Clinical Effectiveness of Ovine Forestomach Matrix for Coverage of Exposed Vital Structures in Complex Diabetic Foot Ulcer Reconstructions

[1]James E. Geiger, Jr. (DPM, CWSP); [2]Richard Kaufman (DPM, CWSP); [3]Brandon Bosque (DPM, CWSP)

[1]Northwestern Medicine , Palos Health, Palos Heights, IL, USA; [2]Piedmont Atlanta Hospital, Atlanta, GA, USA; [3]Aroa Biosurgery Limited, Auckland, New Zealand

INTRODUCTION

Diabetic foot ulcers (DFUs) are the cause of roughly half of all nontraumatic lower limb amputations and are estimated to cost the health system $9-13 billion per year[1]. Advanced technologies that can facilitate viable granulation tissue over exposed vital structures (i.e. bone, tendon, arteries) can shorten time to closure, reduce costs, minimize limb loss, and improve the quality of life for patients. Ovine forestomach matrix scaffold (OFM) provides over 151 native ECM proteins including collagen, elastin, glycosaminoglycans and other components that help to control the inflammatory response and support the deposition of organized new tissue[2,3]. OFM technology has been developed as a robust planar sheet or particulate variation which can be utilized in volumetric, contaminated wounds to safely cover exposed structures with viable granulation and shorten time to definitive closure.

METHODS

All wounds required in-patient surgical management due to tissue necrosis and/or infection which resulted in significant tissue loss and exposed vital structures. Wound dimensions were recorded intra-operatively. OFM sheet and/or particulate$^{\phi}$ was hydrated with saline solution prior to application. The wounds were secured and covered with a non-adherent petrolatum dressing and secondary dressing. Negative Pressure Wound Therapy was utilized on a case-by-case basis. Wounds were assessed weekly, measured, and imaged throughout the treatment course.

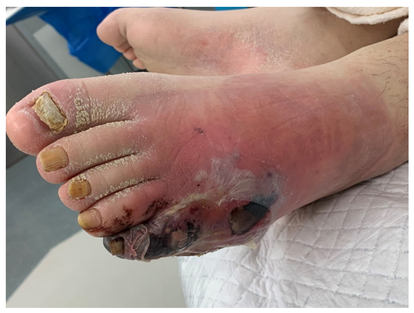
RESULTS

A total of 4 DFU wounds (n=4) were enrolled in the study, with an average wound area of 64.6 cm2 (range 28 to 130 cm2), and wound depth ranged from 2 to 5 cm. All wounds were treated with OFM as part of surgical debridement and soft tissue reconstruction. At 2 weeks, ¾ of the wounds were 100% granulated, covering previously exposed vital structures. The deepest wound had granulated by 6 weeks. All wounds healed during the course of the study (16 weeks). OFM was integrated in all wounds with no infection or complication. This preliminary study supports the use of OFM as a cost-effective clinically effective treatment option to granulate over exposed vital structures and shorten time to definitive closure

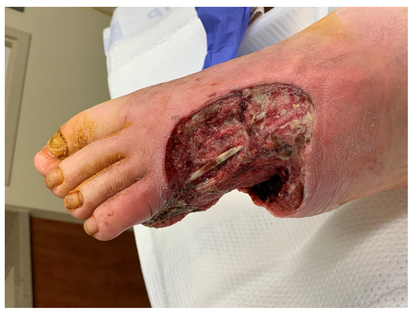
14 days
Median time to 100% granulation tissue

0%
Complication or Infection rate

CASE 1: 28-Year-old male diabetic with peripheral neuropathy, Wagner 4, necrotizing infection, fever and malaise.

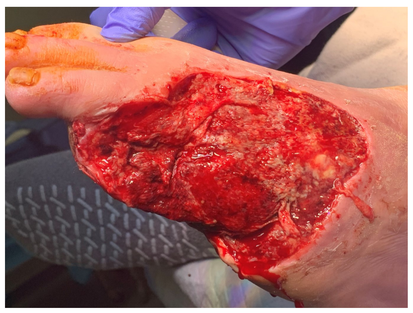


Week 0:



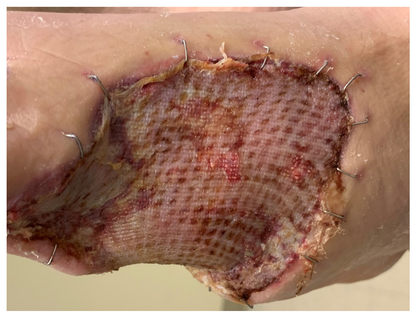
Partial 4th and 5th ray resection, exposed tendon and bone

Week 1:



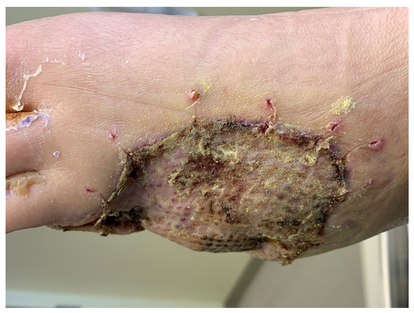
100% Granulation tissue – place STSG

Week 3:



