



# Venous Leg Ulcers

## Clinical Evidence



Endoform® is a unique extracellular matrix (ECM) that supports all phases of wound healing.

It provides a natural, porous ECM scaffold for rapid cell infiltration and 148 secondary molecules important for healing.

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Bohn, G. A. and K. Gass (2014). "Leg ulcer treatment outcomes with new ovine collagen extracellular matrix dressing: a retrospective case series." *Adv Skin Wound Care* 27(10): 448-454.

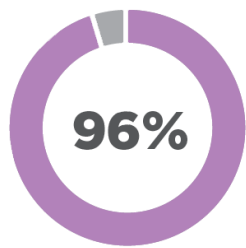
**96% Wound closure at 12 weeks using Endoform<sup>®</sup> to manage VLU's.**

"Investigators in the authors' clinic have **switched to the CECM dressing (Endoform<sup>®</sup>) as the standard venous ulcer dressing under compression** because of its versatility, relatively low cost, and perceived effectiveness."

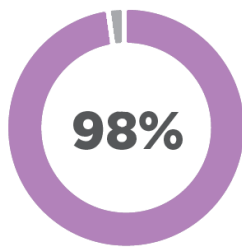
"Since the conclusion of the study, **overall faster wound healing times have been observed**, compared with prior treatment regimens." Bohn and Gass (2014).

Baseline average wound size:  
**3.7 cm<sup>2</sup>**  
Range 0.2 to 23.4 cm<sup>2</sup>

**23**  
Wounds



Wounds closed by  
week 12



Average % wound  
reduction at  
12 weeks

Bohn, G. A. and K. Gass (2014). "Leg ulcer treatment outcomes with new ovine collagen extracellular matrix dressing: a retrospective case series." *Adv Skin Wound Care* 27(10): 448-454.



CASE SERIES

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

Gregory A. Bohn, MD, FACS, and Kimberly Gass, RN

**ABSTRACT**

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

**KEYWORDS:** ovine collagen extracellular matrix, wound care dressing, venous leg ulcer

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**INTRODUCTION**

Venous leg ulcers (VLUs) appear for up to 80% of lower extremity ulcers in the United States<sup>1</sup> and are commonly associated with pain, itching, altered appearance, and decreased mobility, social isolation, depression, and sleep disturbance.<sup>2-4</sup> Treatment costs for VLUs which are directly associated with the need for intensive chronic care average \$500 per month<sup>5</sup> and average \$100,000 per treatment episode.<sup>6</sup> Despite increased focus on prevention and treatment, an estimated 2 million Americans are currently living with a VLU, amounting to an estimated \$1.46 billion in health care costs.<sup>7</sup> These costs do not include the time and effort required by patients to manage their medical and psychological conditions.

In addition to medical leg venous and arterial disease, patients with VLUs experience VLU's local physiology, a major role is that of the physiology of VLU's, contributing to the development and maintenance of VLU's.<sup>8,9</sup> Compression therapy is considered a standard management strategy for venous ulcers, as it provides a mechanical force that is directly opposite to the large body of evidence.<sup>10</sup> Yet, compression therapy is difficult to implement

in a home setting with an acceptable frequency.<sup>11</sup> For example, with compression therapy, the daily closure rates at 30% to 65% at 6 months have been reported.<sup>12,13</sup> Approximately 20% of ulcers healed at 1 year, and approximately 45% healed at 1.5 years.<sup>14</sup>

Although current approaches to treating venous ulcers are effective, a cure has not been demonstrated in the literature, and to have identified the role of collagen-based ECM dressings in improving wound healing by reducing inflammation processes.<sup>15</sup> Use of case history of ECM dressings allow some to improve patient satisfaction and quality of life by use of ECM dressings applied to the wound site, promoting healing and preventing infection.<sup>16</sup> Collagen-based dressings have been shown to be effective in improving wound healing in the microcirculation, less thrombosis and necrosis, and inhibition of matrix metalloproteinases (MMPs) while promoting wound healing and promoting the healing of venous ulcers.<sup>17</sup>

Use of ovine collagen (OC) ECM dressings allow some to improve patient satisfaction and quality of life by use of ECM dressings applied to the wound site, promoting healing and preventing infection.<sup>16</sup>

An ovine collagen ECM dressing, Endoform<sup>®</sup> dressing, allows some to improve patient satisfaction and quality of life by use of ECM dressings applied to the wound site, promoting healing and preventing infection.<sup>16</sup>

An ovine collagen ECM dressing, Endoform<sup>®</sup> dressing, allows some to improve patient satisfaction and quality of life by use of ECM dressings applied to the wound site, promoting healing and preventing infection.<sup>16</sup>

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## Case #1

85-Year-old male with history of recurrent VLU's. Oral antibiotics and antibacterial dressings. Current ulcer measured 3.5 cm x 1.0 cm. Initiated Endoform<sup>®</sup> Natural covered with Hydrofera Blue<sup>®</sup> TRANSFER dressing and compression. 100% Epithelialized by week 5.



Andersen, C., D. Green, J. Santucci and E. Phillips (2018). Improved Venous Leg Ulcer Outcomes Using a Combination of Ovine Extracellular Matrix and Gentian Violet/Methylene Blue Transfer Antibacterial Foam. Symposium for Advanced Wound Care – Fall, Las Vegas, NV.



