

# DEHYDRATED HUMAN AMNIOTIC MEMBRANE ALLOGRAFT FOR WOUND CLOSURE AND MINIMIZING ADVANCED WOUND CARE COSTS

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## BACKGROUND

A leading concern in healthcare and a drain to healthcare costs is the continued rise of serious and significantly complicated chronic lower extremity ulcers.<sup>1,2</sup> In fact, the economic burden of chronic wound care on the US health system is \$25 billion.<sup>3</sup> It is imperative to bring advanced wound care treatments to market for these patients to ensure quality clinical outcomes, reduce or prevent amputation, and to effectively reduce the burden on overall healthcare costs. There is a rapidly growing trend in advanced wound care treatments toward the use of human and/or cellular tissue-based products (HCTP's). Healthcare practitioners have been using human amniotic membrane for wound treatments for nearly a century<sup>4</sup> but that practice became limited due to safety and disease transmission concerns. However, processes have been developed over the last several years which allow the amniotic membrane to be harvested, cleaned and sterilized for use as a tissue for tissue replacement. Beyond safety issues, variable pricing and clinical efficacy must also be considered when making clinical decisions. In a recent case series 3 patients having average wound chronicity of 18 weeks and closed wounds in an average of 7.5 weeks with 3-4 applications of Dehydrated Amniotic Membrane Allograft (DAMA)<sup>5</sup>. This case series demonstrates clinical efficacy and also considers the cost of this HCTP which is a relative newcomer to the advanced wound care market.

## METHODS

As part of a clinical efficacy product evaluation at this outpatient wound clinic, three patients were deemed appropriate and signed release of information/consent forms to be included in this case series. These 3 patients (2 male and 1 female), agreed to applications of DAMA on an every other week basis. All wounds were debrided to a clean viable wound bed prior to application and assessment of vascular status to support healing was confirmed. Age range for the patients: 26 to 61 years. Wound chronicity was from 14 to 38 months. Multiple other advanced wound treatments had been used including NPWT, other HCTP's and silver or collagen dressings. Number of DAMA applications and the cm<sup>2</sup> needed for coverage was recorded at each visit.

## RESULTS

Wound closure was achieved for all three patients' wounds with three to seven applications over a 6-8 week time period. Given the number of applications for each patient and amount of cm<sup>2</sup> of DAMA used for each patient, overall cost of product was only \$9,300 for all three patients. Assuming the same number of applications (14 total) with the appropriate size of tissue available, the costs for Dehydrated human amnion chorion membrane<sup>™</sup> (DHACM) would have been \$17,606.34 and Human fibroblast derived dermal substitute<sup>™</sup> (HFDS) would have been \$19,040. DHACM cost \$8,306.34 more and HFDS \$9,740 more.<sup>6</sup>

### Cost Comparison of 3 Products – 14 Total Applications

DAMA	DHACM	HFDS
\$9,300	\$17,606.34	\$19,040
<b>COSTS</b>	<b>\$8,306.34 more than DAMA</b>	<b>\$9,740 more than DAMA</b>

## CONCLUSIONS

Given the closure rate of these chronic wounds and the cost comparison for same amounts of other HCTP's this relative newcomer should be considered a credible option. These results indicate that larger scale randomized clinical trials that would evaluate BOTH clinical efficacy and healthcare economic benefits of using one HCTP over another are critical for making evidence based clinical decisions in advanced wound care.

References: 1. Boulton AJ, Armstrong DG, Ablert SF, Fikberg RG, Heikman R, et al. Comprehensive foot examination and risk assessment: A report of the task force of the foot care interest group of the AACE. Diabetes Care 2008; 31: 1679-1685. 2. Hozar SE, Cavetta A, Mareri L, et al. Costs and duration of care for lower extremity ulcers in patients with diabetes. Clin Ther 1998; 20:169-181. 3. <http://www.ncbi.nlm.nih.gov/pubmed/19903330>. 4. Davis JW Skin transplantation with a review of 550 cases at the John Hopkins Hospital. Johns Hopkins Med J. 1910; 15: 307-396. 5. Lintzeri, et al. Case Series Demonstrating the Impact of DAMA on Wound Healing in Acute and Chronic Wounds. Conference proceedings, Fall SNAWC 2014.

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<sup>\*</sup> Pricing based on Federal Government Supply Schedule 2014.

