

USE OF DEHYDRATED AMNIOTIC MEMBRANE ALLOGRAFT TO FACILITATE LIMB SALVAGE AND FUNCTION IN PATIENTS AT HIGH RISK FOR AMPUTATION

Margaret Doucette DO, FABPM, CWSP

Chief, Physical Medicine and Rehabilitation, Medical Director; Amputee/Wound Care/High Risk Foot,
Boise VAMC – Boise, ID

OBJECTIVE

The objective of these case series are to establish the efficacy of a Dehydrated Human Amniotic Membrane Allograft* (DAMA) tissue dressing in successful limb salvage and restoration of limb function in patients at high risk for amputation.

BACKGROUND

Case # 1: 89 year old male with severe non-reconstructable PAD, s/p Left BKA with AKA pending due to post op traumatic injury.

DAMA was applied with wound size 5.0 cm x 4.7 cm with 2.3 cm x 1 cm exposed bone. After 8 applications, patient healed and was able to stand in parallel bars with prosthesis and ultimately was able to live independently.

Case # 2: 91 year old male with CVA, diabetes, ABI 0.49, DFU with exposed tendon with failed vascular intervention. Wound measured 1.2 cm x 1.2 cm x 0.7 cm and healed with 2 applications of DAMA. Patient is ambulatory with brace.

Case # 3: 67 year old male with Diabetes, Right BKA, Charcot Left foot, and DFU measuring 2.8 cm x 2.3 cm x 0.5 cm, healed with 5 applications of DAMA despite significant off-loading challenges.

Case # 4: 67 year old male with diabetes, ABI 0.79, Right great toe amputation with dehiscence. Received DAMA with wound 1.7 cm x 1.2 cm x 1 cm, healed with 1 application.

Case # 5: 64 year old male with diabetes, Right BKA, and pressure ulcer from prosthesis measuring 2.3 cm x 1.8 cm with depth to fascia. After 2 months without progress, DAMA applied x 3 with current wound measuring 0.3 cm x 0.5 cm with continuing progress.

RESULTS

All 5 patients healed /regained limb function with use of DAMA application.

CONCLUSIONS

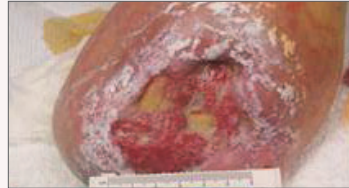
Of the diabetic or vascular patients who were non-healing and at risk for amputation. All of the wound wounds demonstrated healing or closure on average of 3.8 applications of DAMA. In the 2 patients with prior amputations, higher level of amputation was avoided. Our goal of treatment is to successfully salvage the limb and restore function to our veterans at risk for amputation. This treatment enabled all of our veteran patients to heal chronic wounds timely and maintain as much independence as possible.

*AMNIOCEL® is a registered trademark of BiO, LLC made available by Derna Sciences Inc, Princeton, NJ
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CASE 1

Risk Factors: Non-reconstructable vascular disease, failed BKA pending AKA.



4-24-14



5-1-14 – Patient had 2 significant areas of bone exposure, white wick sticking out was in a track of 2 cm length.



7-24-14 – Cyroreversed Amniotic Suspension Allograft™ was injected into the track. After one application the track closed.



9-9-14



After 8+ months of care, patient was able to use a prosthesis and able to live independently due to limb salvage.

CASE 2

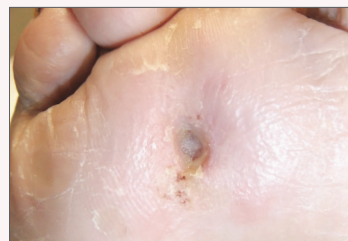
Risk Factors: ABI 0.49



4-24-14



5-23-14



6/6/14

In July the patient moved to Portland to be closer to family. As of 7-7-14, the VA in Portland reported patient tolerated independent ambulation and resumed wearing diabetic footwear with insert. No further follow up or photos were available.

CASE 3

Risk Factors: Contralateral BKA, charcot w/DFU, continued WB (weight bearing/walking).



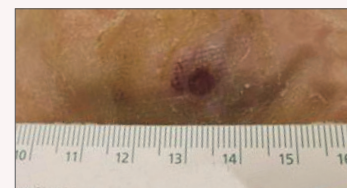
6-9-14



7-21-14



8-11-14



10-20-14

CASE 4

Risk Factors: Toe amputation site, continued smoking, non compliant w/off loading, HgA1C 14.



7-17-14



7-24-14



8-14-14



9-11-14

CASE 5

Risk Factors: Continued use of prosthesis, and wound to fascia.



8-20-14



9-11-14



10-2-14



11-10-14