Management of Venous Stasis Ulcers using Fetal Bovine Acellular Dermal Matrix and Fetal Bovine Acellular Dermal Matrix impregnated with Ionic Silver

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Study Purpose
Venous ulcers (VUs) account for the majority of lower extremity ulcerations. While compression therapy is the standard of care (SOC) for VUs, success rates range from 30 to 60 percent at 24 weeks (Margolis 2000).

Multiple clinical studies have reported Fetal Bovine Acellular Dermal Matrix (FBADM) was successful in healing VUs previously unresponsive to SOC therapy (Lullove 2012, Strauss 2012, Karr 2011). Furthermore, FBADM was found to be a faster and more cost effective treatment than a leading living skin substitute, saving an estimated $2100 per VU (Karr 2011).

FBADM is available in multiple sizes and configurations, including FBADM impregnated with Ionic Silver (FBADM Ag). We present a consistent treatment regimen used by our institution using FBADM and FBADM Ag for VUs in which standard of care treatment had failed.

Fetal Bovine Acellular Dermal Matrix
• Dermal repair scaffold composed of natural fetal bovine collagen fibers
• Up to five year shelf life, non-adherent, room temperature storage
• Available impregnated with Ionic Silver which inhibits microbial colonization of the matrix. The addition of Ionic Silver offers broad spectrum antimicrobial activity covering:
  • Both gram positive and gram negative bacteria
  • Resistant bacteria, such as methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant Enterococcus faecalis (VRE)

Methods
A retrospective study of five patients with eleven chronic VUs treated with FBADM (PriMatrix, TEL Biosciences Inc) and/or FBADM Ag (PriMatrix Ag Antimicrobial; TEL Biosciences Inc) in a wound care center is presented.

FBADM Application
In each case, solid or pre-meshed FBADM was applied to a bleeding wound bed with approximately 1 cm of overlaying uninfected tissue. FBADM immediately absorbed the patient’s blood, which simulated the scaffold with cells and growth factors important for healing.

Care was taken to ensure FBADM was in direct contact with the entire wound base, which permits cell migration and deposition of growth factors into the microscopic interstices of the fetal collagen scaffold.

Dressing Regimen
• A non-adherent contact layer was applied, secured in place with adhesive strips or staples with a fenestrated petrolatum impregnated gauze dressing
• Appropriate secondary dressings were selected to maintain moisture balance and protect the wound from infection
• Standard of care compression therapy consisted of a multi-layer compression bandage system
• Wound dressings were changed weekly during wound débridement and/or FBADM application was performed.

Case 1. Multiple Non-Healing Venous Ulcers

Patient History
• 61 yo male with type II diabetes, high cholesterol, obesity, chronic edema, and hypertension presented with six venous ulcers. Four of the six ulcers measured less than 10cm² but had been present for over one year despite compression therapy. The ulcers were located on the left lateral posterior leg, left distal anterior leg, right medial anterior leg, right lateral lower leg.

• At the time of presentation to our clinic, the patient was currently taking anticoagulants and antibiotics to treat an active infection. Doppler studies were performed to confirm an absence of arterial disease.

UlcercTreatments
• After a course of antibiotic therapy, the four ulcers were débrided and FBADM Ag was applied (left lateral posterior leg ulcer shown in Fig. 2A).
• The fifth ulcer was located on the right medial leg and measured approximately 4.2cm x 3.4cm (Fig. 3A).
• After an initial FBADM Ag application, FBADM was applied twice within three week intervals (Fig. 3B-C). The wound healed after 9 weeks (Fig. 3D).

Case 2. Non-Healing Venous Leg Ulcer

Patient History
• 73 yo female presented with a painful non-healing ulcer on the right lateral ankle measuring 2.5cm x 1.3cm x 0.1 cm. The ulcer had been present for approximately 5 years.
• The patient was allergic to multiple antibiotics and had a medical history of PVD, type II diabetes, obesity, tobacco use, and COPD.

• Doppler studies revealed triphasic waveform despite bilaterally elevated ABIs. An X-ray revealed extensive venous stasis calcification, but no bony disease. The patient was treated with mild compression therapy and various absorbent dressings and silver products.

UlcercTreatments
• After 208 days, wound cultures were negative for infection, but showed signs of chronic inflammatory disease. The wound bed now had minimal drainage, appeared red with minimal slough, but still measured 2.4cm x 1cm x 0.1 cm (Fig. 5A).
• The wound was débrided (Fig. 5B) and FBADM Ag was applied. Weekly dressing changes were performed without disturbing the primary non-adherent contact dressing (Fig. 5C).
• The wound closed just 4 weeks after FBADM application (Fig. 5D).

Summary of Case Results
• Average initial wound size was 3.8 x 5.7 cm²
• The average number of FBADM applications was 2.1 ± 1.6, ranging from 1-6
• Time to healing ranged from 21-112 days (3 - 16 weeks)

Conclusion
FBADM and FBADM Ag were successfully integrated into a sharp débridment and moist wound therapy protocol used by our institution for VUs in which standard of care treatment had failed.

We observed that by applying FBADM to a bleeding wound bed, the activated FBADM fully integrated with the wound base as soon as one week post-application. FBADM was reapplied every 2-3 weeks until wound re-epithelialization was evident. The total number of FBADM applications per wound and average time to healing compliment previously published literature (Karr 2011, Lullove 2012, Strauss 2012) and showcase best practices and techniques for the use of FBADM in recalcitrant venous ulcers.

References
1. Karr JC. Retrospective Comparison of Diabetic Foot Ulcer and Venous Stasis Ulcer Healing Outcome Between a Dermal Repair Scaffold and a Bilayered Living Cell Therapy. Adv Skin & Wound Care (2011)

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