## CASE 1

26 y/o male with right lower extremity surgical dehisced wound. First seen in our clinic on 4/16/14. Very complex medical and surgical history related to Ewing sarcoma right lower extremity requiring excision and reconstruction of his tibia with free fibula from the contralateral side. His chart was reviewed and his surgical history goes back to 12/2013. Most recently on 4/2/14 he was taken back to the OR and had to undergo debridement of wound on left lower extremity, including tendon with bi-pedicle flap over anterior aspect of lower leg. On right leg he underwent debridement of skin and subcutaneous tissue with split thickness skin graft. Skin graft was taken from right thigh and applied right lower leg extremity wound and to left lower leg extremity flap donor site. His left leg was placed in a cast for immobilization post-op. Cast was removed day prior to him being seen in wound clinic. He had an area of exposed tendon at the flap donor site. Flap on anterior left leg and skin graft on right leg had taken on most of wound surface with small open area in each wound.

**Tx in wound clinic:** Immobilizing boot for leg, NPWT with hydrogel/collagen, Serial debridement including part of devitalized tendon.

**DAMA Applications:** Initial application of DAMA on 6/6/14 then 6/20/14 and 7/3/14. Complete re-epithelialization at last clinic visit 7/17/14.



5/2/14

6/6/14

7/8/14

## CASE 2

54 y/o female with PMH: SLE, HTN, osteoporosis, GERD, chronic prednisone therapy for SLE had been followed by foot/ankle and ortho surgeon and infectious disease doctors for ulcer present for > 1 year with concern for osteomyelitis on MRI. PSH: 01/2014 underwent debridement of chronic ulcer to sever hallux valgus deformity right foot. Culture was positive for *Pseudomonas* pathology but negative for osteomyelitis, treated with IV ABX. Surgical wound dehisced after suture removal and sent to wound clinic for treatment 03/2014.

**Initial wound evaluation:** 1.3 cm x 1 cm with 50% granulation and 50% fibrin/slough

**Vascular exam:** Palpable pedal pulses. Normal color and temperature, normal capillary refill. Severe hallux valgus deformity on right with ulceration to dorsal aspect of forefoot over deformity.

**Non-invasive vascular studies:** Normal TCPO2 to forefoot > 60, ABI 1.18 on right non-compressible on left.

Conservative local Tx was attempted with moist wound dressings, including initially antibacterial dressings followed by collagen dressings including trial of small intestinal submucosal wound matrix<sup>™</sup> with no significant improvement.

Once wound was clean from any devitalized tissue it was noted that 50% of surface had exposed capsule. NPWT was attempted to achieve granulation over capsule. Not successful after 2-3 weeks.

9/25/14 we initiated treatment with DAMA wound measured 0.8 cm x 0.9 cm with 50% granulation and 50% exposed capsule.

**DAMA Applications:** 9/25/14, 10/8/14, 10/23/14, 11/6/14. After 2nd application slight granulation over capsule was noted. After 3rd application area of exposed capsule was smaller with 80% granulation and 20% exposed capsule. This patient did not achieve complete closure by end of study period possibly due to other complications, but did have significant reduction in the exposed joint capsule being covered with granulation tissue.



9/25/14

10/8/14

11/6/14

## CASE 3

61 y/o male with chronic diabetic foot ulcer on left heel since Sept 2013. PMH: Severe PAD, uncontrolled DM with complications including retinopathy, CAD, neuropathy and Charcot arthropathy; chronic osteomyelitis. PSH: Trans-tibial amputation of right foot in 2012. After initial consultation with vascular surgery was decided to trial conservative management with local wound care and off-loading. Given that he did not respond we proceeded with angiogram on 9/3/13. Left lower extremity arteriogram with angioplasty of the left anterior tibial and peroneal arteries from a right femoral approach. In addition, he was started with an ArtAssist<sup>®</sup> to help with more collateral flow. MRI 9/5/14 showed early osteomyelitis. Infectious disease consulted and cultures grew MRSA and *Enterococcus*, he was started on IV antibiotics. He has had several periods of improvement followed by deterioration; he had refractory osteomyelitis and received course of HBOT and an additional course of IV ABX followed by oral antibiotics for chronic osteomyelitis. He remained on low dose doxycycline and cephalosporin. Second attempt at revascularization made in 05/14 but given severity of disease decision made to do bypass surgery; underwent left popliteal to dorsalis pedis bypass with reverse saphenous vein graft 5/9/14. He then had revision of the bypass 9/25/14 d/t re-occlusion.

During entire time we continued with local wound care utilizing moist wound dressings, debridement done as necessary, especially after revascularization procedures when had slightly better perfusion. 2 different attempts made to use NPWT and also had 3 applications of small intestinal submucosal wound matrix<sup>™</sup>, to which he did not respond to.

**DAMA Applications:** 6/27/14 1st DAMA application and additional applications: 7/11/14, 7/25/14, 8/8/14, 8/29/14, 10/17/14. On last visit, 11/14/14, wound was completely epithelialized.

(Note: reason for gap in application 8/29/14 to 10/17/14 is because he developed ischemic complications in hand and also had revision of bypass so missed some appointments with being in hospital multiple times and was away part of that time)



7/18/14

11/6/14

11/13/14