**Endoform®** can help to improve healing and lower the cost of VLU management

- **Endoform®** can be used from day one in difficult-to-manage VLUs.\(^1,2,3,4\)
- **Endoform®** does not need to be removed and requires fewer dressing changes than other products; which may lead to greater patient satisfaction and compliance.\(^5\)
- **Endoform®** reduces the cost of VLU treatment because application can be carried out by a range of wound care practitioners (no suturing required) and subsequent applications can be carried out by the patient at home.\(^5\)
- A case series using **Endoform®** was shown to result in 95.7% closure of VLUs in 12 weeks with an average closure time of 7.3 weeks (n=23 wounds, ranging in size from 0.2 – 23.4 cm\(^2\), in 14 patients).\(^5\)
- Early reduction in wound area (20-40% in the first 2-4 weeks of treatment) is a good predictor of healing.\(^6\)

**Clinical Evidence | Treatment of Venous Leg Ulcers (VLUs)**

**Stabilize**

- Hemostasis

**Correct**

- Inflammation

**Build**

- Proliferation

**Organize**

- Remodelling

**Endoform®** can be used at all phases of wound management

In a clinical study, 4 weeks of **Endoform®** treatment resulted in complete closure in 40% of cases (n=28).\(^1\)
References


RX Only. Prior to use, be sure to read the entire Instructions for Use package insert supplied with the product.

For product questions, sampling needs, or detailed clinical questions concerning our products in the US, please call 1-860-337-7730

HCPCS are for reference only and subject to change.

Endoform® is a registered trademark of Aroa Biosurgery Limited.

Appulse

Endoform® Dermal Template is marketed in the USA by Appulse
Use of Ovine Collagen Extracellular Matrix and Gentian Violet and Methylene Blue Antibacterial Foam Dressings to Help Improve Clinical Outcomes in Lower Extremity Wounds

Purpose:
To analyze our clinical outcomes with use of ovine collagen extracellular matrix (CECM)* and gentian violet/ethylene blue (GV/MB) polyurethane (PU) antibiotic 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 as 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 healing, 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 extracellular matrix (ECM) interactions, elevated bioburden and a complex etiology that can include abnormal extracellular matrix (CECM)* and gentian violet/methylene blue (GV/MB) polyurethane (PU) antibiotic foam dressings covered with a GV/MB polyurethane (PU) antibacterial foam dressing to manage bioburden as a secondary treatment.

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 GV/MB PU antibacterial foam dressing to manage bioburden as a secondary dressing in an outpatient setting.

Results:

**Patient demographics**

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>53</td>
<td>100</td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>41.5</td>
</tr>
<tr>
<td>Female</td>
<td>31</td>
<td>58.5</td>
</tr>
</tbody>
</table>

**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 GV/MB PU antibiotic 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 GV/MB PU antibiotic foam dressings.

• Rates of wound size reduction at 4, 8, and 12 weeks were similar between VLUs and DFUs.

---

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 on his heel that was almost closed. Patient was self-healing wound when he changed his dressing and over-tightened the gauze wrap on his left leg.

