14 Weeks

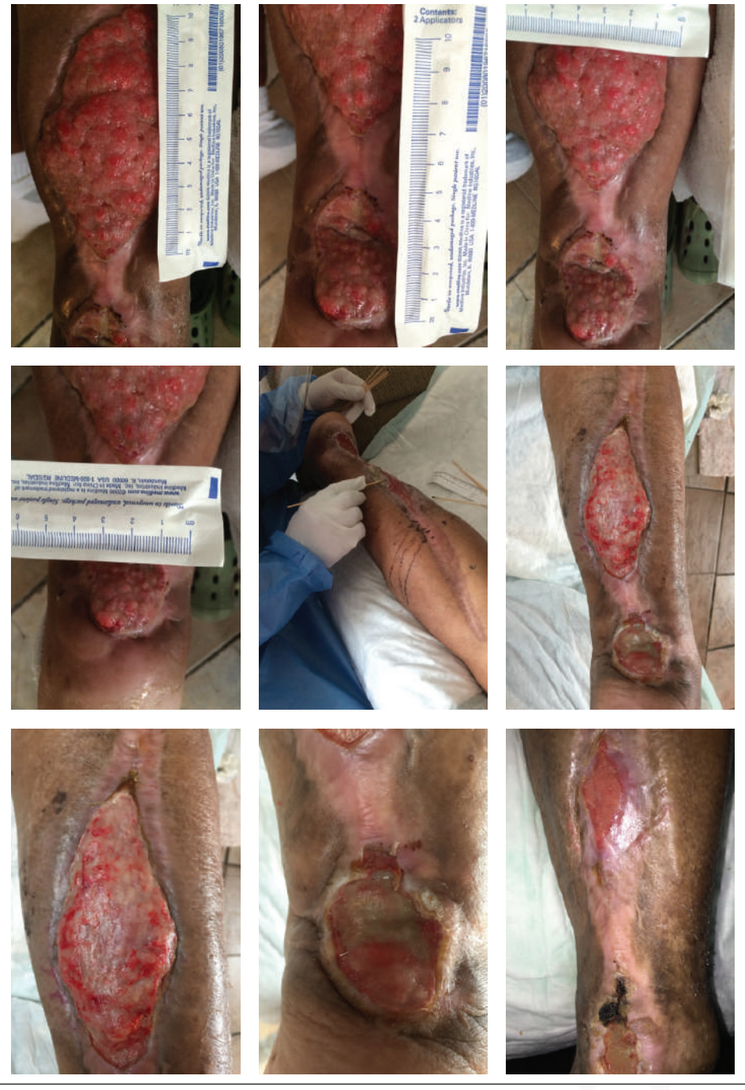


At the time of this study DermaBlue+ Foam, the product used in this study, was sold under the name “RTD Wound Dressing”.

Content adapted from the original publication to change the product name used in the study, from RTD Dressing to DermaBlue+ Foam. No data or conclusions have been altered in these materials.

AN EFFECTIVE AND ECONOMICAL APPROACH TO RESOLVING SEVERE HYPERGRANULATION USING DERMABLUE+™ FOAM WOUND DRESSING: ANTIMICROBIAL POLYURETHANE FOAM WITH INTEGRATED METHYLENE BLUE, GENTIAN VIOLET AND SILVER

SONIA VARGAS RN, WCC, COS-C (APRIL SKYYHOME HEALTH CARE, CORPUS CHRISTI, TEXAS), LEILA ABBOUD, PT, MSC, MBA



INTRODUCTION

Hypergranulation tissue is an excess of granulation tissue beyond the height of the wound surface resulting in a raised mass (or peduncle). Hypergranulation tissue can impede healing by preventing the migration of epithelial cells across the wound surface and increase the risk of infection[1].

This 45 year old patient underwent surgical irrigation and debridement procedures (November 2013) of the right posterior lower leg/calf area for infection and gangrene that resulted from the patient attempting to remove a cactus thorn with dirty tweezers. Patients history indicates a high risk for delayed wound healing and high risk for infection. Patient is immunosuppressed due to the effects of dialysis 3 times a week and history of failed kidney transplant. Patient also presented with renal hypertension and history of anemia which all present a significant role in delayed healing.

Following the procedure, the surgical incision, which extended along the posterior lower leg, from the posterior calf to the achilles, dehisced in two locations. The patient spent three months in hospital and had a failed skin graft.

After discharge from hospital, the patient was seen for wound care by a previous home health agency for daily dressing changes with SilvaSorb® (antimicrobial wound gel)[2] wound dressings with no success. At the time that the patient was transferred to this new team, the patient was at risk for amputation.

PURPOSE

The purpose of this study is to present the treatment outcome of a case with severe hypergranulation on the posterior lower lesion and to present an effective and economical approach to resolving severe hypergranulation with the use of DermaBlue+ Foam Wound Dressing.

MATERIALS / METHOD

On initial presentation (7/14/14) to new home health agency, the patient presented with severe hypergranulation of two open areas of the surgical wound; posterior aspect of calf (W1) and lower aspect on achilles (W2). The wounds cultured positive for S. aureus, E. coli and E. cloacae. The patient was started on Cipro 500mg BID times 5 days which assisted with decreasing bacterial growth.

Weekly application of Silver Nitrate and 2 weekly applications of DermaBlue+ Foam Wound Dressing, a novel new antimicrobial polyurethane foam with three active ingredients integrated into the matrix; Methylene Blue, Gentian Violet and Silver were provided.

The patient was referred to a Podiatrist due to suspected delay in wound healing secondary to patient's abnormal heel-to-toe gait, most evident to the achilles wound. It was suspected that difficulty healing of the lower wound may have been related to the anatomy of the achilles area and subsequent decrease in ankle flexion. A decrease in muscle mass was noted as well. A camboot was prescribed to immobilize the ankle which aided epithelial growth and allowed healing to continue to progress.

RESULTS

7/30/14 -Initial measurements:

- W1-14 cm x 7.5 cm x2.5 cm elevation.
- W2-5.3 cm x 4 cm x 2.0 cm elevation.

The DermaBlue+ Foam was highly absorbent and kept the wound from macerating. By drawing infectious wound exudate away from the wound, DermaBlue+ Foam helped to create a moist wound healing environment, reduce the bioburden, reduce inflammation and promote healing. The addition of gentian violet contributed to the patient remaining free of pain throughout treatment.

Both areas showed the wound edges were well approximated with early epithelial growth noted on 10/22/14. The full thickness wound had a moderate amount of serosanguinous drainage and no foul odor. The wound bed was red with no nonviable tissue noted. The tissue appeared well oxygenated and responded well to DermaBlue+ Foam. No further nitration was needed.

10/22/14 -Measurements results:

- W1-12 cm x 4 cm x 0.2 elevation
- W2-5.4 cm x 2.3 cm x 0 cm elevation.

The treatment duration with DermaBlue+ Foam and silver nitrate was 84 days. (7/30/14 -10/22/14)

CONCLUSION

Despite the patient's very challenging medical history, the DermaBlue+ Foam Wound Dressing eventually helped the wound to full closure.

This home health agency was able to reduce weekly cost of care for this patient by 65%.

- 57% reduction in nurse visit costs.
- 74% reduction in wound dressing costs.

There was no additional need for skin graft or application of costly skin substitutes to close this wound.

Findings:

- Significant wound surface area reduction.
- Hypergranulation tissue reduction.
- DermaBlue+ Foam drew infectious materials away from the wound, reducing bacterial load, reducing inflammation, and creating a healing environment.
- DermaBlue+ Foam managed a large volume of exudate from this wound and helped reduce the bacterial load.

