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CLINICAL EVIDENCE | Endoform® and Hydrofera Blue®

Endoform® can be used with Hydrofera Blue®

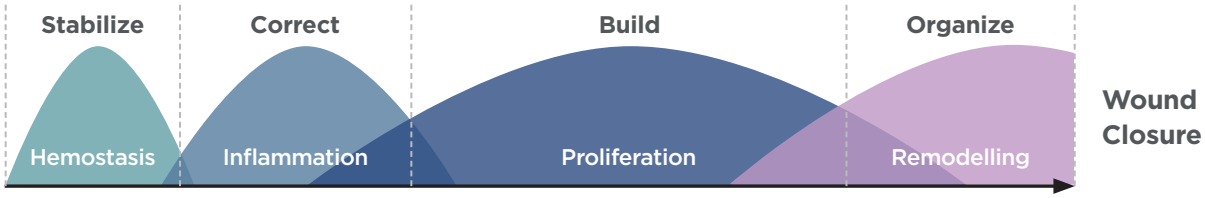
- A variety of wound etiologies can be managed using the complementary products **Endoform®** and **Hydrofera Blue**[1-7].
- **Endoform®** works from within the wound bed, while **Hydrofera Blue®** antibacterial foam dressings promotes a clean, padded environment to protect the tissue during the wound healing process.[4,5]
- The **Endoform®** and **Hydrofera Blue®** combination is an effective way to manage injuries where a cast or padding is required such as foot wounds and pressure ulcer .[1,3]
- Large wounds, such as those with exposed tendon or second degree burns, require substantial rebuilding of tissue; this can lead to extended exposure of the affected area. **Endoform®** can be used within the wound bed to scaffold tissue growth, while **Hydrofera Blue®** protects the healing tissue from infection.[6,7]

Preparing a wound with **Endoform®** and **Hydrofera Blue**[1]

Application of **Endoform®** and **Hydrofera Blue** to a non-healing lower extremity wound[2]

Managing a stage three pressure injury with **Endoform®** and **Hydrofera Blue**[3]

Endoform® can be used at all phases of wound management



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CLINICAL EVIDENCE | Endoform® and Hydrofera Blue

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Natural Dermal Template

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Antimicrobial Dermal Template

References

1. Petrocelli, M. Ostler, M. Liden, B. (2016). Edema reduction with a Novel Total Contact Cast System containing a Miled Compression Sock. Symposium on Advanced Wound Care Fall Las Vegas, NA. **2.** Desvigne, M. N. (2016). Preparing a wound bed before application of cellular tissue based products using an Ovine collagen (CECM) dressing with an intact extracellular matrix. Symposium on Advanced Wound Care Fall, Las Vegas, NA. **3**. Bohn, G. and S. Champion (2016). Improved Healing of Stage 3 Pressure Ulcers Using Extracellular Matrix Collagen Dressing. Sympiosium on Advanced Wound Care. Las Vegas, NA. **4.** Bravo, J. (2014). Case Study 17: Pyroderma gangrenosum, Hollister Incorporated. **5.** Reyna, S. (2018). Case Study 25: Venomous Spider Bite - Left Forearm, Hollister Incorporated. **6.** Zilberman, I. and N. Zolfaghari (2016). Innovative solutions in the management of wounds with exposed tendons utilizing ovine collagen extracellular matrix and gentian violet and methylene blue antibacterial foams. Symposium on Advaanced Wound Care - Atlanta, GA. **7.** Lullove, E. (2016). Use of Ovine Collagen Extracellular Matrix and Gentian Violet and Methylene Blue Antibacterial Foam Dressings to Help Improve Clinical Outcomes in Lower Extremity Wounds. Symposium on Advanced Wound Care - Fall, Las Vega, NA.

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MKT 1484.00 | June 2018

Edema Reduction with a Novel Total Contact Cast System Containing a Mild Compression Sock.

• Michael Petrocelli, DPM • Marta Ostler PT • Brock Liden DPM

Treat the V.I.P.'s in plantar foot ulcers and improve DFU wound outcomes.

V **Vascular Management**
with low-level compression sock

I **Infection Management and Prevention**
with the included gentian violet and methylene blue antibacterial foam* and an ovine collagen dressing with an intact ECM**

P **Pressure Relief**
with TTC system comprised of a clamshell cast with off-loading footplate***

Introduction:

In a November 2014 Off-Loading Consensus Guidelines, it is suggested that vascular management (V) infection management and prevention (I) and pressure relief (P) are essential to diabetic foot ulcer (DFU) healing.[1] Evidence suggests that if V.I.P.'s are aggressively managed, then the wound-healing trajectory will progress.[1] Lower extremity (LE) edema is a common clinical finding in patients with diabetes; however, there is a lack of awareness of how to treat edema without negatively impacting vascularity in the DFU patient.[2] Elevation of the extremity has generally been recommended to reduce edema and prevent other sequential problems such as venous congestion, reduced oxygenation, possible limb pain, slow healing or non-healing wounds and possibly amputation. However, this is not an effective answer to treating edema in a functional patient. LE edema is most often treated with a method of graduated compression therapy to reduce swelling such as a wrap system or compression sock. These methods can enhance fibrinolysis and venous outflow.
An international consensus group has recommended a system for compression bandage systems and recommend categorizing mild compression as <20mmHg.[3] A pilot study concluded mild compression therapy (18-25mmHg) decreased swelling in DFU patients with lower leg edema without comprising vascularity.[2] A decrease in calf circumference, foot circumference, and cutaneous water content without compromise in arterial flow, has been demonstrated in diabetics after wearing mild compression socks.[2]

