

# The Application of Dehydrated Human Amnion Chorion Membrane (dHACM) Allografts to Expedite Healing in Patients with Six Major Types of Refractory Non-Healing Wounds, 157 Cases

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## Background and Purpose

- ❖ A continuation of previous analysis initiated in 2014.
- ❖ A Retrospective Quality Control Analysis to show the efficacy of dHACM in six major types of non-healing wounds.
- ❖ Chronic non-healing wounds including diabetic foot ulcers (DFU), venous stasis ulcers (VSU), pressure ulcers (PU), ischemic ulcers (IU), and surgical wounds (SW) pose a significant economic burden on the society.
- ❖ Human amniotic membrane has been used in a variety of surgical procedures and in wound healing for many decades.
- ❖ Amniotic membrane is a non-vascular tissue consisting of epithelium cells, basement membrane, a thick compact layer and fibroblast layer.
- ❖ The fibrous layer contains cell anchoring collagen types: I, III, IV, V, and VII.
- ❖ Biochemical properties of the membrane may help to reduce inflammation and enhance soft tissue healing.

### Dehydrated Human Amnion/Chorion Membrane (dHACM)

- ❖ Dehydrated human amnion/chorion membrane (dHACM) allografts have become a popular commercially available skin substitute.<sup>1</sup>
- ❖ The material is cleaned, dehydrated, and sterilized by the proprietary PURION® Process which produces a safe tissue with a 5 year, shelf life at ambient conditions.<sup>1</sup>
- ❖ 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 progenitor cells.<sup>2</sup>
- ❖ Randomized controlled trials and clinical studies have established dHACM as an effective treatment for diabetic foot ulcers and venous leg ulcers.<sup>3-6</sup>

### Purpose

To show the effectiveness of dHACM in treating refractory non-healing wounds of various etiologies.

## Methods

### Design

- ❖ A Retrospective Quality Control Analysis of a single podiatry clinic at the Jesse Brown VA.

### Included

- ❖ 157 eligible patients with lower extremity wounds of varying etiology who failed (<50% reduction in wound size) with Standard of Care for at least 4 weeks.

### Treatment

- ❖ Weekly application of dHACM, in micronized, placental matrix, or sheet formulation, after sharp/mechanical debridement as deemed necessary.
- ❖ Offloading, compression therapy, and vascular surgical intervention were utilized as appropriate.
- ❖ Weekly dressing change and dHACM application was performed in our outpatient clinic.

### Analysis

- ❖ Weekly wound measurements were obtained post debridement in the clinic during follow-up visits.
- ❖ Rate of closure using dHACM was calculated for the six types of wounds treated with dHACM.

## Results

- ❖ 157 patients were identified as a potential recipient for dHACM treatment, received treatment (healed, withdrawn, or treatment not initiated)
- ❖ 45% (70) were treated with a combination of dHACM (sheet, micronized, or placental matrix weekly)
- ❖ 126 patients received dHACM application after failure of SOC
- ❖ dHACM treatment was withdrawn in 12 cases
- ❖ Complete healing occurred in 87% (110) of the wounds treated
- ❖ Average number of applications per healed wound was 5.4 applications

dHACM = AmnioFix® and EpiFix® MiMedx Group, Inc., Marietta, GA  
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## Patient and Wound Characteristics

Wound Type	Identified	Treated	Healed	% Male	Mean Age	Mean A1c	Smoker	Mean Wound Duration (weeks)	Wound area (cm <sup>2</sup> )	Mean Application Per Healed Wound
Neuropathic (DFU)	52	43	41 (95%)	100%	67.8	8.5	51.9%	24.3	1.7	5.1
Venous Stasis (VLU)	39	32	28 (87.5%)	100%	69.5	6.8	43.0%	23.7	5.1	5.2
Pressure (PU)	25	18	15 (83%)	84%	72.1	7.3	51.0%	9.7	7.8	9
Ischemic (IU)	9	9	5 (55%)	100%	70	7.4	77.4%	5.8	1.5	3
Surgical	30	22	19 (86%)	91.3%	66.1	7.5	40.0%	12.1	12.3	7.2
Traumatic	2	2	2 (100%)	100%	78	7.2	100%	18	1.5	3
<b>Total</b>	<b>157</b>	<b>126</b>	<b>110 (87%)</b>	<b>95.8%</b>	<b>70.58</b>	<b>7.45</b>		<b>15.6</b>	<b>4.98(cm<sup>2</sup>)</b>	<b>5.4</b>

## Conclusion

- ❖ Based on this analysis, dHACM can significantly expedite healing in refractory wounds of varying etiologies.

### References

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