1) Vuolo, J, Hypergranulation: Exploring possible management options, British Journal of Nursing, Vol 19, No. 6 SUPPL., pp. S4-S8 2010.

2) SilvaSorb® Antimicrobial Wound Gel, is a registered trademark of Medline Industries, Mundelein, Illinois

Content adapted from the original publication to change the product name used in the study, from RTD Dressing to DermaBlue+ Foam. No data or conclusions have been altered in these materials.

Incorporating a New Highly Absorbent Antimicrobial Polyurethane Foam* in a Multimodal High Risk Diabetic Wound Care Algorithm

Dr. Karen Brooks‡, DPM & Mr. Michael Olden‡, H.t, Ost; C-Ped; Pmac

U.S. Department of Veterans Affairs

Introduction

DermaBlue+™ Foam Wound Care Dressing is a novel new, highly absorbent antimicrobial polyurethane foam dressing that has been integrated into our Diabetic Wound Algorithm. DermaBlue+ Foam is recommended to protect the wound from bacterial trapping, as well as bacterial binding, thus preventing biofilm formation. It is a highly conformable and absorptive dressing designed for first line defense for exudative & infection control. It works extremely well with the use of biologicals and prevents the active ingredients in the other modalities from being drawn away and does not appear to impact their effectiveness.

The purpose of this case study is to demonstrate the use of DermaBlue+ Foam and its implementation into a multimodal, high risk, wound care algorithm. This 60 year old, diabetic, male presented with a 5th Ray Amputation that left the patient with a very large wound with exposed internal structures. This dressing is the only one on the market that contains all three known antimicrobials integrated into the foam matrix; methylene blue (0.25 mg/g) and gentian violet (0.25 mg/g) plus a silver compound (Silver Zirconium Phosphate (7 mg/g)). This dressing provides sustained antimicrobial protection and is effective against a broad spectrum of gram negative and gram positive bacteria, yeast and fungi. It is a more effective antimicrobial than dressings that contain organic pigments (methylene blue and gentian violet) alone (1).

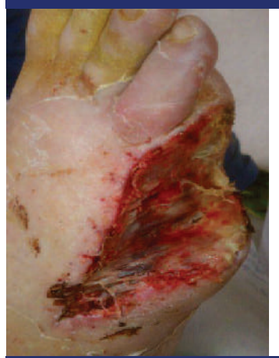
Method

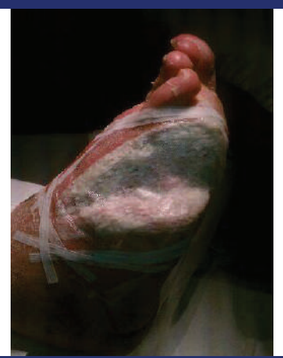
Kerrville Podiatry team performed meticulous wound care with multiple modalities per our High Risk Diabetic Wound Algorithm. Oasis ®, sterile, tri-layer ECM and Grafix® live placental tissue were applied every other week in conjunction with DermaBlue+ Foam placed, over the top, as the sterile absorptive anti-pathogen fixator. DermaBlue+ Foam was used through the duration of the wound care (12 applications).

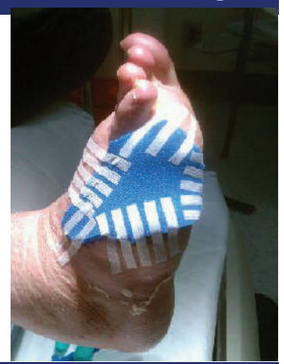
Results

On the initial visit (4/01/2014), the wound was approximately 12.4cm x 4.75cm. As of 6/17/2014 (76 days), the wound was decreased to 1.2cm x 1.0 cm. At this point in time, the patient was discharged from hospital and went to full closure at home. No secondary infections occurred. This large post-surgical site closed rather uneventful and faster than most of this type.

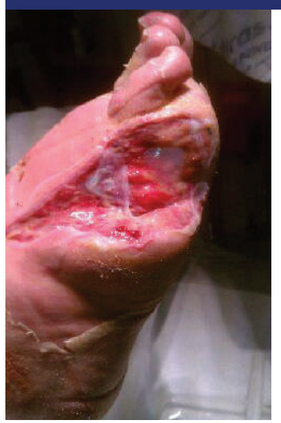
Week 1: Oasis® Matrix & DB+ Foam Wound Dressing

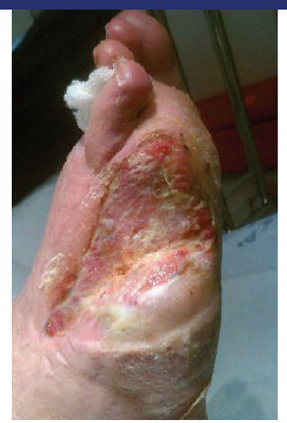


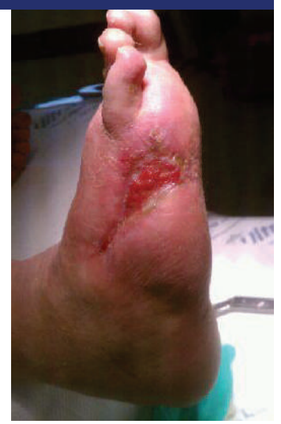




Week 2 (&Grafix®) | Week 6 | Week 10







REFERENCES
1. GWM Products, LLC: Data on file 2014
2. Lo SF, Chang CJ, Hu WY, Hayter M, Chang YT. The effectiveness of silver-releasing dressings in the management of non-healing chronic wounds: a meta-analysis. Journal of Clinical Nursing. 2009 Mar; 18 (5):716-28.

Discussion

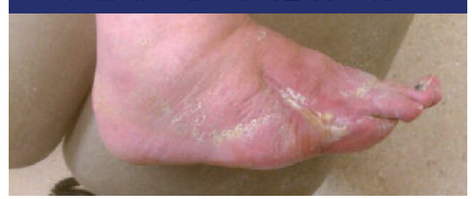
DermaBlue+ Foam controlled the wound bed, keeping it pathogen free, allowing the wound care practitioner to utilize their various wound care algorithms and multiple modalities to complete the healing process. DermaBlue+ Foam allowed for a more stable recovery time (12 weeks), without a need, in this case, for NPWT. No autolytic debridement agents were needed and processed cellular destruction occurred trying to control pathogens. No povidone-Iodine was used. This dressing is cost effective and managed copious exudate, preventing secondary infections during wound care and the healing process.

The addition of silver to this dressing enhances the antimicrobial properties that also have demonstrated benefits to improving wound healing (2). Since this new dressing possesses absorptive and antimicrobial properties, it creates an optimal environment for wound healing and helps to overcome the challenges of a compromised wound-healing environment. Since the silver compound in this dressing is non cytotoxic, this dressing can be used to address wounds throughout the continuum of healing.

Conclusion

This versatile dressing was used throughout the continuum of healing and was easily integrated into the facility wound treatment protocol. It reduces bacterial load and helps prevent the establishment of biofilm allowing wounds to heal without incidence of infection. This wound went on to heal two weeks following discharge from hospital. DermaBlue+ Foam appeared to be compatible with the biologic wound care modalities used.