## Venous Leg Ulcers Clinical Evidence

### Case #2

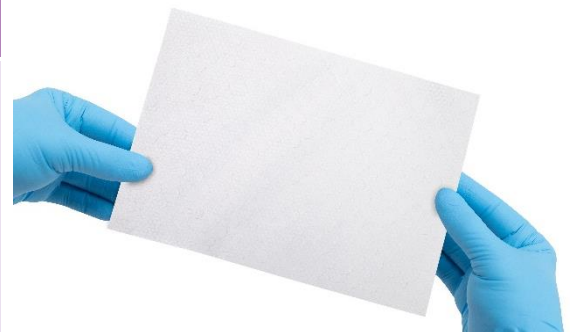
68-Year-old female. Venous disease, with a painful 9 month old non-healing VLU, measuring 3.5 cm x 4.1 cm. Initiated Endoform<sup>®</sup> Natural covered with Hydrofera Blue READY<sup>®</sup> dressing and compression. 80-90% Epithelialized by week 3, closed by week 5.



Courtesy of Gregory Bohn, MD, FACS, FACHM Manistee, MI (2019).

### Endoform<sup>®</sup> Natural High Flow - 8.5 x 6" Size

- Designed for large VLUs and clustered VLUs.
- Simplifies treatment of larger VLUs by providing immediate coverage.
- Available in High Flow for wounds with variable exudate.



### Case #3

67-Year-old male. Venous disease. VLU had failed three 'Cellular and Tissue Products' and a split thickness skin graft. Weekly Endoform<sup>®</sup> Natural covered with Hydrofera Blue CLASSIC<sup>®</sup> dressing and compression. Closed by week 24.



Courtesy of Gregory Bohn, MD, FACS, FACHM Manistee, MI (2019).

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### Technology Comparison

Endoform® is an advanced extracellular matrix (ECM) technology designed to aid soft tissue repair in acute and chronic wounds. Endoform® ECM technology is prepared via minimal processing of sheep forestomach tissue to remove only the sheep cells leaving an intact ECM that functions as a temporary scaffold for cell infiltration. Unlike traditional reconstituted collagen dressings, Endoform® is a native ECM and like other advanced scaffold technologies, Endoform® contains 150+ proteins that aid the tissue repair process<sup>1,2</sup>.

Product	*Accessibility	Coll I	Coll III	Coll IV	Fibronectin	Elastin	Hyaluronic acid	Heparin sulphate	GAGs	Growth factors and cytokines	Basement Membrane	Residual Vascular Channels	Source tissue	Other components
Human tissue ECM	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	-
<b>Endoform® (1,2)</b>	A-code (\$)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Ovine forestomach	None
Promogran™ (3,4,5)	A-code (\$)	✓											Bovine hide	Cellulose
Puracol® (3,6,7)	A-code (\$)	✓											Bovine hide	None
Fibracol™ Plus (3,8)	A-code (\$)	✓											Bovine hide	Calcium alginate
Cutimed® Epiona (5)	A-code (\$)	✓	✓										Bovine hide	Calcium alginate
Biostep™ (3,9)	A-code (\$)	✓											Porcine hide	Cellulose, alginate
OaSIS® (10)	Q-code (\$\$\$)	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	Porcine intestine	None
Epifix® (11,12,13,14)	Q-code (\$\$\$)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		Human amnion	None
Puraply™ (15)	Q-code (\$\$\$)	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	Porcine intestine	Crosslinked

(1) Lun, S., et al. (2010). A functional extracellular matrix biomaterial derived from ovine forestomach. *Biomaterials* 31(16): 4517-4529. (2) Dempsey, S. G., et al. (2019). Functional Insights from the Proteomic Inventory of Ovine Forestomach Matrix. *J Proteome Res* 18(4): 1657-1668. (3) Brett D. et al. A review of collagen and collagen-based wounds dressings. *Wounds* 2008;20:347-56. (4) Cullen et al. The role of oxidised regenerated cellulose/collagen in chronic wound repair and its potential mechanism of action. *The International Journal of Biochemistry & Cell Biology*. 34 (2002) 1544-1556. (5) Wiegand C et al. A novel native collagen dressing with advantageous properties to promote physiological wound healing. *J Wound Care*. 2016;25(12):713-720. (6) Karr J.C. et al. A Morphological and Biochemical Analysis Comparative Study of the Collagen Products, *Adv Skin Wound Care*. 2011, 24(5):208-16. (7) Puracol Safety Data Sheet, 5/28/2015. (8) Fibracol Plus Safety Data Sheet, version 1.0, October 2009. (9) Biostep Safety Data Sheet, June 9, 2009. (10) Badylak, S. F., et al. Extracellular matrix as a biological scaffold material: structure and function. *Acta biomaterialia* 5.1 (2009): 1-13. (11) Koob T. J., et al. Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing. *Int Wound J*. 2013, 10(5):493-500 (12) Koob T. J., et al. Properties of dehydrated human amnion/chorion composite grafts: Implications for wound repair and soft tissue regeneration. *J Biomed Mater Res B Appl Biomater*. 2014, 102(6):1353-62 (13) Koob T. J. et al., Angiogenic properties of dehydrated human amnion/chorion allografts: therapeutic potential for soft tissue repair and regeneration. *Vasc Cell*. 2014, 6:10. (14) Koob T. J. et al., Cytokines in single layer amnion allografts compared to multilayer amnion/chorion allografts for wound healing. *J Biomed Mater Res B Appl Biomater*. 2015, 103(5):1133-40. (15) Fortaderm™ Antimicrobial PHMB Wound, FDA 510K Summary, K051647, 8 Nov 2005.

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