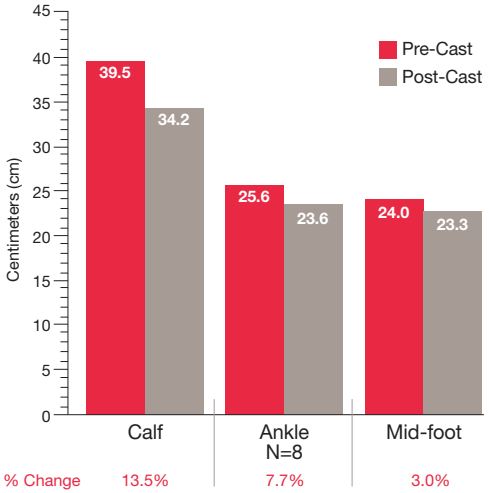
Objective:

The objective of this observational case series was to quantify reduction in calf, ankle and mid foot circumferences with the use of a total contact cast (TCC) system comprised clamshell cast with an off-loading footplate which includes a mild compression sock worn to the knee for DFU patients. All 8 patients were receiving TCC system comprised of a clamshell cast with an off-loading footplate for diabetic ulcer management.

Methods:

This case series of 8 diabetic patients that required off-loading for a plantar ulcer with a TCC system comprised of a clamshell cast with an off-loading footplate. The casts were applied according to manufacturer's instruction for use. Calf, ankle and mid-foot measurements were routinely recorded prior to initial application and weekly prior to each cast application.

Average Limb Circumference Reduction



Conclusions:

Mild compression decreased swelling in diabetic patients with LE edema without complications. As suggested by the V.I.P. concept, use of this TCC system comprised of a clamshell cast with an off-loading footplate reduced the circumference of the calf, ankle, and mid-foot during the management of these DFU patients.

Summary:

In today's high pressure environment to obtain quality wound management for diabetic foot ulcers, wound care professionals must take advantage of all beneficial treatments. Adding a mild compression sock to a TCC improves edema reduction. This is another opportunity for clinicians to begin to improve wound healing outcomes .

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3. Fletcher, J. et al., Principles of compression in venous disease: A practitioner's guide to treatment and prevention of venous leg ulcers. Wounds International, 2013. Available from: www.woundsinternational.com

Financial Disclosure: Authors received an honorarium from Hollister Incorporated.

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Petrocelli, M. Ostler, M. Liden, B. (2016). Edema reduction with a Novel Total Contact Cast System containing a Miled Compression Sock. Symposium on Advanced Wound Care Fall Las Vegas, NA.

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Preparing a wound bed before application of cellular tissue based products using an Ovine collagen (CECM) dressing with an intact extracellular matrix.

• **Michael Desvigne, MD, CWS, FACS, FAACWS**
Plastic & Reconstructive Surgery, Wound Care & Hyperbaric Medicine

Introduction:

With increasing amounts of offerings in dressings for wound closure, the clinician must be careful to choose the best dressing for their patients. There are many clinical reasons for utilizing advanced cellular tissue based products (CTP), but one must weigh the outcomes versus costs. The cost for a standard 2x2 of any of the CTPs can range from the hundreds to thousands of dollars per piece. Healthcare institutions are becoming more cost conscious. Failure of these products can be both costly to the patient and the healthcare system. CECM* provides a broad spectrum MMP reduction[1] before and after CTP utilization. To set up for successful take of a CTP product, one can consider utilizing a CECM both before and after CTP application ("bookend") to help reduce matrix metalloproteinases (MMPs) activity. In addition, CECM provides an intact, native extracellular matrix that helps promotes tissue granulation[2] and epithelialization for final wound closure.[3]

Methods:

In this case, CECM was used before, during and after CTP utilization. Both the CECM and CTP were applied per product recommendations. Wounds were assessed weekly.

Conclusion:

CECM provides assistance with MMP reduction, while the CTP provides scaffolding for cellular growth.[4] Because the exact mechanisms are not known, further research is needed. Early experience of the before and after utilization of CECM with CTP resulted in healing progression and showed positive results in wound closure in this case.

Case Study

Patient: 42 year-old female.

