

# Use of a High-Density ECM for the Management of Deep Diabetic Foot Ulcers: A Case Series

Daniel T. Ferreras (DPM, FAPWCA, AAWC) and Richard L. Crump (LPN); Carl Vinson VA Medical Center, Dublin, Georgia, USA



## INTRODUCTION

Diabetic foot ulcers (DFUs) are chronic non-healing wounds and are estimated to cost the health system \$9-13 billion per year[1]. Advanced technologies that reverse the wound chronicity at an early stage can save money, lives and improve the quality of life for patients. An ovine extracellular matrix scaffold (ovECM) provides over 151 native ECM proteins including collagen, laminin, glycosaminoglycans and other components that help to control the inflammatory response and then support the deposition and organization of new tissue[2,3]. A new laminated ovECM technology has been developed that provides a higher dose of important healing molecules. Because the high-density ECM ('HDECIM') is fabricated with increased volume, it can be utilized in deep wounds to restore protease balance, as well as serve as a scaffold to build granulation tissue and close wounds.

## METHODS

All wounds were debrided during the initial consultation, then as needed during the study. Initial wound dimensions were recorded. HDECIM was cut to size as needed and rehydrated prior to application. The wounds were covered with a non-adherent petrolatum dressing, gauze bandage and compression bandage. Off-loading was utilized on a case-by-case basis. Wounds were assessed weekly, measured, imaged and HDECIM re-applied.

## RESULTS

A total of 4 DFU wounds (n=4) were enrolled in the study, with an average wound size of 5 cm<sup>2</sup> (range 0.8 to 8.82 cm<sup>2</sup>), and wound depth ranged from 0.2 to 1.0 cm. All wounds were debrided and managed with weekly applications of HDECIM. At four weeks, 75% of the wounds were classified as 'responders' having reduced in wound area by >50%. By 12 weeks, 75% of wounds had healed, and the average wound size was 10% (0% to 38%). All wounds healed during the course of the study (15 weeks), with the average healing time was 10 weeks (6 to 15). This preliminary study supports use of HDECIM for the closure of DFU's and supports further clinical studies using this product.

## REFERENCES AND DISCLOSURES

Product was provided by Aroa Biosurgery Limited (New Zealand); \*Surface (Aroa Biosurgery Limited, New Zealand), 1. Centers for Disease Control and Prevention, National Diabetes Statistics Report, 2017. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services., 2017. 2. Dempsey, S.G., et al., "Functional Insights from the Proteomic Inventory of Ovine Forestomach Matrix," J Proteome Res 18(4): 1657-1668. 3. Lun et al, 2010, "A functional extracellular matrix biomaterial derived from ovine forestomach." Biomaterials 31(16): 4517-4529.

"Responders" at 4 weeks:  
**75%**  
>50% reduction in wound area at 4 weeks; n=3/4

Wounds closed:  
**75%**  
By week 12; n=3/4

Average % wound size at 12 weeks:  
**10%**  
(0% to 38%)

### CASE 1

**Patient History:** 73 Year old male diabetic with peripheral neuropathy. A1c = 9.6%, 211.4 lbs, BMI 27.95. History of DFUs and had undergone a debridement to remove a foreign body at left plantar-midfoot.

**Week 0:** Sharp debridement; 6.3 x 1.4 x 0.5 cm; HDECIM applied, and site off-loaded.

**Week 1:** 4.7 x 0.9 x 0.4 cm. Red granulation tissue forming in the wound bed. 61% Reduction in wound volume.

**Week 2:** 3.4 x 0.7 x 0.2 cm. Epithelial tissue advancing and granulation tissue filling wound bed. 72% Reduction in wound volume.

**Week 6:** Healed.



### CASE 2

**Patient History:** 47 Year old obese male diabetic with a history of DFUs, and peripheral neuropathy. A1c = 8.3%, 238.9 lbs, BMI 35.35. Injury at right hallux.

**Week 0:** Sharp debridement; 4.7 x 1.0 x 0.3 cm; HDECIM, specialty superabsorbent pad was modified and used to cover the wound.

**Week 13:** 2.5 x 0.5 cm. Granulation tissue covers wound bed. Hypergranular tissue was removed. 73% Reduction in wound volume.

**Week 14:** 0.7 x 0.2 cm. Epithelial tissue covers the majority of the wound surface. 88% Reduction in wound volume.

**Week 15:** Healed.



### CASE 3

**Patient History:** 55 Year old obese male with history of DFUs, and peripheral neuropathy. A1c = 8.4%, 239.7 lbs, BMI 31.43. Injured at right submet-1.

**Week 0:** Sharp debridement; 3.0 x 2.5 x 1.0 cm with exposed bone; HDECIM applied. **Week 3:** 2.0 x 2.1 cm, 44% reduction in wound volume.

**Week 10:** Healed.



### CASE 4

**Patient History:** 80 Year old obese male with history of DFUs, CHF, peripheral neuropathy, and CKD (Stage 3). A1c = 8.0%, 282 lbs, BMI 39.41. Injured at left submet-2.

**Week 0:** Sharp debridement; 1.0 x 0.8 x 0.2 cm; Contoured application of HDECIM directly to wound bed surface and in contact with wound edges.

**Week 8:** Healed.