Full closure at 12 Weeks



‡ Pedorthic Clinics Kerrville Division-South Texas Veterans Health Care Systems

Poster presented at the Desert Foot Conference – November 2014

Efficacy of Polyurethane Foam with Methylene Blue, Gentian Violet, and Silver Sodium Zirconium Phosphate in Wound Healing

F. Alex Khan APRN, Ali A. Pitafi MD, Faiz Zafaruddin LVN, Pro Healthcare Clinic, Carrollton, Texas

PROBLEM

Bacterial and fungal contamination, inflammation and infection cause delay in wound healing or chronicity in acute wounds. Inflammatory cells, as well as bacteria, produce a number of proteases (including MMPs), which degrade the ECM and growth factors present within the wound bed. Furthermore; bacterial colonization and formation of biofilm provides optimal environment for fungal & bacterial cell survival.

METHOD

In all three presented cases Polyurethane foam dressing with Methylene Blue, Gentian Violet, and Silver Sodium Zirconium Phosphate was utilized until the re-epithelialization was achieved. In addition; Activated Carbon dressing was utilized for 14 days and Bovine Collagen dressing was also used for 14 days.

PRACTICE SETTING

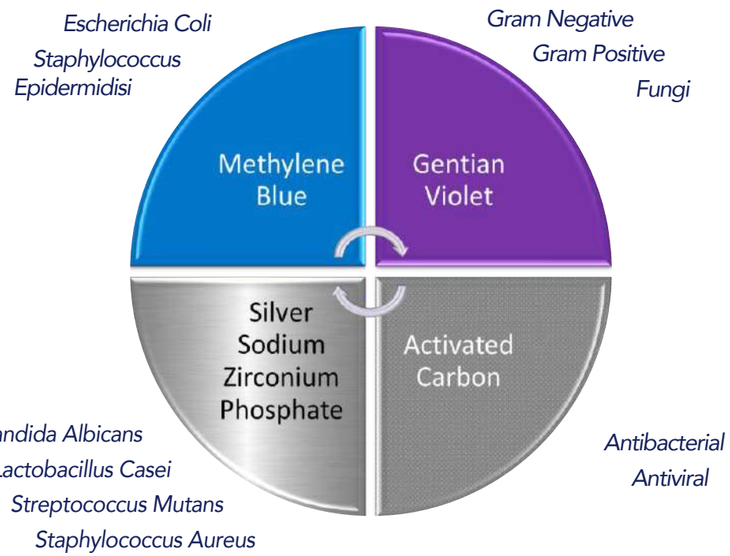
All patients were treated in an outpatient clinic setting and examined by the treating practitioner once (1) a week.

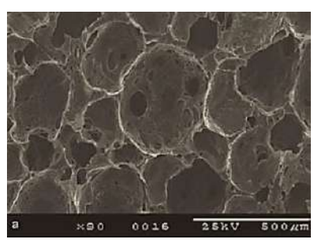
FREQUENCY

Dressing changes were performed by home health licensed nurse twice (2) a week.

RESULT

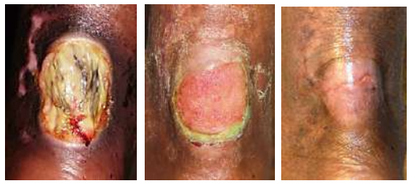
Use of Polyurethane foam dressing with Methylene Blue, Gentian Violet, and Silver Sodium Zirconium Phosphate was found to be exception al in all three reviewed cases. All illustrated wounds healed without any infection. Use of activated carbon dressing also provided additional bio-burden management. Cost of each dressing change was found to be lower than the other polyurethane and silicone foam dressings as well.





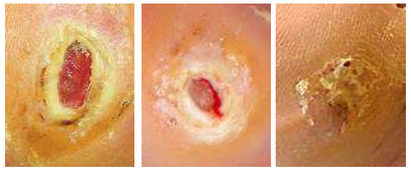
REFERENCES
1. Tatiana N. Demidova-Rice, Michael R. Hamblin, Ira M. Herman (2012). Acute and Impaired Wound Healing: Pathophysiology and Current Methods for Drug Delivery. Advance Skin Wound Care. 2012 Jul; 25(7): 304–314.
2. Dowsett, C., Newton, H. (2005). Wound bed preparation: TIME in practice. Journal of Wounds. UK.
3. C. Piccirillo, S. Perni, J. Gil-Thomas, P. Prokopovich, M. Wilson, J. Pratten and I. P. Parkin. Antimicrobial activity of methylene blue and toluidine blue O covalently bound to a modified silicone polymer surface, J. Mater. Chem., 2009.
4. Sirikamon, S.,Toemsak, S., Sroisiri, T.,Taweechai, A., Momsakchai,. Antimicrobial effects of silver zeolite, silver zirconium phosphate silicate and silver zirconium phosphate against oral microorganisms. Asian Pac J Trop Biomed. 2013 Jan; 3.

CASE #1



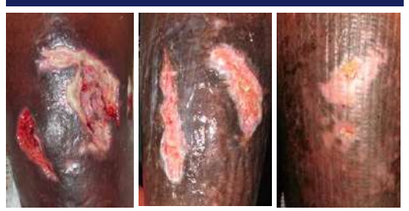
STAGE 4 PRESSURE ULCER I ACHILIES TENDON DIMENSIONS:3.5 x 3.5 x 0.3 CM
HEALING TIME: 32 WEEKS
COST / DRESSING CHANGE: $ 6.00

CASE #2



DIABETIC / NEUROPATHIC ULCER – GRADE 2 FOOT ULCER PLANTAR ASPECT
DIMENSIONS: 2.2 X 1.3 X 0.3 CM
HEALING TIME: 14 WEEKS
COST / DRESSING CHANGE: $5.00

CASE #3



DOG BITE I TRAUMA WOUND I RIGHT SHIN REGION DIMENSIONS: 8.0 X 10.0 X 0.7 CM
HEALING TIME: 28 WEEKS
COST / DRESSING CHANGE: $ 12.00

Content adapted from the original publication to change the product name used in the study, from RTD Dressing to DermaBlue+ Foam.
No data or conclusions have been altered in these materials.

Treatment of a Complex Diabetic Foot Wound with DermaBlue+ Foam™ Wound Dressing*: A unique absorbent antimicrobial polyurethane foam dressing

Dr. Belinda Marcus, MD, FACEP, CWS, Medical Director, North Fulton Hospital, Roswell, GA
and Kathy Kaufman, LPN, CHT, Wound Care Nurse, HyperbaRXs at Northside Forsyth, Cumming, GA

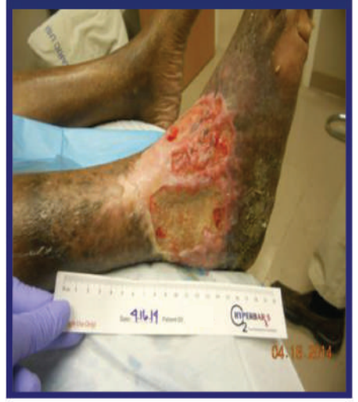
Introduction

This 71 y/o female patient presented to wound clinic with a large 15 month old wound on the lateral aspect of the ankle and dorsum of the foot. Wound cultured positive for *P.aeruginosa*, *MRSA*, and *E. coli* with etiology related to atherosclerosis. Patient has a complicated medical history including Diabetes, Hypertension, Lupus, Crohn's disease, Fibromyalgia, Spinal Stenosis and previous lower extremity Pyoderma Gangrenosum. The patient has a history of systemic immunosuppressant therapy. Previous treatment included multiple oral antibiotics, systemic antibiotics, and debridement.