Past medical history:

- Osteosarcoma of the left lower extremity

Previous wound management:

- Tumor resection and free tissue transfer completed after post-operative radiation. Two non-healing wounds, one in the proximal portion of the flap and the other distally at the level of the Achilles tendon. After 14 months, with failed attempts at surgical closure and moist wound therapy. There was no progression toward healing. There was no evidence of recurrent tumor and cultures were negative. The patient then underwent excisional debridement followed by a single application of CTP. The area was covered with gentian violet and methylene blue (GV/MB) polyurethane (PU) antibacterial foam** dressing. The following week, CECM was added to the treatment and reapplied weekly. In 2 weeks, the distal wound had 100% epithelialization and the proximal wound decreased in size by 20% from initial wound size. At 4 weeks, the larger more proximal wound in the area of radiated tissue injury decreased in size by 50% from initial wound size. At 8 weeks, the proximal wound size decreased by 75% from initial wound size. There was notable granulation tissue and new epithelium around and underlying the CTP. The graft remained adherent.
- Despite improvement at 12 weeks, the proximal wound was not completely healed and the distal wound had a recurrent ulceration. The recurring stalled phase of the wounds became apparent although there was no evidence of infection or recurring trauma. At this time, it was elected to proceed with additional placement of CTP with plans to "bookend" the treatment immediately with additional CECM to assist with MMP reduction.

Initial wound
Pre-debridement

Initial wound
Post-debridement

Week 0
Wound management:
Patient initially seen and treated with debridement and placement CTP. Wound improved but stalled after 8 weeks. Bookending management was initiated with placement of CECM (Figure 1) covered MB/GV antibacterial foam dressing (Figure 2). CECM added and reapplied weekly.

Week 12
Wound management:
Despite improvement proximal wound not completely healed and distal wound with recurrent ulceration. CTP placed. CECM applied over CTP to "bookend" treatment to assist with MMP reduction.

Week 14
Wound management:
Wounds showed significant improvement with increased granulation tissue and epithelialization.

Week 15
Wound management:
(Figure 3) a reduction of 25% and 44 % in the proximal and distal wounds respectively from wound size in figure 1. (Figure 4) Application of CECM. (Figure 5) CECM covered with a non-adherent dressing and GV/MB PU antibacterial foam.

Week 16
Wound management:
A reduction of 55% and 75% reduction respectively from wound size in figure 1. Each week additional CECM was placed followed by GV/MB PU antibacterial foam. Wound treatment is ongoing.

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* Endoform dermal template, Distributed by Hollister Incorporated.
** Hydrofera Blue Ready foam, Distributed by Hollister Incorporated.

Financial disclosure: M. Desvinge received an honorarium from Hollister Incorporated.

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Desvigne, M. N. (2016). Preparing a wound bed before application of cellular tissue based products using an Ovine collagen (CECM) dressing with an intact extracellular matrix. Symposium on Advanced Wound Care Fall, Las Vegas, NA.

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Improved Healing of Stage 3 Pressure Ulcers Using Extracellular Matrix Collagen Dressings.

• Gregory Bohn, MD, FACS, ABPM/UHM, CWSP, FACHM • Sue Champion RN, CWOCN
West Shore Center for Wound Care and Hyperbaric Medicine, Manistee, MI

Purpose:

A retrospective case review was conducted to evaluate the benefit of a combination wound dressing protocol for treating Stage 3 pressure ulcers that could be left on the wound for a week.

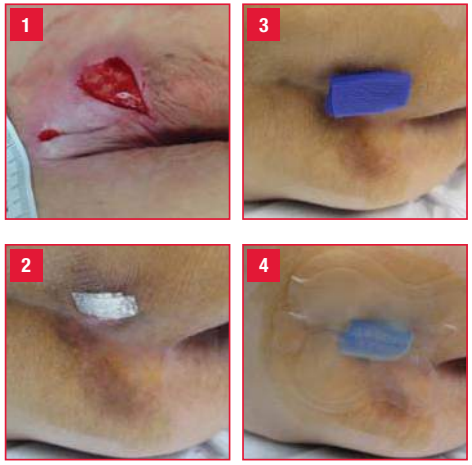
Introduction:

Stage 3 pressure ulcers are a major challenge for the clinician to heal. Using a combination dressing protocol may improve healing. Multiple randomized controlled trials have demonstrated the superiority of hydrocolloid dressings over plain gauze in the treatment of pressure ulcers.[1] One RCT including 65 residents with Stage 3 pressure ulcers in long term care facilities demonstrated similar healing rates of hydrocolloid dressings vs standard collagen dressings.[3] The benefits of collagen to modulate excess matrix metalloproteinase (MMP) activity in a wound have been documented. A low MMP level is conducive to healing rather than a high level which can delay or retard healing.[2] When treated in the outpatient setting, using a dressing that would be effective for the weekly episode of care would be ideal. A combination dressing protocol was developed and evaluated for the treatment of Stage 3 pressure ulcers.

Methodology:

A retrospective case review of 17 patients with Stage 3 pressure ulcers from long term care facilities patients were followed on a weekly basis at the wound care center. Initial excisional debridement was performed in all cases followed by subsequent debridement as needed during the treatment phase. Pressure reduction with mattress overlays and or seat cushions were ordered as needed. As part of the overall wound care plan, the combination dressing protocol developed consisted of a ovine collagen extracellular matrix dressing* (CECM) used as the primary dressing (Photo 2), a hydrogel (if needed for moisture balance), and methylene blue/gentian violet (MB/GV) polyurethane (PU) antibacterial foam** (Photo 3) for management of biodurden, which was held in place with a generic hydrocolloid cover dressing (Photo 4). Dressing changes were performed weekly. Peri-wound skin was prepped with tincture of benzoin swabs to improve adherence of the hydrocolloid cover dressing. If the dressing dislodged before the next weekly clinic visit, care givers were instructed to reapply the collagen and foam portion of the dressing with a hydrocolloid cover. Wound assessment, simple wound measurements, and wound photographs were obtained at each weekly patient visit.

