

USING DEHYDRATED HUMAN AMNIOTIC MEMBRANE ALLOGRAFT TO SUPPORT WOUND HEALING OF DIABETIC FOOT ULCERS

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BACKGROUND

Advanced wound care modalities and treatments are frequently used to facilitate healing of chronic lower extremity ulcers in patients with diabetes.¹

Dehydrated human amniotic membrane allograft (DAMA)[®] provides a matrix for cellular migration and proliferation with essential growth factors.² It has been used to treat a variety of wounds due to its non-immunogenic³, anti-inflammatory⁴ and anti-bacterial⁵ properties. This case series includes 3 patients with chronic diabetic foot ulcers (DFUs) treated with DAMA.

METHODS

DAMA was applied after a failure to demonstrate a 50% reduction in wound size after 4 weeks of treatment with advanced wound care, off-loading and other standards of care. This is based on the literature which demonstrates 50% area reduction as an effective predictor for treatment success.^{6,7} DAMA was applied every other week for a period of 4 weeks. Wound chronicity ranged from 2 months to one year. All wounds were debrided sharply as needed to achieve a clean wound bed prior to product application. Non-adherent dressing was applied over the product and then bolstered with a foam dressing. Patients were seen weekly in the clinic for wound assessment, measurement, photography and documentation of appearance.

RESULTS/CONCLUSION

These three patient cases did demonstrate that after slow or no improvement with standard wound care and advanced modalities such as negative pressure wound therapy (NPWT)[™] and bi-layered bioengineered skin substitute[™], application of DAMA led to a mean wound volume and area decrease which was clinically significant.

This case series illustrates the positive impact of DAMA on wound healing, supporting the use of this product in advanced wound care, particularly DFU's that have stalled or have slow healing and when other risk factors and co-morbidities make quick closure a priority.

References: 1. Høber SE, Camerota A, Marens L, et al. Costs and duration of care for lower extremity ulcers in patients with diabetes. Clin Ther 1998; 20:169-181. 2. Parolini O, et al. Human term placenta as a therapeutic agent: from the first clinical applications to future perspectives. In: Berben E, editor. Human placenta: structure and development. Hauppauge, New York: Nova Science Publishers; 2012. 1-46. 3. Ueda M, Kwon M-K, Sano Y, Sotocoro C, et al. Immunorepressive properties of human amniotic membrane for mixed lymphocyte reaction. Clin Exp Immunol 2002; 129:464-470. 4. Hsu Y, Ma SH, Huang DG, Kim WS, Zhang F. Identification of antiangiogenic and anti-inflammatory proteins in human amniotic membrane. Compa 2000; 19: 348-352. 5. Kjaergaard N, Hein M, Hyttel L, Helming PB, Schroyheyder HC, Uldbjerg N, Madsen H. Antibacterial properties of human amnion and chorion in vitro. Eur J Obst Gyn & Reprod Bio 2001; 94: 224-229. 6. Snyder R, Gardini M, Dargatzis D, et al. A post-hoc analysis of reduction in diabetic foot ulcer size at 4 weeks as a predictor of healing by 12 weeks. Ostomy Wound Manage. 2010; 56(3): 44-50. 7. Wainner RA, Snyder RJ, Cardinal MH. Differentiating diabetic foot ulcers that are unlikely to heal by 12 weeks following achieving 50% area reduction at 4 weeks. Int Wound J. 2011. 8:63-72.

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CASE 1

69 year old male with past medical history of diabetes, PAD and heart disease seen initially for evaluation on consultation in the hospital for diabetic infection of the right foot with underlying PAD. After successful re-vascularization, the patient subsequently underwent fourth and fifth ray resections with digital amputation. Given the large defect, the patient was placed on NPWT and partial closure of the wound was accomplished during his initial resection. The patient continued on appropriate antibiotics and referred to a skilled nursing facility. After completion of five weeks of NPWT and surgical debridement of wound, at week three post-op the patient underwent a bovine wound matrix application[™] and NPWT placed over and continued at 125 mmHg. At week seven post-op, the patient, having healthy granulation tissue and no exposed bone, was started on a course of treatment with DAMA. Immediately following applications of graft and over the course of the next seven weeks, use of NPWT at 125mmHg and proper off-loading was incorporated. Use of non-adherent dressing over the graft and between foam dressing was utilized. At week thirteen post-op, NPWT was discontinued and the patient started on a collagen dressing for 1 week. Thereafter the patient utilized Active Leptospermum Honey (ALH)[™] Gel dressing and dry protective dressing to closure at week twenty post-op.

