

Application of Dehydrated Human Amnion/Chorion Membrane Allograft to Promote Healing of Recalcitrant Wounds in 40 Patients

Laura Heath, DPM, Robert Frykberg, DPM, MPH
Edward Tierney, DPM, Jaminelli Banks, DPM

Desert Foot Conference November 19-21, 2014,
Phoenix, AZ

Phoenix VA Healthcare System

Background

- It is estimated that \$50 billion are spent yearly on wound care within the US and worldwide⁶
- Wounds can be caused by diabetes, trauma, PAD and venous insufficiency
- 2% prevalence of a chronic wound the general population⁶
- Annual cost of wound care on 1 patient is \$30,000
- Venous stasis wounds account for ~50% of all lower extremity wounds
- It is estimated that by 2025, 300 million people worldwide will have diabetes
- Diabetes increases the risk for the development of foot ulcers due to sensory and autonomic neuropathy which reduces sensation leading to weaker tissue
- Diabetics are at a 15-20% risk of a wound in their lifetime
- Diabetic ulcers generally heal slower than a healthy adult and are often complicated by infection³⁻⁵
- Given the clinical risks and high costs associated with treating lower-extremity ulcers, the development of treatment strategies to improve healing rates and reduce time to healing is warranted.
- There have been numerous clinical trials reporting the success of human skin equivalents in promoting rapid healing of chronic diabetic foot ulcers, when compared with standard therapy.

Dehydrated Human Amnion/Chorion Membrane (dHACM)

- PURION[®] Processed dehydrated human amnion/chorion membrane (dHACM) has been shown to contain growth factors that help in wound healing, including PDGF-AA, PDGF-BB, bFGF, TGF-β1, EGF, VEGF, and PIGF, as well as anti-inflammatory interleukins (IL-1ra, IL-4, IL-10), and TIMP-1, TIMP-2, TIMP-4, which help regulate the matrix metalloproteinase activity.¹
- There is increasing evidence that the use of an allograft consisting of dHACM can reduce time to healing of recalcitrant foot ulcerations.²⁻⁴

Purpose

The purpose of this study is to report the use of dHACM in treatment of both diabetic and non-diabetic chronic lower extremity ulcerations in our patient population.

Methods

This is a retrospective study of 40 patients successfully treated with dHACM allograft.

Included

- This study included both diabetic and non-diabetic patients receiving treatment for a chronic lower extremity ulcer that failed to heal for at least 4 weeks.
- We compared wound sizes at initial application, time to healing and number of graft applications between the two groups.

Treatment

- Treatment regimens include sharp debridement to remove non-viable tissue, weekly observational visits and therapies.
- Adjunctive elements include use of moist dressings, antibiotic ointment, NPT and when appropriate, compression, splinting and full-contact casting for pressure distribution.

Results

- 40 total patients treated with dHACM graft to full epithelialization
 - 39 men, 1 woman
- Mean age – 64.3 years (63.5)
- Mean weeks to healing – 5.9 weeks(5)
- Mean number of graft applications – 3.25 (3)
- Mean size of wound at initial application – 3.36cm² (1.5cm²)
- 55% (22/40) of patients were diabetic
 - Of the diabetic population mean Hemoglobin A1c 8.25 (Range 5.4 - 12.9)
 - All of the diabetic population had a form a neuropathy
- 20% of patients had chronic kidney disease
- 22.5% of patients had peripheral vascular disease
 - Mean ABI on affected side 1.36 (Range 0.46 – 1.83, Median 0.87)
 - Patient with ABI of 0.46 took nearly longest to heal at 15 weeks
- 11 wounds were post operative including both dehiscence and intentionally left open wounds post I&D
- Follow up ranged from 4 – 108 weeks

All values in parentheses are median values

References

- Koob TJ, Rennett R, Zabeck N, et al. Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing. *Int Wound J* 2013 Oct;10(5):493-500.
- Zelen CM. An evaluation of dehydrated human amniotic membrane allografts in patients with DFUs. *J Wound Care*. 2013a;22(7):347-348, 350-351.
- Zelen CM, Serena TE, Denoziere G, Fetterolf DE. A prospective randomized comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. *Int Wound J*. 2013;10(5):502-507.
- Zelen CM, Serena TE, Snyder RJ. A prospective, randomised comparative study of weekly versus biweekly application of dehydrated human amnion/chorion membrane allograft in the management of diabetic foot ulcers. *Int Wound J*. 2014;11(2):122-128.
- Sheikh, E, et al. "Use of dehydrated human amniotic membrane allografts to promote healing in patients with refractory non healing wounds." *International Wound Journal* 2013
- Fife, Caroline E., MD, CWS, et al. "Wound Care Outcomes and Associated Cost Among Patients Treated in US Outpatient Wound Centers: Data From the US Wound Registry" *WOUND:S* 2012;24(1):10-17

Results cont.