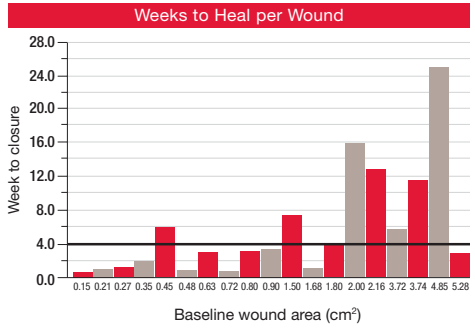
Combination Dressing Protocol



Results:

N patients	17
N wounds	21
Gender	7 males, 10 females
Age (mean, range)	75 years (41 – 93)
BMI (mean, range)	29.1 (13.6 – 64.2)
Braden Scale (mean, range)	15.2 (11 – 17)
Baseline Wound Area (mean, range)	1.62 cm^2 (0.15 – 5.28)

Seventeen patients presented with 21 Stage 3 sacrococcygeal area pressure ulcers. Nineteen wounds were followed to closure. Twelve of nineteen (12/19), 63.2% of the wounds healed in 4 weeks or less. All 19 wounds healed in a mean of 5.6 weeks (range .9-25.1 weeks). Median time to healing was 2.9 weeks. Two patients did not complete the study: One patient moved out of the area, but the wound volume reduced 71% in 6.6 weeks and the other patient deceased with the wound volume reduced 67% at 1 week.



Discussion:

In a comparative randomized controlled trial of 65 residents of skilled nursing home facilities with pressure ulcers, 13 patients had Stage 3 pressure ulcers.[3] Either a collagen dressing or a hydrocolloid dressing were used to treat the wounds. When a collagen or hydrocolloid dressing were used alone, healing at 4 weeks did not occur.

In this retrospective case review, it appeared that using this combination dressing protocol with the CECM collagen dressing used in conjunction with MB/GV PU antibacterial foam and a hydrocolloid, complete healing was observed in 12 of 19 (63.2%) of stage 3 pressure ulcers at 4 weeks.

Conclusion:

Given that wound closure occurred in the majority of these Stage 3 pressure ulcers within 4 weeks, in this retrospective case review it appears to suggest that this dressing protocol did show effective wound closure on a timely basis.

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* Endoform dermal template, Distributed by Hollister Incorporated.
** Hydrofera Blue Ready foam, Distributed by Hollister Incorporated.

Financial Disclosure: The author received an honorarium from Hollister Incorporated.

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CASE STUDY 17 | Pyoderma Gangrenosum

Patient: 54 year-old female with 18 month-old non-healing wound on the lower leg

Past medical history:

- Ulcerative colitis, lower leg edema 1+ varicosities

On admission to wound clinic, treatments were:

- Biopsy: Negative for cancer or vasculitis
- Arterial ultrasound and ankle brachial index were normal
- Oral steroids and antibiotics given for two months
- Hydrofera Blue classic foam in conjunction with a topical steroid around peri-wound skin was applied and secured with a double layer of a tubular compression bandage for 3 months. Patient changed dressings weekly and was seen in the clinic monthly.
- After 3 months of above treatment, due to slow progression of wound, Endoform dermal template was added to wound treatment, covered with non-adherent contact layer, Hydrofera Blue classic foam, topical steroid around peri-wound skin, secured with rolled gauze and double layer of a tubular compression bandage.

Wound prior to using Hydrofera Blue classic foam and Endoform dermal template

Week 0:

Start of using Endoform dermal template

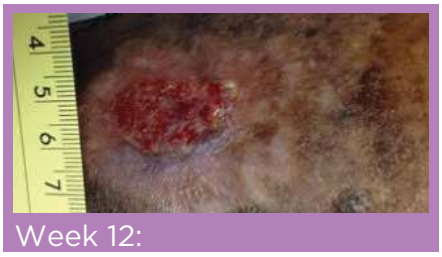
Wound measurements:
5 cm x 3.7 cm x 0.2 cm

Week 4:

Wound measurements:
4.5 cm x 2.7 cm x 0.2 cm

Week 10:

Wound measurements:
3 cm x 2 cm x 0.1 cm



Week 12:

Wound measurements:
2 cm x 1 cm x 0.1 cm

Week 15:

Wound measurements:
0.5 cm x 0.4 cm x 0.1 cm

Week 16:

Wound healed

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CASE STUDY 17 | Pyoderma Gangrenosum

Case provided by:

Dr. Juan Bravo, Medical Director Center for Wound Care and Hyperbaric Medicine at Coral Springs Medical Center, Coral Springs, Florida

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CASE STUDY 25 | Venomous Spider Bite - Left Forearm

Patient: 57 year-old male bitten by a venomous spider on the left forearm.

