Use of a Novel dHAM Amniotic Tissue Allograft* in the Treatment of Lower Extremity Wounds

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ABSTRACT

PURPOSE: To prove the efficacious use of a new dHAM amniotic allograft in lower extremity wounds.

BACKGROUND: Injuries to the skin are extensively costly to the healthcare system. These injuries when caused from metabolic and vascular compromise are even more foreboding for patients. These injuries can result in chronic inflammation, reduced mobility and chronic pain.

METHODS: A retrospective cohort study of 20 patients were selected from the treating physician's own patient population at a single clinical site. Patients underwent a run-in period of 2 weeks, where standard of care was used to clear the wound of bioburden. Applications of novel dHAM amniotic allograft were done at week 1 (2 weeks post run-in), week 3 and week 5, if necessary. Wound measurements were recorded weekly and photographs of the wound were performed weekly. Data was collected through a standard form in each patient's medical record to improve reliability and reproducibility. The data extraction was performed by the primary author and to reduce bias.

CONCLUSIONS: In this review of 20 patients treated with a novel dHAM amniotic allograft, the author was able to effectively close all wounds in approximately 9.9 weeks (58 days). A linear relationship was discovered between wound size in cm^2 and days to closure. Diabetic foot ulcers closed on average in 11.8 weeks (82.6 days), and venous leg ulcers closed in 9.2 weeks (64.4 days). No adverse events were noted secondary to novel dHAM amniotic allograft application, noting that this is a safe and effective treatment option. As of the date of this publication, there are no recurrences of the ulcerations noted.

METHODS

SETTING: A retrospective cohort study of 20 patients were selected from the treating physician's own patient population at a single clinical site.

SAMPLE: Age ranges were from 55 to 100 with a median of 74.5 years. 9 patients are male and 11 patients are female. BMI ranged from 24.85 to 41.19 with a median BMI of 28.40. Wound sizes ranged from 2.0 cm^2 to 14.5 cm^2 with a median of 7.45 cm^2. Wound types were as follows: venous leg ulcer (n=10), diabetic foot ulcer (n=8) and other autoimmune (n=2). 8 of the 20 patients were diagnosed with peripheral arterial disease (40%), while in total, 14 of the 20 patients (60%) had peripheral vascular disease.

MEASURES: Wound measurements (in cm) and photographs of the wound were performed and recorded weekly. Data was collected through a standard form in each patient's medical record to improve reliability and reproducibility.

INTERVENTION: All subjects completed the study protocol without fall-out. Application of the dHAM was performed at week 1, 3 and 5. No adverse effects reported nor were there any medical interventions made that compromised the study population.

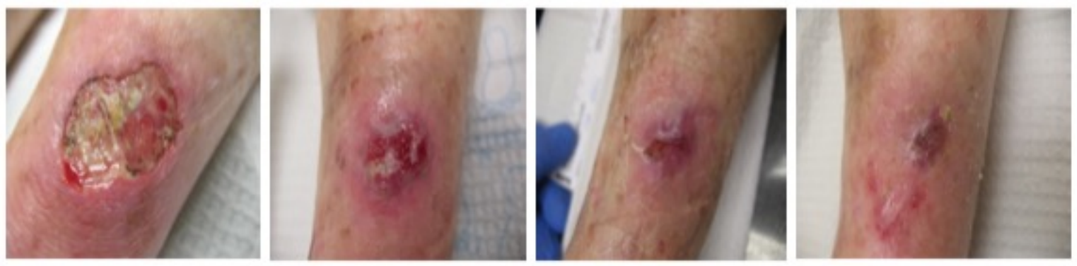
ANALYSIS: A linear regression relationship was noted via a Pearson Coefficient (0.46 to standard) was noted significantly showing linear healing rates within this cohort protocol from wound size and days to closure.

BACKGROUND

Venous leg ulcers are the most common wound type in the United States and affect between 500,000 to 2 million people annually.[1] In the United Kingdom, for example, the median duration of venous ulcers is 9 months, and 20 percent of ulcers do not heal within 2 years.[2] Diabetic foot ulcers are less common but more costly in the United States. An estimated 29.1 million people have diabetes mellitus[3], and the estimated lifetime incidence of a diabetic foot ulcer is 25%.[4] Diabetic foot ulcers continue to be a major cause of morbidity and immobility are a leading cause of nontraumatic lower extremity amputation. The annual cost of diabetic foot ulcers was $245 billion in 2012.[5] While $70 billion of this cost was associated lost work production, the remaining $176 billion was incurred as excess healthcare expenditures.[5] This population also has a three-year cumulative mortality rate of 28%.[6]

LIMITATIONS

The limitations with retrospective cohort studies of this type result in major biases that impact the recall of former exposure to risk variables. Among the biases which can negatively impact the veracity of this type of study are selection bias and misclassification or information bias as a result of the retrospective aspect. With retrospective studies, the temporal relationship is frequently difficult to assess. The primary investigator in this retrospective study could not control exposure or outcome assessment but instead had to rely on patient compliance. Due to the small nature of the study population, rare occurrences of wound healing cannot be measured without a larger sample of study patients.