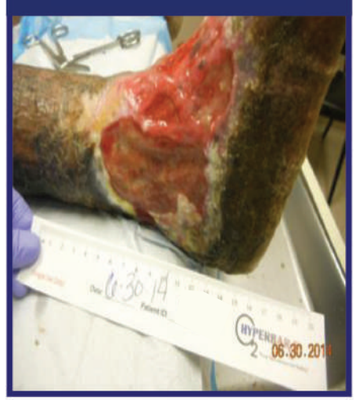
The purpose of this study is to demonstrate the benefits of DermaBlue+ Foam Wound Care Dressing in managing these large lower extremity wounds complicated by a complex medical history, including diabetes and autoimmune disease. This dressing is the only one on the market that contains all three known antimicrobials integrated into the foam matrix: methylene blue (0.25 mg/g) and gentian violet (0.25 mg/g) plus a silver compound (Silver Zirconium Phosphate (7 mg/g).

This dressing provides sustained antimicrobial protection and is effective against a broad spectrum of gram negative and gram positive bacteria, yeast and fungi. It is a more effective antimicrobial than dressings that contain organic pigments (methylene blue and gentian violet) alone (1).

Initial Assessment
(15 mo. wound)



Week 6 (Prior to DB+)



Method

Wound measurements were recorded on each visit. Initially the patient was managed for 6 weeks with oral antibiotics, debridement, compression and advanced wound care dressings including: Silvaklenz™/Silvion™, Enluxtra™, Drawtex® and Cutimed®. DermaBlue+ Foam was started, in addition to oral antibiotics, due to an increase in wound size, exudate and foul odor with prior treatment. Percent wound surface area reduction was calculated and monitored following the commencement of DermaBlue+ Foam wound dressing. The patient received treatment with a cryopreserved amniotic cell injection 5 months into her treatment.

*At the time of this study DermaBlue+ Foam was sold under the name "RTD Wound Dressing".

Content adapted from the original publication to change the product name used in the study, from RTD Dressing to DermaBlue+ Foam.
No data or conclusions have been altered in these materials.

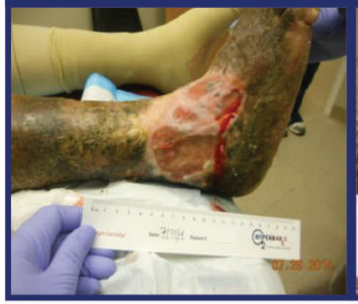
Results

The wound measurement was 8.0 x 9.0 x 0.2 cm (72 cm^2) at the time that DermaBlue+ Foam wound dressing was initiated. Percent wound surface area reduction (WSAR) in 4, 8 and 12 weeks was 26% (53.6 cm2), 53% (34.1 cm2), 84% (11.34 cm^2), respectively. The wound continues to heal gradually. The wound measured 2.2 x 1.1 x 0.1cm at 7 months post DermaBlue+ Foam and was reduced to 2.42 cm^2 (97% WSAR).

Discussion

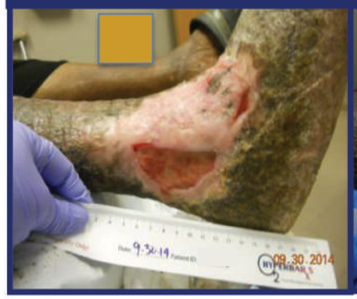
DermaBlue+ Foam helped to control the wound bed contamination and reduce the surface bioburden. The wound began healing despite the fact that it was frequently complicated by infection through out treatment. DermaBlue+ Foam has been shown to be effective in reducing commonly found wound bacteria (2). Since this new dressing possesses absorptive and antimicrobial properties, it creates an optimal environment for wound healing and helps to overcome the challenges of a compromised wound-healing environment such as this. Since the silver compound in this dressing is non cytotoxic, this dressing could be used throughout the continuum of healing.

4 Weeks with DB+ -26% WSAR

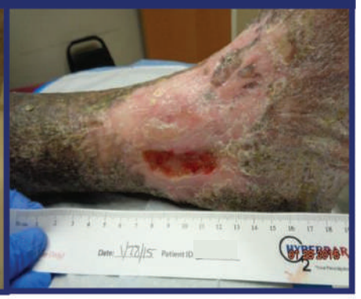


8 Weeks with DB+ -53% WSAR

12 Weeks with DB+ -84% WSAR



7 Months with DB+ -97% WSAR



Conclusion

This 76 year old patient was immunosuppressed and had a very complicated medical history, including Diabetes, Hypertension, Lupus, Crohn's disease, Fibromyalgia, Spinal Stenosis and Pyoderma Gangrenosum. The outcome with DermaBlue+ Foam was very positive with 84% WSAR in after 12 weeks. This dressing appeared to help "kick start" the healing process where other dressings were not as effective. This complex chronic wound continues to improve with the use of DermaBlue+ Foam wound dressing.

References:
1) Data on file.
2) Achterberg J, Abboud L. Case Closed: Opening the door to closing challenging wounds.Ostomy Wound Manage.2014;61(3):12-14.

An Economical Treatment Protocol for Peristomal Skin Excoriation

JAMES MCLEAN, BSN, RN, CWOCN, WOUND AND OSTOMY SPECIALIST | KLARUS HOMECARE, FORT WORTH, TX

Introduction

Approximately 45% of stoma patients experience peristomal skin excoriation.1 Common causes include mechanical trauma, infectious dermatitis, and pyoderma gangrenosum. Pyoderma gangrenosum most often is associated with inflammatory bowel disease; presentation may begin with mild excoriation that rapidly develops into painful, pyogenic ulcers within hours or days. Regardless of the cause, the consequences of peristomal excoriation are troublesome for the patient and costly from a health-economic viewpoint. Early intervention and treatment of excoriated skin results in better outcomes for patients.2

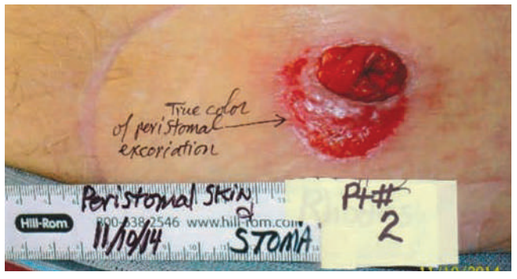
The unique properties of the DermaBlue+™ Foam Wound Dressing provide an excellent care option, effectively and quickly healing peristomal skin excoriation. The DermaBlue+™ Foam Wound Dressing is a highly absorbent, ready-to-use polyurethane foam dressing available in 1/8-inch thickness. It is the only dressing on the market that contains 2 known organic active ingredients integrated into the polymer matrix — methylene blue (0.25mg/g) and gentian violet (0.25 mg/g) — plus a silver compound (silver zirconium phosphate [7 mg/g]). This dressing provides sustained antimicrobial protection and is effective against a broad spectrum of Gram-negative and Grampositive bacteria, yeast, and fungi. The 3 active ingredients, including silver, provide combined antimicrobial properties that have demonstrated effectiveness with common wound pathogens, such as Staphylococcus aureus, methicillin-resistant S. aureus (MRSA), Escherichia coli, Pseudomonas aeruginosa, and Bacillus subtilis.3 In addition, this dressing is hydrophilic and possesses absorptive properties that create an optimal environment for wound healing.

For use with an ostomy, the 1/8-inch thickness DermaBlue+™ Foam Wound Dressing can be easily cut to wound size or into the shape of a ring. If cut to form a ring, the outer diameter of the dressing should be trimmed to fit just inside the adhesive rim of the ostomy pouch. The inner diameter of the dressing should be trimmed to fit the stoma. The dressing can be left in place for up to 3 days.4 The following case study presents a cost-effective and beneficial treatment for peristomal skin excoriation using DermaBlue+™ Foam Wound Dressing.