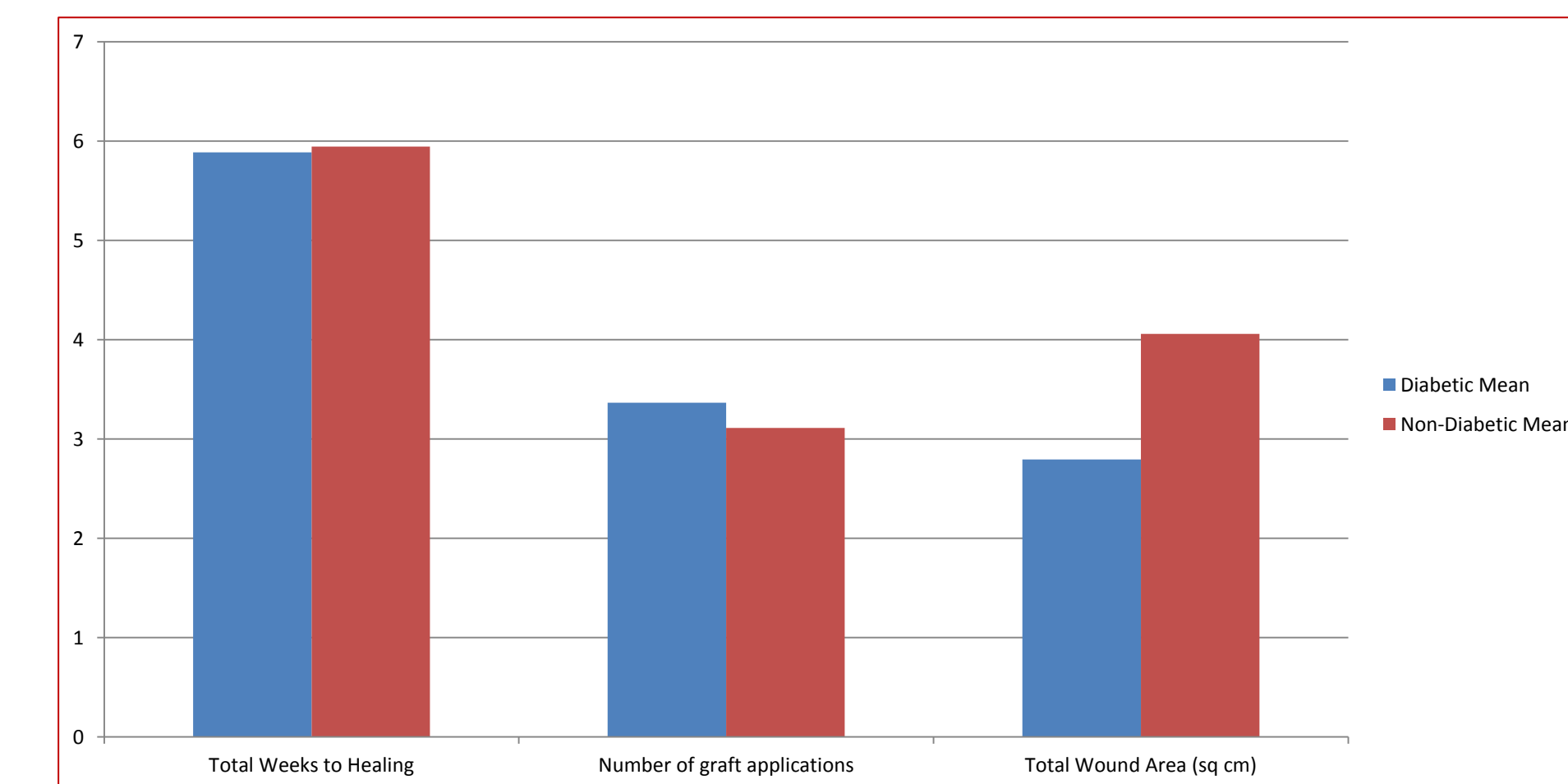
Case Example

- 68 year old diabetic male with history of chronic kidney disease as well as long history of carcinomas
- 5 weeks s/p BCCA excision
- Initially plan for NPWT post operatively, but able to close primary in OR
- Initial measurements 1.0cm x 1.0cm proximal and 1.0cm x 0.7cm distal
- Concurrently began radiation treatment for throat cancer at time of surgery



	Diabetic n=22	Non- Diabetic n=18	Overall n=40
Age (years)	65	63.4	64.3
HgA1c	8.25		
Wound Size at 1 st dHACM	2.79 cm ²	4.06 cm ²	3.36 cm ²
dHACM Applications	3.36	3.11	3.25
Weeks to Closure	5.89	5.94	5.91

Data presented as averages.



Conclusions

- Dehydrated human amnion/chorion membrane allograft is a viable option for treatment of patients with ulcerations refractory to standard of care therapy.
- dHACM is an option for treating diabetic wounds as well as venous, traumatic or post operative wounds
- Treatment should be monitored weekly to assess true healing.