**Week 0:**
- 4.5 cm x 4.5 cm x 0.4 cm ulcer
- Initial presentation
- Achilles tendon not involved

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

**Week 5:**
- Complete epithelialization

**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 x 0.1 cm ulcer
- 90% wound closure

**Wound treatment:**
- CECM dressing applied with MB/GV PU antibacterial foam cover with dressings applied twice a week.

**Week 15:**
- Complete epithelialization

<table>
<thead>
<tr>
<th>Case Study 1</th>
<th>Mixed Vascular Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex:</strong></td>
<td>Female</td>
</tr>
<tr>
<td><strong>Co-morbidities:</strong></td>
<td>Non-insulin dependent diabetes, Congestive heart failure, Congestive obstructive pulmonary disease, Peripheral vascular disease</td>
</tr>
<tr>
<td><strong>Wound Type:</strong></td>
<td>Mixed Vascular</td>
</tr>
<tr>
<td><strong>Wound Location:</strong></td>
<td>Left ankle</td>
</tr>
<tr>
<td><strong>Wound Age:</strong></td>
<td>1 year</td>
</tr>
<tr>
<td><strong>Previous Treatments:</strong></td>
<td>Compression, Sharp debridement, Silver dressing, Steroid therapy</td>
</tr>
<tr>
<td><strong>Secondary Dressing:</strong></td>
<td>Non-adherent dressing, Rolled gauze, Compression therapy, Offloading pressure device</td>
</tr>
<tr>
<td><strong>Outcomes:</strong></td>
<td>Granulation tissue at Week 5, Complete healing at Week 11</td>
</tr>
<tr>
<td><strong>Endoform applications:</strong></td>
<td>9</td>
</tr>
</tbody>
</table>

### Wound Area over Time

![Wound Area Graph](image_url)

**Week 0:**

**Week 7:**

**Appulse**

**A R O A**
Initial Preparation
The wound was surgically debrided down to viable tissue and irrigated with hypochlorous acid solution and treated with a silver dressing and compression. The wound was assessed for visible signs of infection (i.e., absence of swelling, pain, purulent drainage, or tracking into the deep tissue planes). The wound had to remain free of infection to start using the Endoform dermal template. Silver dressing treatments were stopped at this time.

Endoform dermal template Application
Using aseptic technique, Endoform dermal template was trimmed to roughly overlap the wound margins, placed on the wound bed and rehydrated with sterile saline. Following hydration, the color of the dressing changed from white to opaque. Light pressure was applied to the dressing to ensure that it conformed to the underlying wound bed. The dressing was covered with a non-adherent secondary dressing. Compression stockings, exudate control and offloading were used as required.

Follow-Up
The patient received weekly follow-up, during which time the wound was debrided as required and irrigated to remove loose material. The Endoform dermal template was reapplied on a weekly basis. Changes in the wound granulation tissue, epithelial tissue and wound dimensions were monitored and recorded using digital photography.

Observations
In approximately three days, the dressing had adhered to the underlying wound bed. After seven days, the dressing was completely integrated into the wound bed. In some cases, only remnants of the dressing remained as an off-white gel that was allowed to remain in place during subsequent applications of Endoform dermal template.

Case provided by:
Liden BA, Ward BR, May BCH; Early Clinical Findings From The Use Of Endoform Dermal Template (Ovine Forestomach Matrix) To Treat Recalcitrant Wounds; Presented at Symposium on Advanced Wound Care, April 14-17, 2011 Dallas, TX.
## CASE STUDY 3 | Mixed Vascular Etiology

<table>
<thead>
<tr>
<th><strong>Sex:</strong></th>
<th>Female</th>
</tr>
</thead>
</table>
| **Co-morbidities:** | Diabetes  
Congestive heart failure  
Venous reflux |
| **Wound Type:** | Mixed vascular |
| **Wound Location:** | Left lower medial leg, anterior ankle |
| **Wound Age:** | 1+ year |
| **Previous Treatments:** | Compression  
Sharp debridement  
Enzymatic debrider  
Growth factos  
Skin substitute (x4)  
Silver dressing |
| **Secondary Dressing:** | Non-adherent dressing  
Rolled gauze |
| **Outcomes:** | Granulation tissue at week 4  
Complete Healing at week 9 |
| **Endoform applications:** | 6 |

### Wound area over time

![Wound area over time graph](image)
Initial Preparation
The wound was surgically debrided down to viable tissue and irrigated with hypochlorous acid solution and treated with enzymatic debriding agent and compression. The wound was assessed for visible signs of infection (i.e., absence of swelling, pain, purulent drainage, or tracking into the deep tissue planes). The wound had to remain free of infection to start using the Endoform dermal template. Previously used dressings and enzymatic debriding treatments were stopped at this time.

Endoform dermal template Application
Using aseptic technique, the Endoform dermal template was trimmed to roughly overlap the wound margins, placed on the wound bed and rehydrated with sterile saline. Following hydration, the color of the dressing changed from white to opaque. Light pressure was applied to the dressing to ensure that it conformed to the underlying wound bed. The dressing was covered with a non-adherent secondary dressing. Compression stockings, exudate control and offloading were used as required.