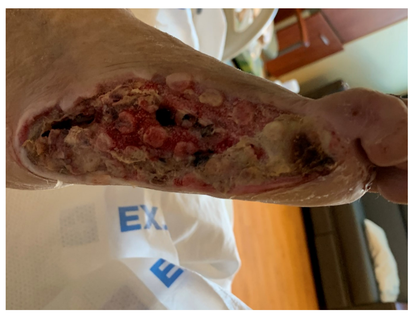
90% STSG take

Week 5:

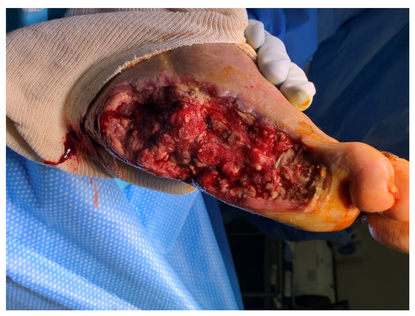


Healed

CASE 2: 73-Year-old male diabetic with CKD, peripheral neuropathy, prior partial 4th&5th ray resections, Wagner 4, necrotizing infection, fever and malaise

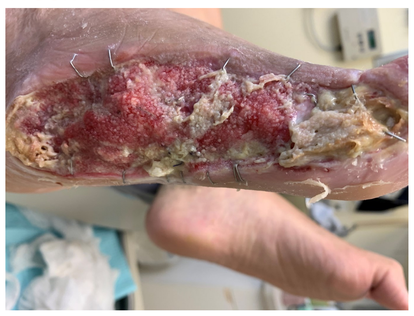


Week 0:



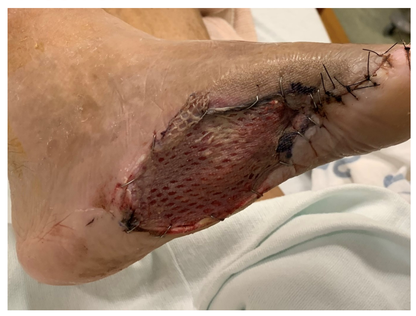
Sharp debridement, exposed bone and joint capsule.

Week 2:



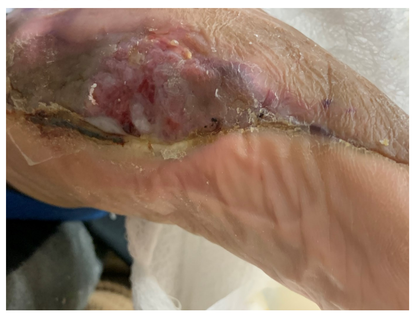
100% Granulation tissue

Week 8:



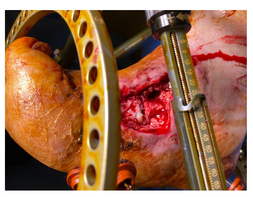
STSG placed

Week 16:

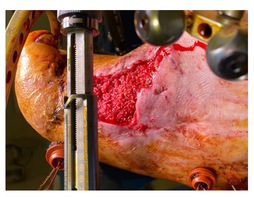


Healed

CASE 3: 52-Year-old obese male diabetic with Charcot, and peripheral neuropathy. Surgical dehiscence of Charcot reconstruction.

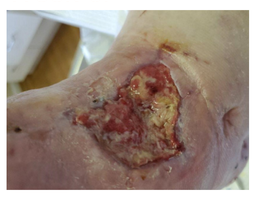


Week 0:



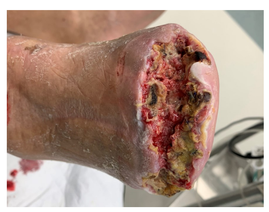
Sharp debridement; 7 x 6 x 5cm with exposed bone and joint. OFM particulate applied in void, covered with OFM sheet and NPWT

Week 6:



Sharp debridement; 7 x 6 x 5cm with exposed bone and joint. OFM particulate applied in void, covered with OFM sheet and NPWT

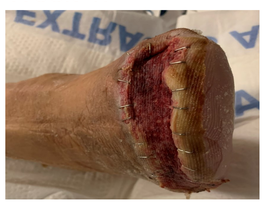
CASE 4: 54-Year-old male diabetic with PAD, peripheral neuropathy, TMA dehiscence.



Week 0:

Sharp debridement; 7 x 4 x 2 cm; exposed bone. OFM sheet applied with NPWT

Week 1:



100% granulation tissue coverage of bone, depth filled. Ready for STSG

REFERENCES AND DISCLOSURES

Product was provided by Aroa Biosurgery Limited (New Zealand). $^{\phi}$Myriad Matrix™ and Myriad Morcells™ (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.