

CASE SERIES DEMONSTRATING THE HEALING CAPABILITY OF DIABETIC FOOT ULCERS USING DEHYDRATED AMNIOTIC MEMBRANE ALLOGRAFT

Barry I. Rosenblum, DPM, FACFAS

Associate Chief of Podiatry, Beth Israel Deaconess Medical Center and Assistant Clinical Professor of Surgery, Harvard Medical School, Boston, MA

BACKGROUND

Non-healing diabetic foot ulcers (DFUs) are often the first step towards limb amputation in patients with diabetes.¹ Despite attempts at off-loading, establishing good arterial flow, and controlling infection, there is a subset of patients who do not show healing and amputation is eminent. Various types of advanced therapies have been developed with the goal of restoring the defective healing pathway seen in diabetic patients. Recently, dehydrated amniotic membrane allograft (DAMA) has been shown to initiate the cascade of healing in recalcitrant DFUs.²

METHODS

When first presented with a novel technology such as DAMA we often choose only the most challenging patients on which to evaluate as was the case with this series of 8 non-healing wounds. Eight patients with diabetes were identified having non-healing foot ulcerations where amputation was being considered as the next treatment option. The chronicity of the wounds ranged up to 3 years and these patients had undergone a variety of treatments, including bi-layer skin grafts³, silver dressings, negative pressure wound therapy (NPWT), aggressive debridement and attempts at off-loading with total contact cast. Having failed healing even with the advanced treatment modalities described above, these patients were chosen to have DAMA applied to their wounds.

RESULTS

In total, these 8 patients' wounds healed in an average of 8.2 weeks after an average of 2.75 DAMA applications. The average surface area of the wounds was 4.5cm² with the largest being 34.94cm². The largest wound healed in only 28 days after being present for 3 years.

CONCLUSIONS

This series describes patients who were at significant risk for amputation who had failed other advanced therapies. This data suggests that DAMA, in a select subset of patients with non-healing DFUs, can be beneficial in preventing amputation and in helping to heal wounds that have failed other advanced therapies.

SAMPLE CASES

CASE 1

54 year old male with history of diabetes, neuropathy, chronic osteomyelitis and multiple plantar amputations. Patient presented with a bilateral DFU over metatarsal head. Patient was selected for DAMA treatment after more than a year of failed standard wound care treatment which included; bi-layer skin grafts, NPWT, silver dressing, silvadene and betadine. Patient received a total of 3 DAMA applications with secondary treatments of petrolatum non-adherent gauze dressing⁴, gauze, and TCC. Wound size at initial application was 1.5 cm x 1.0 cm x 0.5 cm. By the second week wound size decreased to 0.9 cm x 0.4 cm x 0.2 cm and by week 3 wound measured 0.4 cm x 0.3 cm x 0.1 cm. Complete healing occurred 73 days after first application.



CASE 2

36 year old female with poorly controlled diabetes and neuropathy with chronic history of DFUs, and significant Charcot foot with left ankle medial aspect DFU. Patient had a long history of failed therapies which includes; NPWT, bi-layer skin grafts, betadine, and variety of advance wound care dressings including silver dressings. Patient was selected for DAMA treatment after more than a year of failed treatments. Patient received a total of 3 DAMA applications every two weeks with secondary treatments of petrolatum non-adherent gauze dressing, super absorbent dressings⁵ and TCC. Wound size at initial application was 5.8 cm x 4.3 cm x 0.8 cm. By the second application wound size decreased to 3 cm x 3.9 cm x 0.5 cm and by the third application wound decreased to 0.9 cm x 0.5 cm x 0.1 cm. Complete healing occurred 28 days after first application.

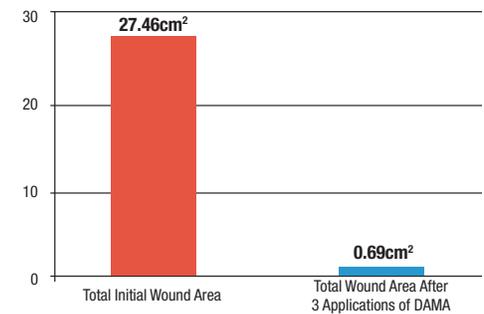


CASE 3

61 year old female with history of diabetes, neuropathy, osteomyelitis and Charcot foot. Long history of DFUs with Charcot deformity that has healed and reopened. Patient presented with right plantar mid foot ulcer. Patient has a long history of failed therapies which include: standard wound therapies, debridements, and calcium alginate dressings. Patient was a good candidate for DAMA due to long history of failed treatments. Patient received a total of 3 DAMA applications every two weeks with secondary treatments of petrolatum non-adherent gauze dressing, gauze and TCC. Wound size at initial application was 1.7 cm x 0.6 cm x 0.5 cm. By the second treatment wound decrease to 0.4 cm x 0.3 cm x 0.1 cm and by the third treatment reduced even further to 0.4 cm x 0.3 cm x 0.1 cm. Complete healing occurred 54 days after the first application.



Summary of Total Wound Area in Cases Above



References: 1. Incidence of diabetic foot ulcer and lower extremity amputation among Medicare beneficiaries, 2006-2008, www.afric.gov. 2. Zelen CA, Seneta TE et al. A prospective randomized comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. Int Wound J. 2013; 10(1): 1-6.

¹AMNIOCEL[®] is a registered trademark of B&D, LLC made available by Derna Sciences Inc., Princeton, NJ

²Apligraf[®], Organogenesis, Canton, MA

³ADAF[®] Syntegra, Gambek, UK

⁴XTRASORB[®] Dressings, Derna Sciences Inc., Princeton, NJ

Derna 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.