DEHYDRATED AMNIOTIC MEMBRANE ALLOGRAFT THERAPY FOR COMPLICATED NON-HEALING WOUNDS: A PROMISING THERAPY WHERE OTHER TREATMENTS HAVE FAILED

Daniel J. Beless MD, FCCWS, FACEP and Belinda Marcus, MD, FACEP, CWS
Hyperbaric Physicians of Georgia

OBJECTIVE

Patients referred to wound centers frequently have complicated wounds and co-morbidities that contribute to poor wound healing. Amniotic allografts have been shown to promote healing for many years.

METHODS

This three patient case series demonstrates the effectiveness of Dehydrated Amniotic Membrane Allograft (DAMA)* on chronic non-healing wounds that have failed other advanced therapies. Two of these patients' wounds were present for greater than two years and were treated with the standard of care for advanced therapies, including negative pressure wound therapy (NPWT), multiple skin equivalents, and referrals to vascular specialists. Patients' wounds were deemed unable to heal due to co-morbidities.

RESULTS

All three cases responded positively to DAMA. Patients were able to avoid additional surgery, and wounds progressed to healing. Each of these patients had been treated with aggressive advanced wound care modalities to the extent their underlying condition allowed, but were trending toward failure and amputation. Average number of DAMA units utilized in these challenging patients was three. Patients' wounds were helped to heal in an average of 12 weeks.

CONCLUSIONS

Amniotic allograft demonstrated remarkable ability to help salvage complicated wounds in compromised hosts where other advanced wound care modalities had previously been unsuccessful. It should be considered as adjunctive modality for salvage of complicated wounds.

References: 1. Azuara-Blanco, A., Pillai, C.T., and Dua, H.S. Amniotic membrane transplantation for ocular surface reconstruction. Br J Ophthalmol. 1999; 83: 399–402 2. Eriksson, E. (2008), Guidelines for the treatment of wounds. Wound Repair and Regeneration, 16: 721–722. doi: 10.1111/j.1524-475X.2008.00425.x

*AMNIOEXCEL is a registered trademark of BioD, LLC made available by Derma Sciences Inc, Princeton, NJ
**Integra® Bilayer Wound Matrix®, Integra Life Sciences, Plainsboro, NJ
***Apligraf®, Organogenesis, Canton, MA
**** AMNIOMATRIX is a registered trademark of BioD, LLC made available by Derma Sciences Inc, Princeton, NJ

Derma Sciences provided an educational grant to support this research. The information may include a use that has not been approved or cleared by the Food and Drug Administration.

CASE 1

Patient is an immunocompromised host with prior history of Stage IV Non-Hodgkin's Lymphoma that had undergone total body radiation, chemotherapy, and had bone marrow transplant from his sister 19 years prior. Subsequently, he had developed Graft vs. Host disease, chronic sclerodermatitis with multiple ulcers, pulmonary fibrosis, and small arterial disease with chronic distal extremity ischemia. He had undergone BK level amputation of the right leg and post operatively developed focal skin necrosis of the central portion of the amputation flap. He underwent hyperbaric oxygen therapy (HBOT), IV antibiotics for wound infection, and advanced wound therapy, however, the wound stalled. Due to prior radiation and sclerodermatitis he was not a good candidate for traditional skin graft.

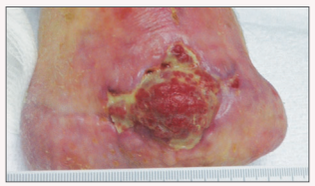
PMH: Stage IV Non Hodgkin's Lymphoma - s/p total body radiation, chemotherapy, bone marrow transplant (sister) 19 yrs prior. Graft vs. Host disease with pulmonary fibrosis, chronic sclerodermatitis with chronic ulcers, osteomyelitis, on chronic immunosuppression due to transplant and graft vs. host disease.

Treatments prior to DAMA: Hyperbaric oxygen therapy (HBOT), IV antibiotics for MRSA, silver gel, petrolatum gauze dressing, and debridement

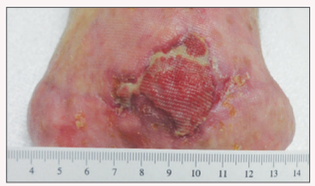
Application of DAMA: 2/26/14

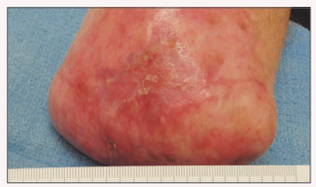

1/16/14


2/19/14


2/26/14


3/5/14


3/20/14


6/4/14

CASE 2

96-year-old male developed a non-healing ulcer following radiation treatment of a squamous cell cancer of left lower leg in 2012. Post radiation treatment, he developed progressive ulceration, tissue necrosis, chronic infection and the wound has large area of exposed tendon. The wound had profuse drainage and the patient had severe pain for 6 months prior to referral ,yet he remained ambulatory. Treatment prior to arrival included topical medicines and Dakin's soaked gauze.

Complicating issues include: advanced age, COPD on continuous O_2 @ 2lit / min, local radiation therapy, recurrent multidrug resistant *Pseudomonas* and MRSA infections, and recurrent pneumonia.

Vascular studies: ABI R leg 0.75, left leg (wound location) 1.0 but occlusion posterior tibial artery on Doppler.

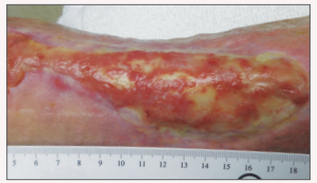
PMH: COPD O_2 dependent 2 lit /min, squamous cell cancer left lower leg treated with radiation therapy 2012, recurrent pneumonia, recurrent *Pseudomonas* and MRSA infection

Treatments prior to DAMA: Topical Dakin's soaked gauze, ultrasonic debridement of necrotic tissue, topical silver wound gel, IV antibiotics, negative pressure wound therapy, immobilization of limb, mild compression wrap. Patient was not candidate for HBOT due to severity of COPD.

Application of DAMA: 10/30/13, 11/20/13, 1/8/14, 5/8/14 and 6/4/14


10/2/13


12/23/13


2/5/14


3/12/14


6/18/14


8/26/14

CASE 3

43-year-old male with a non healing, chronic diabetic ulcer. Patient reports the left ulcer appeared in 5/2012 and progressed to a deep infection, requiring hospitalization and surgical debridement as well as IV antibotics.

PMH: Diabetes, recurrent infections, multiple surgical debridements.

Treatments prior to Cyropresevered Amniotic Suspension Allograft** **(CASA):** Debridements, IV antibiotics, bi-layered wound matrix**, bi-layered bioengineered skin substitute***.

Application of CASA: 7/10/13


3/19/13


7/10/13


7/17/13 – Day 7


7/23/13 – Day 14


7/31/13 – Day 21


10/15/13