

An Initial Retrospective Quality Control Analysis of Lower Extremity Ulcer Recurrence Post dHACM in a High Risk Veteran Patient Population in Chicago



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Background

Overview

- Chronic non-healing wounds including diabetic foot ulcers (DFU) and venous stasis ulcers (VSU) present a significant health care issue facing many veterans.
- Therapies that promote rapid and complete healing, thus reducing the risk for infection and amputation, can substantially improve quality of life while decreasing financial burdens to the individual and society overall.

Dehydrated human amnion/chorion membrane is an effective treatment modality for chronic wounds

- PURION[®] Processed dehydrated human amnion/chorion membrane (dHACM) products serve to regenerate damaged tissue and contain human extracellular matrix components, essential growth factors, and specialized mediating cytokines to modulate inflammation, reduce scar tissue formation, and enhance tissue healing.¹⁻³
- Published clinical studies have established dHACM as an effective treatment for diabetic foot ulcers and venous leg ulcers.⁴⁻⁵

Durability of healed wounds

- It has been suggested that patients with a healed ulcer should not be referred to as cured, but rather as being in remission.⁶
- For DFUs, overall recurrence rates of 35-60% over 3 years, increasing to 70% over 5 years have been reported.⁷
- Wound healing outcomes need to be measured by the durability of their results, not just healing.
- In a published study, 17 of 18 (94.4%) DFUs healed with dHACM remained healed at the 9-12 month follow-up visit study.⁸

Purpose

- To report the results of a retrospective quality control analysis to evaluate ulcer recurrence of healed lower extremity wounds in our patients receiving dHACM.

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Methods

- We performed a quality control analysis on 20 lower extremity ulcers (DFU and VLU) healed with dHACM in our VA clinic.

Results

	DFU (n=15)	VLU (n=5)
Age (yrs)	69.9 ± 5.8 69 (63, 83)	69.8 ± 11.8 64 (59, 87)
Wound size (cm ²)	4.6 ± 9.0 1.4 (0.18, 35)	8.7 ± 8.8 4.4 (0.49, 22.5)
A1c (%)	9.0 ± 1.9 8.9 (5.7, 12.1)	8.6 ± 2.1 8.3 (5.9, 11.3)
Grafts to closure (#)	7.0 ± 5.4 6 (2, 25)	5.8 ± 2.6 5 (3, 10)
Recurrence (#)	2	2

- Overall, 4 of the 20 wounds recurred (80% of the wounds remained healed)
- Two of the DFUs recurred
 - 67 y/o, A1c 12.1, initial DFU size of 12.9 cm², Left sub 1st MPJ – reopened after 2 weeks
 - 65 y/o, A1c 11.6, initial DFU size of 0.18 cm², Right sub cuboid - reopened after 13 weeks
- Two of the VLUs recurred after being healed for approximately 12 and 24 weeks

Conclusion

- This retrospective analysis shows that the utilization of dHACM in chronic lower extremity wounds in a high-risk veteran patient population poses a valuable adjunct treatment modality resulting in durable wounds and low rates of wound recidivism.

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