

Application of Air-Dried Human Amniotic Membrane (dHAM)\*  
on a Nonhealing Diabetic Foot Ulcer for a Wheelchair-Bound  
Patient with Chronic Kidney Disease and Hypertension

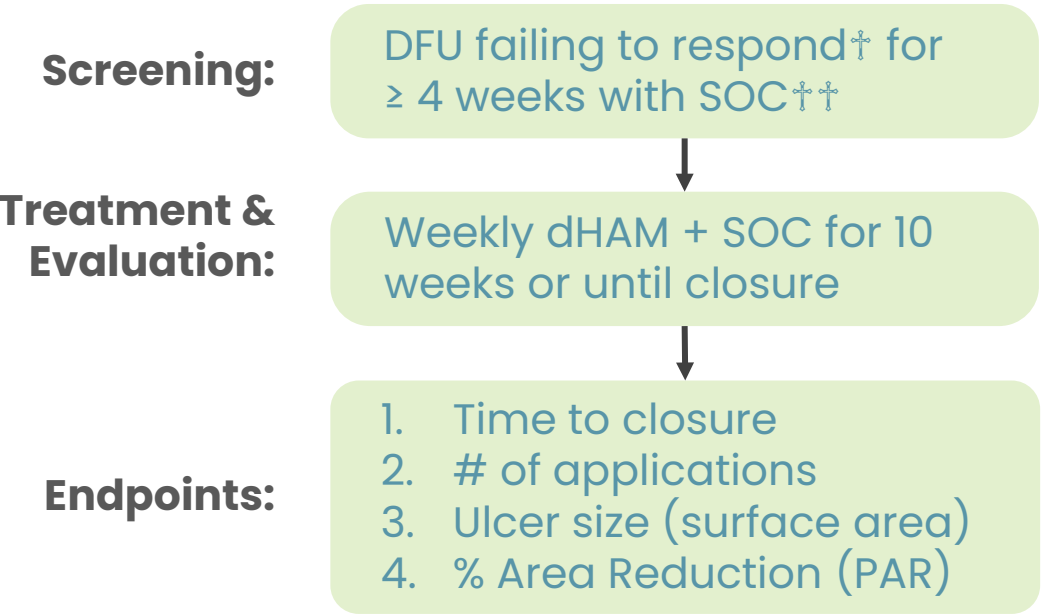
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INTRODUCTION

Diabetic foot ulcers (DFUs) remain a significant clinical and economic healthcare burden, affecting 1 in 4 patients with diabetes and is a leading cause of lower-extremity amputations. This case study evaluates the effectiveness of air-dried human amniotic membrane (dHAM)\* in the treatment of a chronic, nonhealing DFU. The patient is a wheelchair-bound 100-year-old, female with a history of type 2 diabetes, dementia, ataxia, chronic kidney disease, hypertension, and steatosis. The ulcer remained refractory to SOC management for over one month. Advanced intervention with dHAM was initiated to promote expedited wound healing.

Product notation: \*dHAM processed by FORMULA/5™ proprietary processing method (C5 Biomedical, FL)

METHODS



†Failure to respond defined as < 50% ulcer area reduction<sup>1</sup>.  
††SOC comprises comprehensive assessment, offloading, debridement, and moisture management<sup>1</sup>.

RESULTS

Patient presented with a nonhealing, full-thickness, Wagner Grade 2 DFU on the right heel that persisted despite over 1 month of SOC (**Fig. 1a**). At Baseline, wound surface area measured 1.12 cm<sup>2</sup> and dHAM treatment was initiated (**Fig. 1b**). One week later, wound area reduced to 0.6 cm<sup>2</sup> (**Fig. 1c**) corresponding to 46.4% PAR (**Fig. 2**). By Week 2, the wound area reduced by 71.4% from baseline to 0.32 cm<sup>2</sup> (**Fig. 1d**). By Week 3, wound achieved closure with 100% epithelialization (**Fig. 1e**).



**Fig. 1a: Screening (10/21/24)**  
Wound Area: 1.62 cm<sup>2</sup>  
SOC administered



**Fig. 1b: Baseline (10/30/24)**  
Wound Area: 1.12 cm<sup>2</sup>  
1 x 2 cm dHAM applied



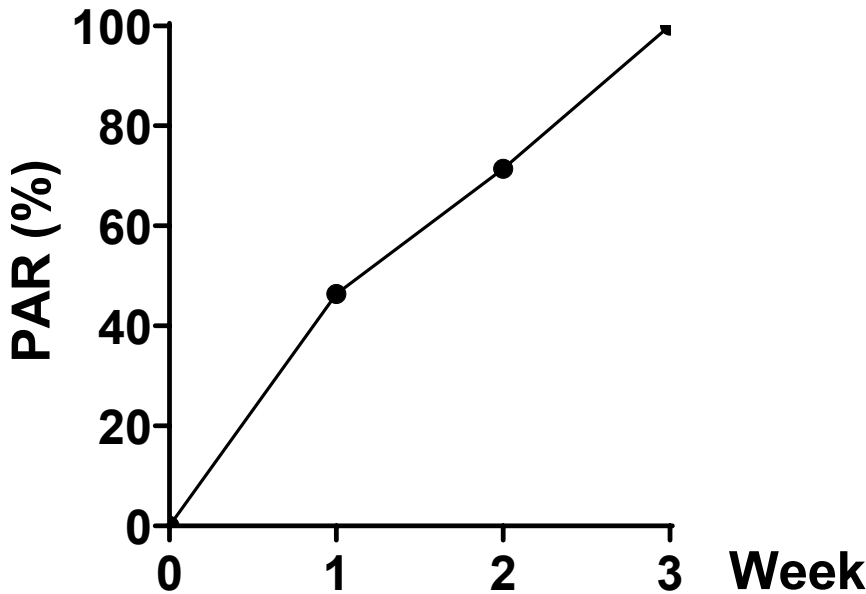
**Fig. 1c: Week 1 (11/04/24)**  
Wound Area: 0.6 cm<sup>2</sup>  
1 x 2 cm dHAM applied



**Fig. 1d: Week 2 (11/12/24)**  
Wound Area: 0.32 cm<sup>2</sup>  
1 x 2 cm dHAM applied



**Fig. 1e: Week 3 (11/19/24)**  
Wound closed



**Fig. 2:** PAR calculated at each treatment visit as % reduction in wound area from baseline.

CONCLUSION

In summary, this case study demonstrates complete wound closure following 3 weekly applications of dHAM in conjunction with SOC over a 3-week period, with no reported adverse events. The observed healing outcomes may be associated with the inherent biological properties of dHAM. As an adjunctive treatment option for chronic ulcers, dHAM may support improved wound progression and contribute to functional recovery and quality of life in patients with DFUs.

REFERENCES:  
1. Local Coverage Determination (LCD): Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL39764). Effective April 13, 2025.