Treatment of Lower Extremity Chronic Wounds with Dehydrated Human Amnion/Chorion Membrane (dHACM): A Vascular Compromised Cohort (ABI<.65)

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Background

There are currently no advanced wound healing modalities indicated specifically for patients with chronic lower extremity wounds having ankle-brachial index (ABI) of ≤ .65. dHACM (EpiFix®/AmnioFix®) is minimally manipulated dehydrated human amnion/chorion membrane allograft. It is an operationally and clinically efficient material available in multiple sizes that can be transported and stored at ambient temperature for 5 years, reducing wastage and eliminating sub-zero storage issues.

Purpose

To measure dHACM's healing potential in documented chronic wounds (≤50% surface area reduction in 4 weeks) with vascular compromise (ABI ≤.65).

Methods

- We identified patients with wound chronicity and abnormally low ABIs, having the most commonly seen chronic wound types in our clinic: plantar surface diabetic ulcer, mixed arterial/venous wounds, surgical dehiscence post BPG, and guillotine type amputation.
- Patients were seen weekly or bi-weekly based upon wound severity and received a minimum documented 4 weeks of standard wound treatment with ≤50% wound closure during the time frame prior to initiation of dHACM therapy.
- Standard care consisted of: wound measurements, sharp debridement, appropriate off loading, compression, and dressings.
- Patients received the same level of care after initiation of dHACM.
- Both micronized and sheet formulations of dHACM were utilized.
- dHACM was applied on a bi-weekly basis.

Results

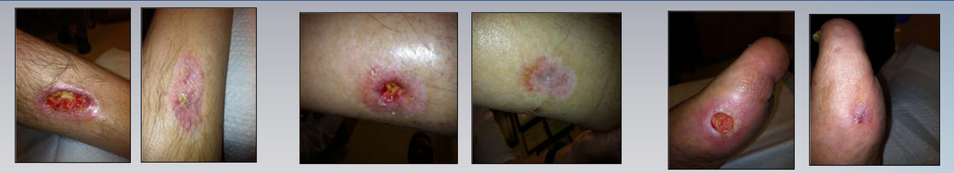
	Average	Range
ABI	.48	(.26-.62)
Wound Age	15.5 weeks	(6-24 weeks)
Wound Size	18.35 CM^2	(1-70 CM^2)
Applications to Closure	4.4	(1-7)
Cost to Closure	$3015.80	($895-$6779)
Weeks to Closure	7.42	(2-14)

SB225.001

Cases

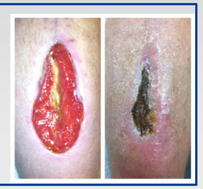
Mixed Etiology Venous/Arterial in Paraplegic

- Medical hx: 65 yo, CVA, GERD, HTN, Meniere's Disease, Paraplegic (Gun shot wound), Neurogenic Bladder, AAA. Surgical hx: Coccyx Flap
- ABI – .46
- 3 wounds of 6 month duration: left shin (4.2x2x.5cm), calf (1x1cm), and toe (1.2x1.2 cm)
- Shin healed after 3 dHACM applications. Calf and toe after 4 applications



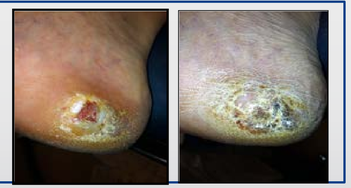
Fem/Distal BPG Dehiscence

- Medical hx- 62 yo, PVD, HTN, HDL, PTSD, Bipolar, Neuropathy, Hyperkalemia, DM
- Surgical hx- Right Fem/Pop, Duodenal Sphincter Repair, Lumbar Repair, C4/C5 fusion, Penile implant, Right Fem/Distal BPG
- ABI - .26 (occluded graft)
- 6 week history of Pretibial dehiscent wound 8 x 3.5 cm, with exposed tendon
- Dopplerable pulse after 4 applications. Complete closure after 6 applications of dHACM



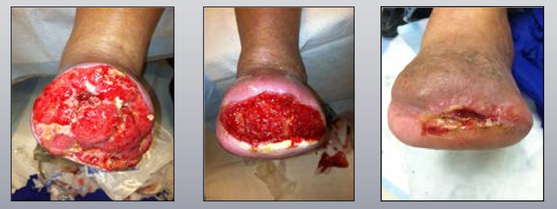
Plantar Surface DFU

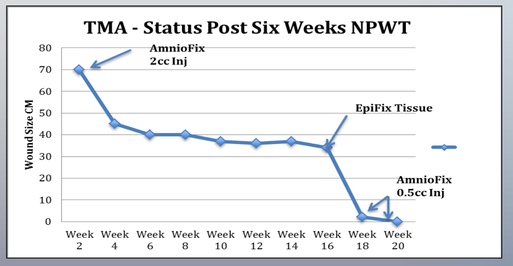
- Medical hx – CKD III, DM, CAD, Neuropathy, Depression, Claudication
- Surgical hx – PTCA
- AIC – 7.4; Albumin – 3.7; ABI - .57; Tcpo2 – 35
- Right medial Ulceration with 9 week Duration – 1.4 x .9 cm
- 3 dHACM applications 6 weeks – closed



TMA – 6 weeks NPWT

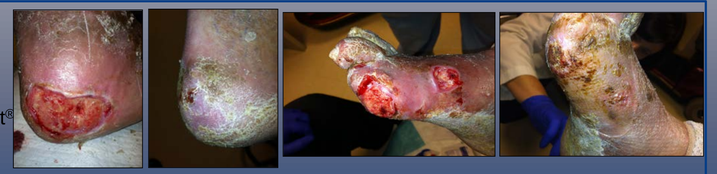
- Medical hx- – DM, GERD, CKD III, anemia, CBP, Arthritis, Pancytopenia, IGA, Neuropathy, Diverticulitis
- Surgical hx- – left TMA
- AIC-9.2; Albumin 4; ABI - .62; TCPO2-16
- 6 weeks V.A.C. ® post TMA – 10x7cm with 2.5cm track to first met
- Treatment 2cc dHACM injection x3 and dHACM allograft x1
- Healed after 4 applications





Contralateral BKA/ Mixed Arterial/Venous

- Medical hx- 65yo, DM, Neuropathy, HTN, CAD, Venous Stasis
- TCPO2-22; A1C- 11.5
- Previous Tx – Unna's boot, Medihoney®, Dermagraft®
- Wound Age – heel 14 weeks, VLU 36 weeks, 4 weeks 1st MPJ and Dorsal
- 1st MPJ healed 1 application, 5th MPJ healed 5 applications, Heel healed after 7 applications.



Conclusion

While larger, randomized controlled clinical trials may be needed to validate our findings, we believe dHACM to be an extremely efficacious and cost effective alternative in patients failing to achieve appropriate wound area reduction in a timely manner. In this subset of patients, when compared to our previously utilized advanced wound care modalities, we realized a 75% cost savings.