DATE	WOUND MEASUREMENT	DATE	WOUND MEASUREMENT
2/14/14 – Initial DAMA application	4.4 x 2.0 x 1.0 cm	3/28/14	1.0 x 0.8 x 0.5 cm
2/21/14	3.5 x 1.5 x 0.9 cm	4/4/14	0.5 x 0.4 x 0.4 cm
2/28/14 – 2nd DAMA application	3.0 x 2.0 x 0.8 cm	4/11/14	0.3 x 0.3 x 0.4 cm
3/7/14	2.8 x 1.8 x 0.8 cm	4/18/14	0.3 x 0.3 x 0.3
3/14/14	2.0 x 1.5 x 0.7 cm	4/25/14	0.2 x 0.2 x 0.2
3/21/14 – 3rd DAMA application	1.3 x 1.0 x 0.6 cm	5/18/14	Wound closed



2/20/14



3/07/14



3/14/14



4/04/14

CASE 2

45 year old female with past medical history of diabetes, hypertension and renal disease seen for evaluation of recurrent left hallux ulceration. Patient was treated by outside physician for this ulceration for greater than three weeks with conservative modalities, including damp to dry dressing without off-loading. Patient has history of osteomyelitis in the same foot, which was treated with surgical resection several years prior and deemed non-contributory. Initial wound care after presentation with off-loading utilizing CAM walker and conservative measures consisting of ALH dressing, followed by silver dressings for four weeks. At this time, after failing seven weeks of conservative management and with four weeks of proper debridement and off-loading, the patient being an appropriate candidate initiated treatment with DAMA. Between applications of DAMA over the course of eight weeks until closure, use of ALH dressing and proper off-loading was incorporated.

DATE	WOUND MEASUREMENT	DATE	WOUND MEASUREMENT
3/10/14 – Initial application DAMA	4.4 x 2.0 x 1.0 cm	4/10/14 – 3rd DAMA Application	0.8 x 1.0 x 0.2 cm
3/14/14	2.5 x 3.0 x 0.3 cm	4/15/14	0.6 x 0.6 x 0.1 cm
3/19/14	2.0 x 2.8 x 0.3 cm	4/22/14 – 4th DAMA Application	0.4 x 0.4 x 0.1 cm
3/25/14 – 2nd DAMA Application	1.0 x 2.7 x 0.3 cm	5/6/14	0.2 x 0.1 x 0.1 cm
4/2/14	1.0 x 1.1 x 0.3 cm	5/13/14	Wound Closed



3/10/14



3/28/14



4/15/14



5/06/14

CASE 3

68 year old male with past medical history of diabetes, peripheral arterial disease, hypertension and foot ulceration seen on consultation in the hospital initially for non-healing left foot ulceration of six months duration. Patient had undergone attempted percutaneous revascularization and was deemed to have sufficient flow for healing of lower extremity wounds.

Patient was taken to the OR and underwent incision and debridement with fifth digit amputation and fifth ray resection. Given active infection, patient was placed in NPWT at 150 mmHg, was placed on appropriate IV antibiotics and was placed in a skilled nursing facility. Two weeks post-operatively and again at four weeks post-operatively, the patient underwent grafting with bovine tissue matrix. At week eight post-op, the patient, having healthy granulation tissue and no exposed bone, was started on a course of treatment with DAMA. Immediately following applications of DAMA and over the course of the next seven weeks, use of NPWT at 150mmHg and proper off-loading with a CAM walker boot was incorporated. Use of non-adherent dressing over the graft and between foam dressing was utilized. NPWT was discontinued at week sixteen and subsequent grafts were applied with non-adherent dressing and dry protective dressing applied. The wound was near closure on 8/13/14 and patient was then lost to final follow-up.

DATE	WOUND MEASUREMENT	DATE	WOUND MEASUREMENT
5/5/14 – Initial DAMA application	5.8 x 3.0 x 0.4 cm	6/19/14	3.5 x 1.0 x 0.4 cm
5/14/14	5.4 x 2.8 x 0.4 cm	7/9/14 – 3rd DAMA Application	3.0 x 0.5 x 0.4 cm
5/23/14	5.0 x 2.2 x 0.4 cm	7/23/14	2.0 x 0.5 x 0.4 cm
5/28/14	5.0 x 2.0 x 0.4 cm	8/6/14	1.5 x 0.4 x 0.3 cm
6/6/14 – 2nd DAMA Application	5.0 x 1.1 x 0.4 cm	8/13/14	1.2 x 0.3 x 0.2 cm



5/05/14



5/14/14



8/13/14