Case Study

A 70-year-old man presented with a partial colectomy with temporary colostomy that was created on July 15, 2014 due to a perforated colon resulting from a motor vehicle accident. The patient had a pacemaker and experienced generalized weakness. Peristomal excoriation was a frequent problem for this patient; it was exacerbated over the previous 3 months due to the leakage of acidic liquid stool. On initial assessment, the peristomal wound measured 3.8 cm x 2.0 cm and was located 4–9 o'clock of the stoma site. The patient reported pain at the wound site. Prior treatment for the excoriation included daily cleansing of the site and daily pouch changes administered by a wound, ostomy, continence (WOC) nurse, with no improvement.

FIGURE 1



A. Peristomal wound: November 10, 2014, Initial DB+ placement

B. November 17, 2014, The wound completely closed in 1 week

The DermaBlue+™ Foam treatment protocol was initiated November 10, 2014. The treatment was provided by a WOC nurse as follows: DermaBlue+™ Foam Wound Dressing, 1/8-inch thickness, was cut to wound size and placed on the wound. A convex pouch with a wafer was attached using tube paste around the precut opening for the stoma. An ostomy belt was used to maintain a snug fit. At a follow-up visit the following day to evaluate the effectiveness of the treatment protocol, significant improvement, including a reduction in pain, was noted; subsequent follow-up visits occurred on November 14, 2014 and November 17, 2014. The wound was completely resolved on November 17, 2014 (see Figure 1a,b). DermaBlue+™ Foam was discontinued, and the patient continued with pouch changes every 3 days.

Before use of DermaBlue+™ Foam, treatment for this patient cost the home health agency an average of $405 per week (daily skilled nursing visits [SNVs] plus $90 pouch supplies). After treatment with DermaBlue+™ Foam, the cost of treatment for this patient averaged $114 per week (2 SNVs per week plus $24 pouch supplies).

Conclusion

The DermaBlue+™ Foam Wound Dressing provides an effective option for treating peristomal excoriation related to trauma, fungal and bacterial infection, and pyoderma gangrenosum. In this case, the wound resolved in 1 week. The patient reported less pain following the use of DermaBlue+™ Foam (likely due to the dressing's gentian violet). In addition, a cost savings of 72% was achieved for the agency. Ultimately, a quicker healing time for peristomal wounds could help save a home health agency staff time and money on costly ostomy and wound care products. Managing peristomal excoriation quickly and effectively also results in a better quality of life for individuals living with an ostomy.

References
1. Colwell J, Goldberg M, Carmel J. The state of the standard diversion. J Wound Ostomy Continence Nurs. 2001;28(1):6–17.
2. Alvey B, Beck DE. Peristomal dermatology. Clin Colon Rectal Surg. 2008:21(1):41–44.
3. DermaRite Industries, LLC. Data on File 2021.
4. DermaRite Industries, LLC. DermaBlue+™ Foam Wound Dressing Instructions for Use.

Case Studies

Treatment of a Dehisced Surgical Wound with DermaBlue+™ Foam Transfer Wound Dressing

A conformable absorbent antimicrobial polyurethane foam dressing

Steven Antokal RN, BSN, CCCN, CWCN, CWS, DAPWCA
Eula Reynolds RN, MSN, CWS, DAPWCA
Elaine McGowan RN BSN CWCN

INTRODUCTION

The purpose of this study is to demonstrate the benefits of a wound treatment plan consisting of an antimicrobial polyurethane foam dressing, to support physiologic wound healing and reduce risk of infection versus traditional wound care consisting of a dry dressing applied three times per day.

Patient is 30 years old with dehisced surgical wound (C-Section) which occurred on October 1, 2020. The surgical site dehisced approximately twelve hours following a Caesarean section resulting in exposure of adipose tissue.

The patient was discharged home on October 3, 2020 with a treatment consisting of xeroform and a dry cover dressing. Skin Prep was added to the initial treatment plan to protect the periwound skin from damage associated with repetitive removal of tape and maceration due to wound exudate on the surrounding skin.

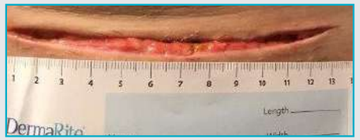
- **The patient's discharge orders** included referral to a wound clinic. The patient was seen at the wound clinic on October 5, 2020; treatment remained xeroform + dry cover dressing.
- **October 10, 2020 –** The wound showed no progress in healing and the wound bed was pale. Consequently, the dressing was changed to a wet-to-moist Dakin's Solution 0.25% to be applied daily for one week. The periwound skin protection continued with Liquid Barrier Skin Prep, and a waterproof composite cover dressing was used to protect the wound from contamination.
  A liquid protein supplement (DermaRite ProHeal® Critical Care) was added to support wound healing. The hydrolyzed collagen and whey protein provided 17 grams of protein per fluid ounce.
- **October 15, 2020 –** The treatment plan was changed to antimicrobial DermaBlue+™ Foam Transfer dressing covered with transparent film, which conformed to the site of the wound, and allowed for the antimicrobial foam dressing to remain in place for the recommended wear time of up to 3 days.

RESULTS

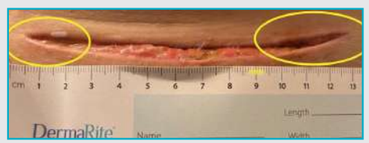
0n November 18, 2020, the wound was closed. DermaBlue+™ Foam Transfer demonstrated absorptive and antimicrobial properties that created an optimal environment for wound healing. In addition, since the silver compound in DermaBlue+™ Foam Dressing is non-cytotoxic, the dressing was able to be used throughout the continuum of healing with no ill effects.

Surgical Dehiscence

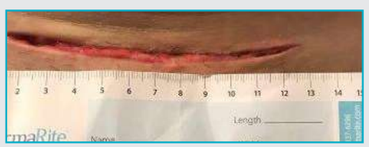
10.1.20



10.12.20



10.14.20



10.15.20

11.18.20

BACKGROUND

DermaBlue+™ Foam Transfer Dressing contains three known antimicrobials integrated into its foam matrix: Methylene Blue (0.25 mg/g), Gentian Violet (0.25 mg/g), and a silver-based compound (Silver Zirconium Phosphate (7 mg/g)). Gentian Violet has a lengthy history as a bacteriostatic and bactericidal medicinal agent, and was first introduced as an antiseptic in 1891[1], while the bacteriostatic action of Gentian Violet against Gram-positive microorganisms was noted in 1912.1 Methylene Blue was the first synthetic compound used as an antiseptic in clinical therapy as well as an antiseptic dye to be used therapeutically.[2]

Antimicrobial agents such as silver have been used for hundreds of years in wound care.3 Silver is a common agent that is used to kill bacteria, as its ions are highly reactive and affect multiple sites within bacterial cells, ultimately causing bacterial cell death. Silver ions aid in cell death by binding to bacterial cell membranes, causing disruption of the bacterial cell wall resulting in cell leakage.[3] The addition of non-cytotoxic silver to the DermaBlue+™ Foam Dressing enhances the antimicrobial effectiveness of the dressing and helps reduce bacterial load to improve wound healing. DermaBlue+™ Foam Dressing provides sustained antimicrobial protection and is effective against a broad spectrum of gram-negative and gram-positive bacteria as well as yeast and fungi. Available data suggests that when antimicrobial agents are combined and react together against bacteria, the effects can be greater than the reaction of one antimicrobial agent alone.[4] The active ingredients in DermaBlue+™ Foam Dressing are integrated into the dressing, preserving the structure of the polyurethane foam, and allowing for optimal absorption of exudate and infectious material. The dressing draws exudate away from the wound bed vertically due to the capillary wicking action of the foam.