Age of wound:

- 2.5 Weeks

Previous Treatment:

- IV antibiotics and steroids while inpatient
- Two oral antibiotics as outpatient
- Collagenase ointment applied to wound when seen in the wound clinic at 2.5 weeks.

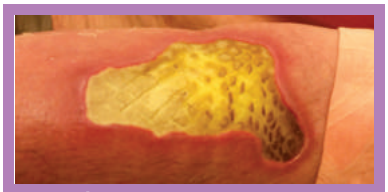
Initial Wound: Week 1

Wound Measurements:
12.1 x 6.4 x 0.1 cm

Wound Description:
Wound completely covered with dry slough, periwound edges rolled with mild border of erythema, patient reported no pain and had paresthesia in left forearm, but had 5/5 muscle strength and full range of motion. 1+ pitting edema in left wrist

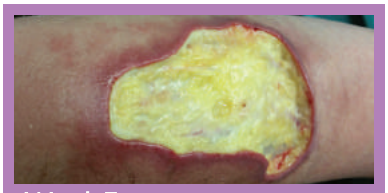
Week 2:

Wound Description:
Wound completely covered with dry slough, periwound edges rolled with mild border of erythema, patient reported no pain and had paresthesia in left forearm, but had 5/5 muscle strength and full range of motion. 1+ pitting edema in left wrist
Wound Management:
The slough was crosshatched with a scalpel. Collagenase was applied nickel thick daily and covered first with saline moistened gauze, then dry gauze & tape.



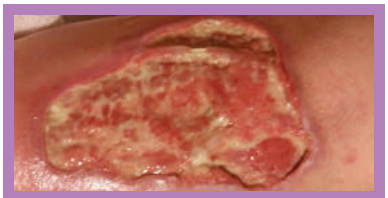
Week 3:

Wound Description:
Wound completely covered in slough. Patient still had no pain and continued reporting paresthesia of left forearm. 1+ pitting edema in left wrist.
Wound Management:
The slough was debrided. Collagenase ointment was continued along with weekly debridements.



Week 5:

Wound Description:
Wound completely covered in slough. Patient still had no pain and continued reporting paresthesia of left forearm. 1+ pitting edema in left wrist.
Wound Management:
Wound debrided. Collagenase ointment applied to wound base and cover with saline-moistened Hydrofera Blue classic dressing which may help with autolytic debridement and may help flatten wound edges.



Week 6:

Wound Measurements:
10.3 x 8.2 x 0.2 cm, undermining from 10-11 o'clock 0.5 cm and 1-2 o'clock 0.6 cm

Wound Description:
Wound slough reduced. Proximal portion exhibits rolled wound edges. Patient still had no pain and continued reporting paresthesia of left forearm. 1+ pitting edema in left wrist.
Wound Management:
Wound debrided and collagenase ointment discontinued. Began using Endoform dermal template with saline-moistened Hydrofera Blue classic foam dressing secured with rolled gauze and tape. Dressing changes three times weekly. Patient seen in wound clinic every 2 weeks.

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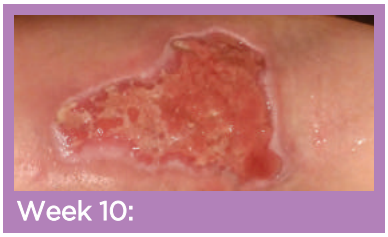
CASE STUDY 25 | Venomous Spider Bite - Left Forearm

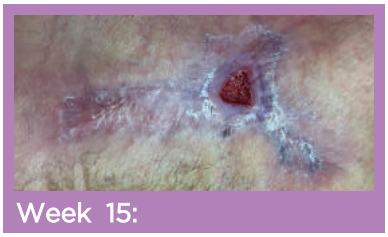


Week 10:

Wound Measurements:
6.3 x 4.9 x 0.1 cm

Wound Description:
Wound bed mostly covered with granulation tissue with small amount of scattered slough and slight hypergranulation. Periwound edges are flattening. Patient still reports no pain but continues to report paresthesia. 1+ pitting edema in left wrist edema in left wrist

Wound Management:
Wound bed and edges debrided. Endoform covered with saline-moistened Hydrofera Blue classic foam dressing and secured with rolled gauze and tape. Dressing changes three times per week. Patient reminded to elevate left arm to alleviate swelling. Patient continued to return to wound clinic every 2 weeks.

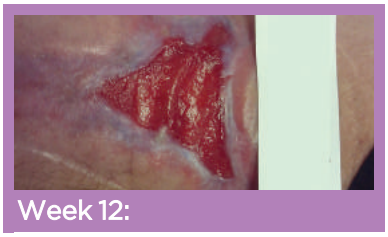


Week 15:

Wound Measurements:
1.2 x 1 x 0.1 cm

Wound Description:
Wound completely covered with granulation tissue, periwound edges pink and flat. Patient still reports no pain but continues to report paresthesia. 1+ pitting edema in left wrist.