Follow-Up
The patient received weekly follow-up, during which time the wound was debrided as required and irrigated to remove loose material. The Endoform dermal template was reapplied on a weekly basis. Changes in the wound granulation tissue, epithelial tissue and wound dimensions were monitored and recorded using digital photography. The wound was monitored for a further four weeks.

Observations
In approximately three days, the dressing had adhered to the underlying wound bed. After seven days, the dressing was completely integrated into the wound bed. In some cases, only remnants of the dressing remained as an off-white gel that was allowed to remain in place during subsequent applications of Endoform dermal template.

Case provided by:
Liden BA, Ward BR, May BCH; Early Clinical Findings From The Use Of Endoform Dermal Template (Ovine Forestomach Matrix) To Treat Recalcitrant Wounds; Presented at Symposium on Advanced Wound Care, April 14-17, 2011 Dallas, TX.
Patient: 53-year-old male, presented with a venous ulcer wound to the left ankle

Wound characteristics and prior treatment:

The wound was treated initially with zinc-paste-impregnated gauze and an alginate dressing.

Treatment:

- Wound cleansed with normal saline
- Sharp debridement to remove devitalized wound base tissue
- Endoform dermal template was applied, covered with a secondary foam dressing, and secured with tape

Results:

- Initial wound measurement after debridement was 1.0cm x 1.0cm x 0.2cm
- After seven weeks of treatment, wound had decreased to 0.2cm x 0.2cm x 0.1cm
CASE STUDY 9 | Venous Ulcer

Case provided by:
Maeve Curran, PT, CWS, CLT; Desert Regional Medical Center, Palm Springs, CA
Leg ulcer treatment outcomes with new ovine collagen extracellular matrix dressing: a retrospective case series.

Bohn GA, Gass K.

Abstract

The purpose of this study was to describe the rate of closure observed in venous leg ulcers during treatment with ovine collagen extracellular matrix dressings and compression. Fourteen patients with 23 wounds were retrospectively evaluated with respect to healing rates, time to closure, and weekly facility charge fees.

PMID: 25108432 DOI: 10.1007/0-387-28120-3_8

Leg Ulcer Treatment Outcomes with New Ovine Collagen Extracellular Matrix Dressing: A Retrospective Case Series

Bohn, Gregory A, MD, FACS; Gass, Kimberly RN

Leg ulcer treatment outcomes with new ovine collagen extracellular matrix dressing: a retrospective case series.

The purpose of this study was to describe the rate of closure observed in venous leg ulcers during treatment with ovine collagen extracellular matrix dressings and compression. Fourteen patients with 23 wounds were retrospectively evaluated with respect to healing rates, time to closure, and weekly facility charge fees.

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Proactive and Early Aggressive Wound Management: A Shift in Strategy Developed by a Consensus Panel Examining the Current Science, Prevention, and Management of Acute and Chronic Wounds.

Abstract

Normal wound healing is accomplished through a series of well-coordinated, progressive events with overlapping phases. Chronic wounds are described as not progressing to healing or not being responsive to management in a timely manner. A consensus panel of multidisciplinary wound care professionals was assembled to (1) educate wound care practitioners by identifying key principles of the basic science of chronic wound pathophysiology, highlighting the impact of metalloproteases and biofilms, as well as the role of the extracellular matrix; and (2) equip practitioners with a systematic strategy for the prevention and healing of acute injuries and chronic wounds based upon scientific evidence and the panel members' expertise. An algorithm is presented that represents a shift in strategy to proactive and early aggressive wound management. With proactive management, adjunct therapies are applied preemptively to acute injuries to reduce wound duration and risk of chronicity. For existing chronic wounds, early aggressive wound management is employed to break the pathophysiology cycle and drive wounds toward healing. Reducing bioburden through debridement and biofilm management and using collagen dressings to balance protease activity prior to the use of advanced modalities may enhance their effectiveness. This early aggressive wound management strategy is recommended for patients at high risk for chronic wound development or for those demonstrating non-healing chronic wounds. In their own practices, the panel members apply this systematic strategy for all patients presenting with acute injuries or chronic wounds.