DermaBlue+™ Foam Transfer has been shown to be effective in reducing commonly found wound bacteria. The dressing possesses absorptive and antimicrobial properties and was able to be used to gently fill the wound bed and create an optimal environment for wound healing. In addition, since the silver compound in DermaBlue+™ Foam Dressing is non-cytotoxic, the dressing was able to be used throughout the continuum of healing with no ill effects.

REFERENCES

1. Alexander M. Maley, MD and Jack L. Arbiser, MD, PhD Gentian Violet: A 19th Century Drug Re-Emerges in the 21st Century Department of Dermatology, Emory University School of Medicine, 101 Woodruff Circle, Suite 5309, Atlanta. and Atlanta Veterans Administration Hospital, Atlanta, GA
2. Berneth H (2008). Azine dyes. In: Ullmann's Encyclopedia of Industrial Chemistry. Weinheim, Germany: Wiley-VCH Verlag GmbH & Co. K GaA, pp. 475–514.
3. International consensus. Appropriate use of silver dressings in wounds. An expert working group consensus. London: Wounds International, 2012.
4. Runze Li, Jie Chen, Thomas C. Cesario, Xin Wang, Joshua S. Yuan, Peter M. Rentzepis Synergistic reaction of silver nitrate, silver nanoparticles, and methylene blue against bacteria https://doi.org/10.1073/PNAS.1611193113

Content adapted from the original publication to change the product name used in the study, from RTD Dressing to DermaBlue+ Foam.
No data or conclusions have been altered in these materials.

Uses of a Novel New Absorbent Antimicrobial Polyurethane Foam Wound Dressing

DR. BELINDA MARCUS, MD, FACEP, CWS, MEDICAL DIRECTOR AND KATHY KAUFMAN, LPN, CHT, WOUND CARE NURSE, HYPERBARXS AT NORTHSIDE FORSYTH, ATLANTA, GA

Introduction

Objectives:
1. Describe a new unique highly absorbent antimicrobial wound dressing
2. Identify the indications for use, versatility, and application of this new dressing
3. Describe the outcomes of 5 clinical case studies

Chronic non-healing wounds represent a problem for clinicians. The more difficult it is for chronic wounds to heal, the greater the potential burden to patients, their families, and the healthcare system. Treating wounds is most challenging when they become chronic. The prevalence of chronic wounds increases with age and compounding medical conditions. An estimated 6 million patients in the U.S. have chronic wounds, representing an estimated annual $20 billion burden on the healthcare system[1]. It is therefore important to effectively address wound concerns early and help prevent non-healing chronic wounds.

The purpose of this case series is to demonstrate the effectiveness of a novel new highly absorbent polyurethane foam dressing for both chronic wounds and its efficacy as a first line therapy. Clinical case studies will be presented that demonstrate the versatility and functionality of DermaBlue+™ Foam Wound Dressing. This dressing is the only one on the market that contains known organic active ingredients integrated into the foam matrix; methylene blue (0.25 mg/g) and gentian violet (0.25 mg/g) plus a silver compound (Silver Zirconium Phosphate (7 mg/g)). This dressing provides sustained antimicrobial protection and is effective against a broad spectrum of gram negative and gram positive bacteria, yeast and fungi. It is a more effective antimicrobial than dressings that contain organic pigments (methylene blue and gentian violet) alone[2].

Method

Five clinical cases are described in terms of the presenting problem, duration, etiology and prior modalities used. All wounds were treated with DermaBlue+™ Foam Wound Dressing. All wounds were followed through to full closure (Table 1) .

Results

Duration of the wounds presented ranged from 14 days to 8 months. Wound types included, three surgical, one trauma and one drug eruption case. Time to heal ranged from 11 days to 7 weeks. All came to full closure. Many wounds had failed to heal with other wound dressings and modalities used previously (Table 1).

Table 1: Patient Demographics, Wound Etiology and Wound Healing Times

Case	Wound Type	Etiology	Age	Duration	Products Used Prior to DB+ Foam	Healing Time
1	Surgical	Non-healing following duplex scan	81	2 months	Therahoney/Cutimed, Versatel, Cutimed Gel	36 days (5 weeks)
2	Surgical	Non-healing post laminectomy infection and retained sutures	80	8 months	Multidex, Silvion, Alginate, Stimulen, Polymem	11 days
3	Surgical	Non-healing post-op, Removal of basal cell carcinoma	90	3 months	Multidex, Therahoney, Stimulen powder, Polymem, Arglase/Polysporin powder	51 days (7 weeks)
4	Leg Ulcer	Trauma	76	14 days	Multidex, Compression, Prisma, Silvion	40 days (6 weeks)
5	Leg Ulcer	Drug eruption reaction	88	4 months	Silvion and Silvaklenz	61 days (8 weeks)

Content adapted from the original publication to change the product name used in the study, from RTD Dressing to DermaBlue+ Foam.
No data or conclusions have been altered in these materials.

09/2016

Uses of a Novel New Absorbent Antimicrobial Polyurethane Foam Wound Dressing

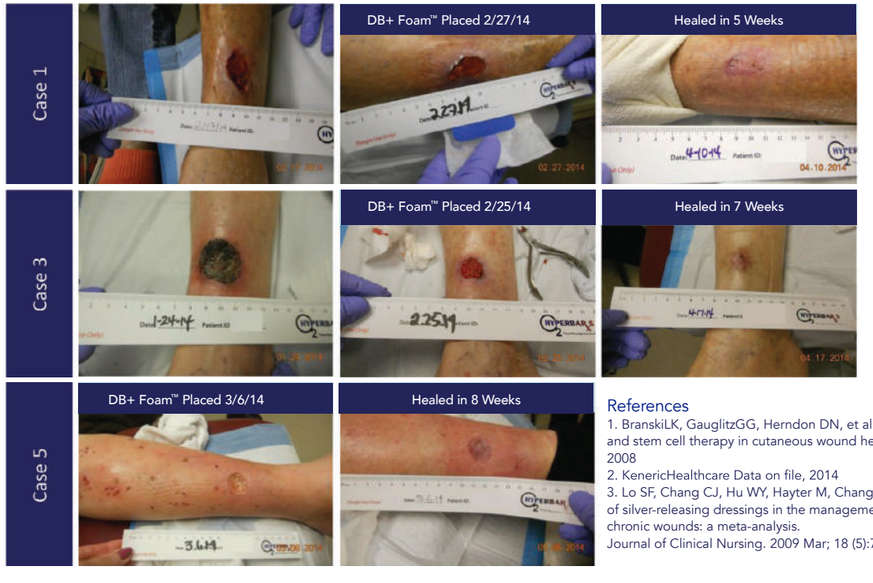
DR. BELINDA MARCUS, MD, FACEP, CWS, MEDICAL DIRECTOR AND KATHY KAUFMAN, LPN, CHT, WOUND CARE NURSE, HYPERBARXS AT NORTHSIDE FORSYTH, ATLANTA, GA

Discussion

The DermaBlue+™ Foam Wound Care Dressing was found to be effective at closing a number of wounds that were non-healing; despite multiple other wound care interventions. By using this dressing as the first choice for treatment, this dressing could help to prevent wounds from becoming chronic and requiring advanced interventions such as systemic antibiotics, surgical debridement, enzymatic debridement, and negative pressure wound therapy. The addition of silver to this dressing enhances the antimicrobial properties that also have demonstrated benefits to improving wound healing[3]. Since this new dressing possesses both absorptive and antimicrobial properties, it creates an optimal environment for wound healing and helps to overcome the challenges of a compromised wound-healing environment.