Wound Treatment:
Saline-moistened Hydrofera Blue classic foam dressing only used at this point covered with an occlusive dressing. Dressings changed three times per week. Patient reminded to elevate left arm to alleviate swelling. Patient to return in 2 weeks.



Week 12:

Wound Measurements:
5 x 3.9 x 0.1 cm

Wound Description:
Wound completely covered with red granulation tissue. Periwound edges are completely flat. Patient still reports no pain but continues to report paresthesia. Trace edema noted in left wrist.

Wound Management:
No debridement necessary at this visit. Endoform covered with saline-moistened Hydrofera Blue classic foam dressing secured with rolled gauze and tape. Dressing changes three times per week. Patient reminded to elevate left arm to alleviate swelling. Patient continued to return to wound clinic every 2 weeks.

Week 17:

Wound Measurements:
1.2 cm x 1 cm x 0.1 cm

Wound Description:
Wound closed with cicatrix noted (scar). Patient continues to report paresthesia. Trace edema noted in left wrist.

Case provided by:

Sarah Reyna MNSc, CNP, AGACNP-BC-Saline Memorial Wound Healing Center, Benton, Arkansas

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Innovative solutions in the management of wounds with exposed tendons utilizing ovine collagen extracellular matrix and gentian violet and methylene blue antibacterial foams.

• **Dr. Igor Zilberman, DPM** • **Nooshin Zolfaghari DPM, CWS, MPH,** South Florida Lower Extremity Center, Hollywood, FL

INTRODUCTION:

Tendons are anatomical structures that connect muscle to bone. They are composed of parallel bundles of collagen fiber and often appear at striated white or cream yellow structures in wound beds.[1] Tendons are nourished by blood vessels and by diffusion of nutrients from synovial fluid.[2] Because nourishment is disrupted when the tendon is exposed, meticulous care must be provided to prevent infection and desiccation. Either of these two may result in loss of tendon viability.[3]

Tendons may be exposed in trauma wounds, stage IV pressure wounds, diabetic wounds, and contaminated or infected surgical wounds.[4] Chronic wounds represent a failure in the normal order and sequence of wound healing. Changes in local pH, temperature, and amounts of chemical reactants are all factors influencing wound healing.

The three main components of local wound management include debridement, infection/inflammation, and moisture balance. Bioburden, or critical bacterial colonization, leads to persistently high levels of matrix metalloproteinases (MMP) being released from inflammatory cells that digest the normal collagen scaffold in the base of a healing wound.[5] Addressing these key barriers to wound healing with use of advanced wound care products may assist to achieve tendon coverage and promote wound healing.

OBJECTIVE:

To describe the use of an ovine collagen with an intact ECM* (CECM) and gentian violet and methylene blue (GV/MB) polyurethane (PU) and/or polyvinyl alcohol (PVA) antibacterial foam**, *** in wounds with exposed tendons.

METHODS AND MATERIALS:

Patients were selected with wounds containing either partial or complete tendon exposure. The CECM dressings and GV/MB foams were changed according to product instructions. Assessments and measurements were performed by the clinician weekly.

CONCLUSION:

The use of the CECM dressing with GV/MB antibacterial foams in this case series were helpful in the management of these complex wounds. Complete tendon coverage and resolution of wounds were without complication.

Case Study 1 - Surgical wound- Right Dorsal Foot

Patient: 41 year-old male presented to emergency room with cellulitis, swelling and a blister on right hallux and metatarsal. Abscess was noted on the right lateral dorsal foot. MRI revealed osteomyelitis.

Past medical history:
- Hypertension, diabetes.

Wound history:
- First ray resection on right foot with debridement of abscess on right dorsal foot. IV antibiotics. Hospitalized for 1½ weeks.

Previous treatment:
- Negative pressure wound therapy (NPWT) alone during hospital stay. CECM, hydrogel, covered with non-adherent contact layer and NPWT for 5 weeks.

Treatment:
- NPWT discontinued. Treatment changed to CECM covered with MB/GV PVA antibacterial foam covered with dry gauze and secured with gauze wrap. Dressings changed every other day.

Week 0 Wound measurement:
9.8 cm x 7.0 cm x 0.5 cm
Wound Description:
Granulating tissues with some non-viable tissues. Extensor tendon 3, 4 and 5 exposed.

Week 6 Wound measurement:
7.4 cm X 5.0 cm
Wound Description:
Hypergranulating tissues. 20% of tendon exposed.

Week 2

Week 8 Wound measurement:
5.0 cm X 3.4 cm
Wound Description:
100% granulating wound bed with smooth flat wound edges. No tendons exposed.

Week 4 Wound measurement:
7.5 cm x 5.5 cm

Week 15
100% re-epithelialized.

Case Study 2 - Dehisced surgical wound - 2nd right toe

Patient: 59 year-old female presented to clinic with dehisced surgical incision on 2nd right toe osteomyelitis.

Past medical history:
- Hypertension, hepatitis C.

Wound history:
- Revision of hammertoe on right 2nd toe.

Previous treatment:
- N/A.

