Clinical and Cost Effectiveness of Dehydrated Human Amniotic/Chorionic Membrane Allografts for the Treatment of Non-Healing Wounds

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Abstract

Rapid and complete wound healing reduces the risk for infection and amputation, and can improve quality-of-life while decreasing financial burdens to the individual and society.(1) For >100 years, human amniotic membrane has been used in a variety of clinical applications.(2,3) The development of a process to clean, sterilize, and dry human amnion/chorion membrane obtained from screened and tested donors has resulted in a dehydrated human amnion/chorion membrane (dHACM) allograft available in various configurations and sizes which can be stored at ambient temperature for up to 5 years.(4) Our purpose was to evaluate the clinical and cost effectiveness of dHACM in a series of patients with non-healing wounds. We conducted a chart review of six patients with 9 non-healing wounds (7 diabetic foot ulcers, 1 surgical wound and 1 venous leg ulcer) treated with bi-weekly application of dHACM for a maximum of 10 weeks. Treatment consisted of bi-weekly dHACM application after sharp debridement as needed, followed by standard topical dressings. Weekly dressing change and wound assessment to determine rate of closure based on complete epithelialization of prior wound bed was performed. Cost comparisons were made using list pricing and assuming equal effectiveness of dHACM versus treatment with Human Fibroblast Derived Dermal Substitute (HFDDS). Within 4 weeks of dHACM initiation, the average wound area reduction was 67% and complete epithelialization occurred in 2 of 9 wounds. Mean number of dHACM applications was 3.2 per wound. Mean cost of dHACM per wound was $1562 compared to $8722 if the wound had been treated with HFDDS. Use of dHACM versus HFDDS resulted in an overall cost savings of $64,444, or $7160 per treated wound. The availability of multiple graft sizes and positive clinical outcomes may influence cost effectiveness of dHACM. dHACM appears to be a cost effective option for the treatment of non-healing wounds.

Background

Rapid and complete wound healing reduces the risk for infection and amputation, and can improve quality-of-life while decreasing financial burdens to the individual and society.(1) For >100 years, human amniotic membrane has been used in a variety of clinical applications.(2,3) The development of a process to clean, sterilize, and dry human amnion/chorion membrane obtained from screened and tested donors has resulted in a dehydrated human amnion/chorion membrane (dHACM) allograft available in various configurations and sizes which can be stored at ambient temperature for up to 5 years.(4)

*Dehydrated human amnion/chorion membrane (dHACM *)*

- PURION® processed dHACM has been shown to contain many growth factors that help in wound healing, including PDGF-AA, PDGF-BB, bFGF, TGF-β1, EGF, VEGF, and PlGF. (5)
- In addition to growth factors, cytokines including anti-inflammatory interleukins (IL-1ra, IL-4, IL-10) and the TIMPs (TIMP-1, TIMP-2, TIMP-4) which help regulate the matrix metalloproteinase (MMP) activity are also present in dHACM.(5)
- Results from *in vitro* and *in vivo* experiments clearly established that dHACM contains one or more soluble factors capable of stimulating local mesenchymal stem cell migration and recruitment. (5)
- PURION® processed dHACM has been shown to retain biological activities related to wound healing, including the potential to positively affect four distinct and pivotal physiological processes intimately involved in wound healing: cell proliferation, inflammation, metalloproteinase activity, and recruitment of local progenitor cells. (5)

Study Design and Purpose

We conducted a chart review to evaluate the clinical and cost effectiveness of dHACM in a series of patients with non-healing wounds.

Methods

Included

- Six patients with 9 non-healing wounds (7 diabetic foot ulcers, 1 surgical wound and 1 venous leg ulcer) treated with bi-weekly application of dHACM for a maximum of 10 weeks.

Treatment

- Treatment consisted of bi-weekly dHACM application after sharp debridement as needed, followed by standard topical dressings.

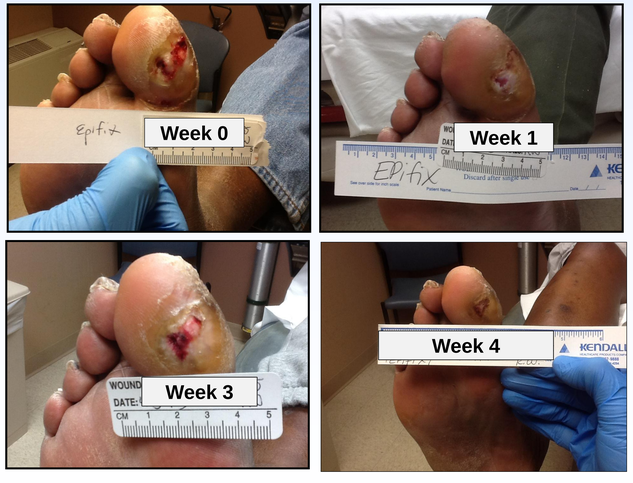
Analysis

- Weekly dressing change and wound assessment was performed to determine rate of closure based on complete epithelialization of prior wound bed.
- Cost comparisons were made using list pricing and assuming equal effectiveness of dHACM versus treatment with Human Fibroblast Derived Dermal Substitute (HFDDS).