Conclusion

This novel new antimicrobial dressing is effective at drawing protein rich wound exudate away from the wound, creating a healing environment and bringing difficult to heal wounds to closure. This versatile dressing was used throughout the continuum of healing and was easily integrated into facility wound treatment protocol. Initial experience has been primarily with non-healing wounds. It is recommended to use this dressing as a first line therapy, to minimize the risk of wounds becoming chronic and helping to reduce time to heal, thereby reducing the burden of non-healing wounds on the patient, their families and the healthcare system.



References
1. BranskiLK, GauglitzGG, Herndon DN, et al. A review of gene and stem cell therapy in cutaneous wound healing. Burns. Jul 4 2008
2. KenericHealthcare Data on file, 2014
3. Lo SF, Chang CJ, Hu WY, Hayter M, Chang YT. The effectiveness of silver-releasing dressings in the management of non-healing chronic wounds: a meta-analysis.
Journal of Clinical Nursing. 2009 Mar; 18 (5):716-28.

DermaRite®

Case Studies of Hard-to-Heal Wounds Treated Successfully with an Antimicrobial Foam Dressing

dermarite.com/case-studies-of-hard-to-heal-wounds-treated-successfully-with-an-antimicrobial-foam-dressing/

DermaRite April 27, 2021

An estimated 6.7 million Americans are living with chronic wounds.[1,2] A chronic wound is one that fails to progress through a normal, orderly, and timely sequence of repair, or in which the repair process fails to restore anatomic and functional integrity after three months[3] Some chronic wounds can take decades to heal and can ultimately lead to isolation and family distress.[3]

A summary of recent case studies illustrates the successful use of an antimicrobial foam wound dressing* as part of the overall treatment approach to healing complex recalcitrant wounds.

Study	Care Setting	Patient age	Wound type	Duration of wound prior to treatment with DermaBlue+™ Foam	Time to Healing with DermaBlue+™ Foam
Marcus 2015	Outpatient clinic	71	Diabetic foot wound	450 days	84 days
Marcus 2014	Outpatient clinic	90	Surgical wound, non-healing post-op, Removal of basal cell carcinoma	240 days	51 Days
		88	Leg Ulcer, drug eruption reaction	120 days	56 days
		80	Surgical wound, non-healing post laminectomy infection and retained sutures	90 days	11 Days
		81	Surgical wound, non- healing	60 days	36 Days
Warren 2013	Nursing Home	64	Pyoderma Gangrenosum Posterior leg	365 days	48 days
		61	Pyoderma Gangrenosum 6 wounds on lower legs	240 days	161 days
		83	Stage 3 Pressure Injury-heel	150 days	82 days

*The product used in the case studies was RTDTM Wound Dressing, Keneric Healthcare, Irvine, Texas. The RTDTM dressing was acquired in 2018 by DermaRite Industries, LLC and re-branded as DermaBlue+TM Foam. No data or conclusions have been altered in the case study materials.

Wound Types: The patients featured in the case studies suffered from a variety of longstanding wounds, including diabetic wounds, dehisced surgical incisions, vascular leg ulcers, pressure injuries and wounds due to Pyoderma Gangrenosum.

Care Settings: All patients were being cared for in a nursing home or at home. Each patient's wound care treatment plan was developed and directed by a wound care physician or a certified wound care nurse.

Prior Course of Treatment: Patients had been treated for 60 days to 450 days prior to the addition of **DermaBlue+TM Foam** to the comprehensive treatment plan. A variety of dressings in the following categories had been used to manage moisture and bioburden and support autolytic debridement:

moist gauze	collagen	silver hydrofiber
silver hydrogel	calcium alginate	specialty absorptive
honey	foam (with surfactant)	specialty wound filler
silver contact layer	silicone foam	compression for VLUs

Some of the patients also underwent surgical debridement or sharp debridement, and some received synthetic skin substitutes, IV antibiotics, hyperbaric oxygen treatment and/or NPWT as part of their wound care.

Outcomes Achieved following the addition of DermaBlue+TM Foam to the treatment plan:

As part of a comprehensive plan of care, DermaBlue+ TM Foam worked where other dressings failed. 87% of patients achieved wound healing in less than 90 days following the introduction of DermaBlue+TM Foam to their dressing regimen.

DermaBlue+™ Foam and DermaBlue+™ Foam Transfer are flexible, ready-to-use absorbent antimicrobial foam dressings infused with **Methylene Blue**, **Gentian Violet**, and **silver zirconium phosphate**.

DermaBlue+™ Foam combines triple-action antimicrobial protection with a unique micro-pore foam that wicks exudate away from the wound and kills over 99% of bacteria within, helping to disrupt the formation of biofilm and aiding in the healing of even the most challenging chronic wounds**.**

How DermaBlue+™ Foam works: ACS and triple antimicrobial actions

The DermaBlue+™ Foam Dressing Advantage

- Three effective ingredients, Methylene Blue, Gentian Violet, and non-cytotoxic silver provide broad-spectrum antimicrobial activity.
- Patented process embeds the antimicrobials into the foam itself – ingredients will not wash away, no unwanted skin discoloration, and no interference in the foam's absorbency.

- Proprietary micro-pore foam wicks exudate vertically into the dressing and away from the wound bed.
- Highly absorbent, flexible, light weight, comfortable and resilient.
- Ready to use and easy to apply – either side can be applied to the wound and no need to hydrate before use.
- Can be cut to fit, layered, and used for wounds with tunneling or undermining.
- Promotes optimal wound bed temperature.
- Gentle and effective for use during all phases of wound healing.

References:

1. L.E.K. Consulting 2014 Market Analysis "Market Sizing and Assessment of Outsourced Outpatient Wound Care"
2. US Census data
3. Bowers S., Franco E. *Chronic Wounds: Evaluation and Management.* American Family Physician. 2020;101(3):159-166**.**
4. Marcus B., Kaufman K., (2015, November) *Treatment of a Complex Diabetic Foot Wound with RTD™ Wound Dressing: A unique absorbent antimicrobial polyurethane foam dressing* [Poster presentation] Desert Foot Conference Phoenix, AZ
5. Marcus B., Kaufman K., (2014, September, October) *Uses of a Novel New Absorbent Antimicrobial Polyurethane Foam Wound Dressing* [Poster presentation] Clinical Symposium on Advances in Skin & Wound Care – Sept 2014 and Symposium on Advanced Wound Care (SAWC) Fall – Oct 2014
6. Warren S., Smith D., (2013) *Use of RTD Wound Dressing in 168 LTC Patients* [Poster presentation] Utah