Treatment:
- Sutures removed. Applied CECM, hydrogel and covered with MB/GV antibacterial PU foam dressing. Dressings changed weekly.

Week 0 Wound measurement:
2.0 cm x 1.4 cm x 0.3 cm
Wound Description:
Granulating tissues with extensor tendon exposed.

Week 7
Wound Description:
100% granulating tissues. Tendon covered.

Week 3 Wound measurement:
1.5 cm x 0.7 cm x 0.3 cm

Week 9
100% re-epithelialized.

Week 5 Wound measurement:
0.8 cm x 0.4 cm x 0.2 cm

Case Study 3 - Pressure Ulcer - Achilles

Patient: 80 year-old male living in a skilled nursing facility, bed bound with 3 month old pressure ulcer to the achilles.

Past medical history:
- Peripheral vascular disease, congestive heart failure.

Wound history:
- N/A

Previous treatment:
- Enzymatic debrider for 4 weeks to remove black eschar.

Treatment:
- Applied CECM, covered with MB/GV PU antibacterial foam, secured with gauze wrap. Dressings changed every other day.

Week 0 Wound measurement:
5.5 cm x 2.5 cm x 1.0 cm
Wound Description:
Achilles tendon exposed.

Week 5 Wound measurement:
Proximal - 0.8 cm x 0.3 cm
Distal - 2.0 cm x 0.5 cm

Week 2 Wound measurement:
4.5 cm x 1.2 cm x 1.0 cm

Week 6
Re-epithelialized

Week 3 Wound measurement:
Wound split into 2.
Proximal - 1.0 cm x 1.0 cm x 0.2cm
Distal - 3.0 cm x 1.2 cm x 0.2 cm
Granulating tissues, tendon covered.

Case Study 4 - Diabetic Foot Ulcer – Left First Metatarsal

Patient: 51 year-old male with diabetic foot ulcer.

Past medical history:
- Diabetic with abscess on left first metatarsal.

Wound history:
- N/A

Previous treatment:
- Incision and drainage of abscess with debridement of necrotic tissues.
- Systemic antibiotic for 2 weeks.
- Wound dressings: Wet to dry dressings for 2 weeks.

Treatment:
- Applied CECM, covered with MB/GV PU antibacterial foam, secured with stretch gauze and elastic bandage. Dressings changed weekly.

Week 0 Wound measurement:
8.5 cm x 4.0 cm x 0.5 cm
Wound Description:
70% Red granulating tissues with 30% tendon exposed.

Week 4 Wound measurement:
8.0 cm x 3.0 cm x 0.2 cm
Wound Description:
100% red granulating tissues. Tendon completely covered with granulation tissues.

Week 1 Wound measurement:
8.5 cm x 3.5 cm x 0.5 cm
Wound Description:
80% red granulating tissues with 20% tendon exposed.

Week 8 Wound measurement:
4.6 cm x 3.0 cm x 0.2 cm
Wound Description:
Wound continues to reduce in size.

Week 2 Wound measurement:
8.5 cm x 3.5 cm x 0.2 cm
Wound Description:
Tendon continued to be covered with granulation tissue.

Week 10
Wound Description:
Re-epithelialized

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** Hydrofera Blue Ready foam, Distribute by Hollister Incorporated.
*** Hydrofera Blue classic foam, Distributed by Hollister Incorporated.

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Use of Ovine Collagen Extracellular Matrix and Gentian Violet and Methylene Blue Antibacterial Foam Dressings to Help Improve Clinical Outcomes in Lower Extremity Wounds

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Purpose:

To analyze our clinical outcomes with use of ovine collagen extracellular matrix (CECM)* and gentian violet/methylene blue (GV/MB) polyurethane (PU) antibacterial foam dressings** in treating chronic lower extremity wounds.

Introduction:

Chronic lower extremity wounds are increasingly more prevalent and complex to treat, and are a significant cause of morbidity and drain on healthcare resources worldwide. Patient comorbid conditions such diabetes, peripheral vascular disease and obesity can delay wound healing, and must be clinically addressed to correct causes of tissue damage. In addition to underlying medical conditions, chronic wounds are characterized by a complex etiology that can include abnormal cell-extracellular matrix (ECM) interactions, elevated bioburden levels and bacterial biofilm, imbalances of matrix-metalloproteinases (MMP), and an unresolved inflammatory response—all of which can damage the wound ECM.[1,2] Dressings that provide broad spectrum MMP reduction along with inherent aspects of an ECM may contribute to improved wound healing outcomes and shorter treatment times.[3] Preliminary reports of a CECM dressing have demonstrated benefits in chronic wound healing.[4,5]

Methodology:

- Retrospective chart analysis was performed on observational data of consecutive patients with chronic lower extremity ulcers who were managed with CECM as a primary dressing and MB/GV PU antibacterial foam dressing to manage bioburden as a secondary dressing in an outpatient setting.
- All patients were treated twice weekly in the clinic for the first four weeks. During the first visit, wounds were cleansed with saline or dermal cleanser, sharp debrided as needed, and a CECM dressing covered with a MB/GV PU antibacterial foam was placed. At the mid-week appointment, wounds were again cleansed and examined, but not sharp debrided. An additional CECM dressing was placed if the previous CECM dressing was fully integrated into the wound and the MB/GV PU antibacterial foam was replaced.
- After the initial four week period, patients received once weekly treatment consisting of cleansing, sharp debridement as needed, and a CECM dressing covered with a GV/MB PU antibacterial foam until wound was healed.