Results

- Within 4 weeks of dHACM initiation, the average wound area reduction was 67% and complete epithelialization occurred in 2 of 9 wounds.
- Mean number of dHACM applications was 3.2 per wound.
- Mean cost of dHACM per wound was $1562 compared to $8722 if the wound had been treated with HFDDS.
- Use of dHACM versus HFDDS resulted in an overall cost savings of $64,444, or $7160 per treated wound.

Case 3. 100% healed after 2 dHACM applications.



dHACM = EpiFix®, MiMedx Group Inc., Marietta, GA

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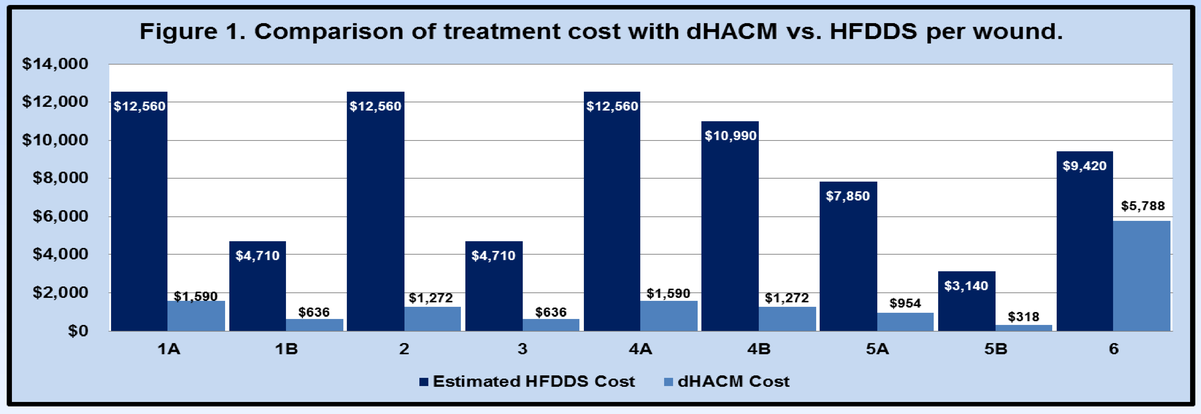
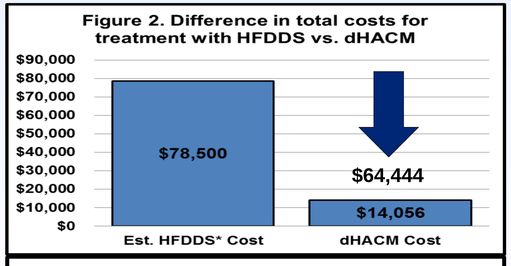
Results

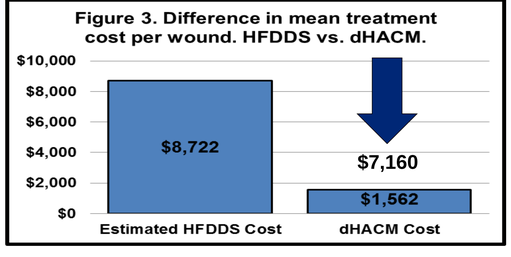
Table 1. Cases examined.

Patient	Pre - dHACM Area (cm^2)	Post dHACM Area (cm^2)	% Area Reduction – 4 weeks	% Area Reduction - current	dHACM Applications	dHACM Cost	HFDDS* Cost
1A	0.25	0.01	64%	96%	5	$ 1,590	$ 12,560
1B	0.35	0.04	89%	89%	2	$ 636	$ 4,710
2	0.80	0.25	39%	69%	4	$ 1,272	$ 12,560
3	0.25	0	100%	100%	2	$ 636	$ 4,710
4A	0.10	0.1	-20%	0%	5	$ 1,590	$ 12,560
4B	0.15	0.01	93%	93%	4	$ 1,272	$ 10,990
5A	0.21	0.09	81%	57%	3	$ 954	$ 7,850
5B	0.72	0	100%	100%	1	$ 318	$ 3,140
6	12	0.27	60%	98%	3	$ 5,788	$ 9,420
			67%	78%	Total Cost	$ 14,056	$ 78,500

** HFDDS = Human Fibroblast Derived Dermal Substitute. Cost model assumes equal effectiveness of HFDDS and dHACM.*







Conclusions

- The availability of multiple graft sizes and positive clinical outcomes may influence cost effectiveness of dHACM.
- dHACM appears to be a cost effective option for the treatment of non-healing wounds.
- Assuming equal effectiveness, treatment with dHACM may result in substantial cost savings vs. treatment with HFDDS.

References

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