Synopsis of Case Studies

DermaBlue+™ Foam Case Studies: Home Health

Study Name /Date	Authors	Presented at Conference	Study Site	Care Setting	Patient Age	Wound Type	Age of wound before use of DermaBlue+Foam	DBF Dressing Change Frequency	Time to Healing	Case Notes
Treatment of a Dehisced Surgical Wound with DermaBlue+Foam Transfer Wound Dressing	**ANTOKAL**	No	Private Residence	**Home Care and Outpatient Wound Clinic**	30	Dehisced surgical wound lower abdomen	15 days	every 3 days	**34 days**	Previously tried xeroform + dry sterile dressing, Dakin's wet to moist
Management Of Lower Extremity Wounds In Clients With High Risk For Wound Infection	**KHAN**	No	ProHealthcare.us	**Home Health**	88	Female with trauma wound in left shin	not specified	3 times per week	**6.5 Weeks**	Although the reimbursement/payor source is not identified, it is important to note that a dressing change frequency of 3x per week is very typical. Also important to note that Medicare Part B reimburses for a foam dressing at a 3x/week rate
					78	Male, Neuropathic Ulcer, Ankle	not specified	3 times per week	**15.5 Weeks**	
					74	Male, Surgical Wound (amputation), right big toe	not specified	3 times per week	**10.2 Weeks**	
					72	Female, Arterial Wound, multiple ulcers, right foot	not specified	3 times per week	**14 Weeks**	
Efficacy of Polyurethane Foam with Methylene Blue, Gentian Violet, and Silver Sodium	**KHAN**	**SAWC Spring 2016**	Pro Healthcare Clinic, Carrollton, Texas	**Outpatient Clinic and Home Health**	Not Available	Stage 4 pressure injury, Achilles tendon	not specified	2 times per week	**32 Weeks**	Patients were seen 1x/week in outpatient clinic and had dressing changes 2x/week by home health
					Not Available	Diabetic/neuropathic ulcer, Grade 2	not specified	2 times per week	**14 weeks**	used in conjunction with carbon dressing (14 days) and collagen dressing (14 days)
An Economical Treatment Protocol for Peristomal Skin Excoriation	**MCLEAN**	No	KLARUS HOMECARE, FORT WORTH, TX	**Home Health**	70	Male, partial colectomy, peristomal wound	post-op wound	3 dressing applications in 1 week	**1 Week**	**weekly cost of care prior to DB+ was $405, after DB weekly cost reduced to $114 - 72% savings**
An Effective and Economical Approach to Resolving Severe Hypergranulation Using DermaBlue+™Foam Wound Dressing: Antimicrobial Polyurethane Foam with Integrated Methylene Blue, Gentian Violet and Silver	**VARGAS**	No	APRIL SKYYHOME HEALTH CARE, CORPUS CHRISTI, TEXAS	**Home Health**	45	Male, immunosuppressed, large dehisced wounds on leg with severe hypergranulation	180 days	2 times per week	**84 days**	Used in conjunction with silver nitrate. Had previously had a failed skin graft and SilvaSorb had been used in the prior nursing home with no success. Not fully healed by the end of study: "Both areas showed the wound edges were well approximated with early epithelial growth noted on 10/22/14. The full thickness wound had a moderate amount of serosanguinous drainage and no foul odor. The wound bed was red with no nonviable tissue noted. The tissue appeared well oxygenated and responded well to DB+. No further nitration was needed." **Reported 57% reduction in nurse visit costs, 74% reduction in wound dressing costs.**

Synopsis of Case Studies

DermaBlue+™ Foam Case Studies: Outpatient Wound Clinic

Study Name /Date	Authors	Presented at Conference	Study Site	Care Setting	Patient Age	Wound Type	Age of wound before use of DermaBlue+Foam	DBF Dressing Change Frequency	Time to Healing	Case Notes
Uses of a Novel New Absorbent Antimicrobial Polyurethane Foam Wound Dressing *NOTE: 5 patients in study all listed individually at right*	**MARCUS**	**2014 Clinical Symposium on Skin & Wound Care** **2014 Symposium on Advances in Skin & Wound Care**	HYPERBARXS AT NORTHSIDE FORSYTH, ATLANTA, GA	**Outpatient clinic**	81	Surgical wound, non-healing following duplex scan	60 days	Not specified	**36 Days**	Previously tried Therahoney/Cutimed, Versatel, Cutimed Gel
					90	Surgical wound, Non-healing post-op, Removal of basal cell carcinoma	240 days	not specified	**51 Days**	Previously tried Multidex, Therahoney, Stimulen powder, Polymem, Arglase/Polysporin powder
					80	Surgical wound, Non-healing post laminectomy infection and retained sutures	90 days	not specified	**11 Days**	Previously tried Multidex, Silvion, Alginate, Stimulen, Polymem
					76	Leg ulcer, Trauma	14 days	not specified	**6 Weeks**	Previously tried Multidex, Compression, Prisma, Silvion
					88	Leg Ulcer, Drug eruption reaction	120 days	not specified	**8 Weeks**	Previously tried Silvion and Silvaklenz
Treatment of a Complex Diabetic Foot Wound with DermaBlue+Foam Wound Dressing: A unique absorbent antimicrobial polyurethane foam dressing	**MARCUS**	**2015 Desert Foot Conference**	HYPERBARXS AT NORTHSIDE FORSYTH, CUMMING, GA	**Outpatient clinic**	71	Large diabetic foot wound	450 days	not specified	**97% reduction in wound surface area in 210 days**	Initially the patient was managed for 6 weeks with oral antibiotics, debridement, compression and advanced wound care dressings including: SilvaklenzTM/SilvionTM, EnluxtraTM, Drawtex® and Cutimed®. DB+ was started, in addition to oral antibiotics, due to an increase in wound size, exudate and foul odor with prior treatment. **84% WSAR after 12 weeks and continued to heal.**
Incorporating a New Highly Absorbent Antimicrobial Polyurethane Foam* in a Multimodal High Risk Diabetic Wound Care Algorithm	**OLDEN/ BROOKS**	**2014 Desert Foot Conference**	PEDORTHIC CLINICS KERRVILLE DIVISION-SOUTH TEXAS VETERANS HEALTH CARE SYSTEMS	**Outpatient clinic**	60	Diabetic male with 5th Ray Amputation	post-op wound	1 x per week	**12 Weeks**	Used in conjunction with Oasis, sterile, tri-layer ECM and Grafix live placental tissue. Poster notes 12 applications of blue foam and the biologics

DermaBlue+™ Foam Case Studies: Long Term Care

Study Name /Date	Authors	Presented at Conference	Study Site	Care Setting	Patient Age	Wound Type	Age of wound before use of DermaBlue+Foam	DBF Dressing Change Frequency	Time to Healing	Case Notes
Use of DermaBlue Foam Wound Dressing in 168 LTC Patients	**WARREN**	No	11 nursing homes in Utah	**Long-Term Care**	Not Available	Stasis Ulcer Healing Averages	Not Available	not specified	**Average of 27 days**	For patients with stasis ulcers: Average Percent of Wound Healed - 76.10%
					Not Available	Diabetic Ulcer Healing Averages	Not Available	not specified	**Average of 22 days**	For patients with diabetic ulcers: Average Percent of Wound Healed - 67.91%
					61	Pyoderma Gangrenosum; 6 wounds on lower legs	240 days	not specified	**162 days**	Treated at Univ. of Utah Medical Center for 8 months; unable to suppress wound infection during that time
					83	Stage 3 Pressure Injury on heel	150 days	not specified	**82 days**	Previously treated with Aquacel Ag x 5 months
					64	Pyoderma Gangrenosum Posterior leg	365 days	not specified	**48 days**	Previously tried NPWT and HBOT x 1 year

DermaBlue™+ Foam

DermaBlue™+ Foam Transfer

To learn more about DermaBlue™+ Foam, or to order a sample:

Contact your DermaRite Sales Rep

Email info@dermarite.com

Call 800-337-6296

Explore DermaRite's complete catalog of skin care, wound care, and nutritional products online at

dermarite.com

DermaRite®