Initial Presentation | 4 weeks | 8 weeks | Closure 12 weeks

Case Study: 79 y/o female patient with history of severe LE edema and CAD presented with non-healing wound to posterior left leg. Surgical debridement performed under study protocol with 3 applications of dHAM.

RESULTS

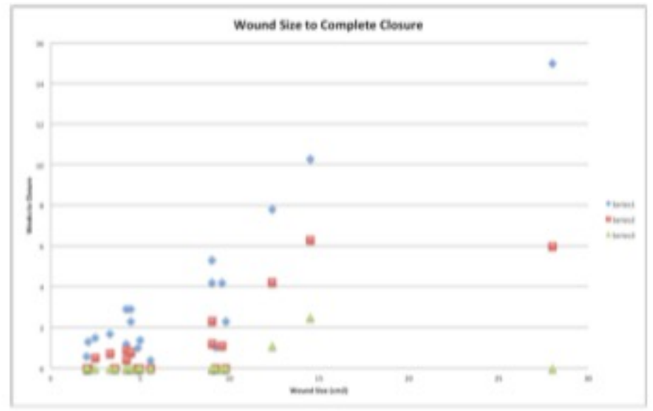
Table 1: Demographic Data

Patient	Age	Gender	BMI	Location	Etiology
1	69	F	26.45	FOOT	RA
2	100	M	27.89	LEG	CAD,CVI, VLU
3	78	F	26.63	FOOT	RA
4	68	M	37.3	FOOT	DM
5	74	M	25.84	FOOT	DM
6	62	F	26.57	LEG	CVI, CAD, VLU
7	62	F	26.57	LEG	CVI, CAD, VLU
8	62	F	26.57	LEG	CVI,CAD, VLU
9	79	F	29.12	LEG	CVI, VLU
10	81	M	35.94	FOOT	DM
11	90	F	24.66	LEG	CVI, VLU
12	82	M	26.32	FOOT	OM, Trauma, DM
13	74	F	23.94	LEG	CVI,VLU
14	89	M	27.73	LEG	CVI, VLU
15	58	M	41.19	FOOT	DFU
16	75	F	22.42	LEG	CVI,VLU
17	55	M	32.28	FOOT	DFU
18	92	F	24.85	LEG	CVI, VLU, PAD
19	56	F	27.3	VLU	DM,PVD,Autoimmune
20	62	M	28.5	FOOT	DFU, HIV

Table 2: Closure Results

Patient	Initial Size	4 weeks	8 weeks	12 weeks	# Applications	Weeks to Closure
1	2.1	1.3	0	0	2	6
2	4.88	1	0	0	2	6
3	2	0.6	0	0	2	5
4	28	15	6	0	3	12
5	4.2	1.2	0.4	0	3	11
6	5.6	0.4	0	0	2	6
7	9.24	1.05	0	0	2	7
8	9.8	2.31	0	0	2	6
9	9	5.32	1.2	0	2	12
10	3.6	0	0	0	1	4
11	3.3	1.7	0.7	0	3	10
12	14.5	10.3	6.3	2.5	3	26
13	9.6	4.2	1.1	0	3	12
14	4.5	2.3	0.8	0	3	10
15	2.5	1.5	0.5	0	3	12
16	12.4	7.8	4.2	1.1	3	14
17	4.2	2.9	0.9	0	3	11
18	4.5	2.9	0.8	0	3	9
19	5	1.4	0	0	2	7
20	9	4.2	2.3	0	3	12

Figure 1: Wound Size to Closure



DISCUSSION

In this review of 20 patients treated with this novel dHAM amniotic allograft, the author was able to effectively close all wounds in approximately 9.9 weeks (58 days). A linear relationship was discovered between wound size in cm^2 and days to closure. Diabetic foot ulcers closed on average in 11.8 weeks (82.6 days), and venous leg ulcers closed in 9.2 weeks (64.4 days). No adverse events were noted secondary to novel dHAM amniotic allograft application, noting that this is a safe and effective treatment option. More importantly, the average closure rate of 46% at 4 weeks is demonstrative of accelerated wound healing in populations with severe comorbidities and obesity factors. The average wound healing time was 58 days. These findings support the use of this particular dHAM CTP in the treatment of these patient populations.

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The investigator maintained complete independence in the conduct of this research

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