Results:

Patient demographics	n	%
Patients (n)	53	
Male	22	41.5%
Female	31	58.5%
Mean age (years)	75.9	
Mean Body Mass Index (BMI)	28.3	
Wounds treated (n)	53	
Mean wound area at presentation (cm2)	5.8	

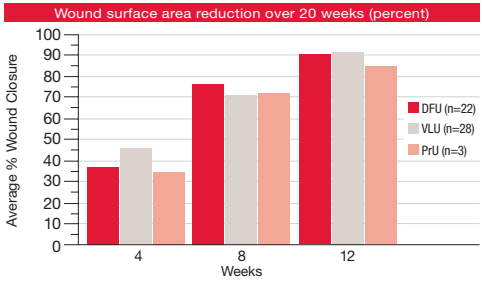
- Fifty-three patients with 53 wounds were treated.
- Types of wounds treated were diabetic foot ulcers (n=22), venous leg ulcers (n=28), and heel pressure ulcers (n=3).
- Average BMI for study population was 28.3 using a standard BMI formula with a BMI between 25 and 30 being overweight; average patient age was 75.9 years.
- Mean percent wound size reduction at 4 weeks was 38.5%; mean wound size reduction at 8 and 12 weeks was 73.3% and 91.3%, respectively.
- 11/22 (50.0%) DFUs and 13/28 (46.4%) VLUs achieved at least 40% closure at week 4.
- Average time to heal for all wounds was 10.6 weeks (range: 5 to 24 weeks).
- All wounds were 100% re-epithelialized by week 20 except one DFU that was re-epithelialized at week 24.
- All patients responded well to treatment, with no reported adverse reactions or adverse side effects.

Discussion:

- Overall, the use of CECM covered with MB/GV PU antibacterial foam in an overweight, advanced-age population was successful with an average time to closure of 10.6 weeks for wounds in this series.
- It is interesting to note that 24/25 wounds that did not achieve greater than 40% wound surface area reduction by week 4 progressed to complete closure by week 20, with no additional wound treatment besides weekly application of CECM and MB/GV PU antibacterial foam dressings.
- Rates of wound size reduction at 4, 8, and 12 weeks were similar between VLUs and DFUs.

Patient outcomes

Wounds treated (n)	n (%)	Avg area at 0 weeks (cm2)	Avg time to healing (weeks)	Avg % area closed at 4 weeks	Avg % area closed at 8 weeks	Avg % area closed at 12 weeks	≥40% closure at 4 weeks n(%)	≥40% closure at 8 weeks n(%)	100% closure at 12 weeks n(%)	100% closure at 20 weeks n(%)
	53 (100.0)	5.8	10.6	38.5%	73.3%	91.3%	25 (47.2)	49 (92.5)	31 (58.5)	52 (98.1)
DFU (n)	22 (41.5)	6.4	10.6	38.1%	76.5%	90.6%	11 (50.0)	20 (90.9)	13 (59.1)	21 (95.5)
VLU (n)	28 (52.8)	5.8	10.4	39.2%	70.9%	92.6%	13 (46.4)	26 (92.9)	17 (60.7)	28 (100.0)
PrU (n)	3 (5.7)	2.3	12.0	35.1%	72.0%	84.3%	1 (33.3)	3 (100.0)	1 (33.3)	3 (100.0)



- Compared to VLUs, DFUs showed a slightly greater percent size reduction rate at 8 weeks, but a lesser size reduction at 12 weeks. This is consistent with our observation that DFUs in this series took longer than VLUs to progress to full healing during the re-epithelialization phase, but considerably more research is required to validate this observation.
- Drawing conclusions regarding pressure ulcer healing in this series was difficult due to low subject numbers.

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** Hydrofera Blue Ready foam, Distributed by Hollister Incorporated.

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Case Study

Patient: 66 year-old male patient with history of T2DM and HIV presented with anterior left ankle wound secondary to increased compression from treatment of pressure ulcer to heel that was almost closed. Patient was self-treating wound when he changed his dressing and over-tightened the gauze wrap on his left ankle.

Week 0: 4.5 cm x 4.5 cm x 0.4 cm
- Initial presentation
- Anterior tibialis tendon exposed

Wound treatment:
Sharp debridement, CECM dressing applied with MB/GV PU antibacterial foam cover with dressings applied twice a week.

Week 7
- Complete granulation over the tendon with contraction of wound edges

Wound treatment:
CECM dressing applied with MB/GV PU antibacterial foam cover with dressings applied one time a week.

Week 13: 1.2 cm x 1.2 cm x0.1 cm
- 93% wound closure

Wound treatment:
CECM dressing applied with MB/GV PU antibacterial foam cover with dressings applied one time a week.

Week 15
- Complete epithelialization

Appulse

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