

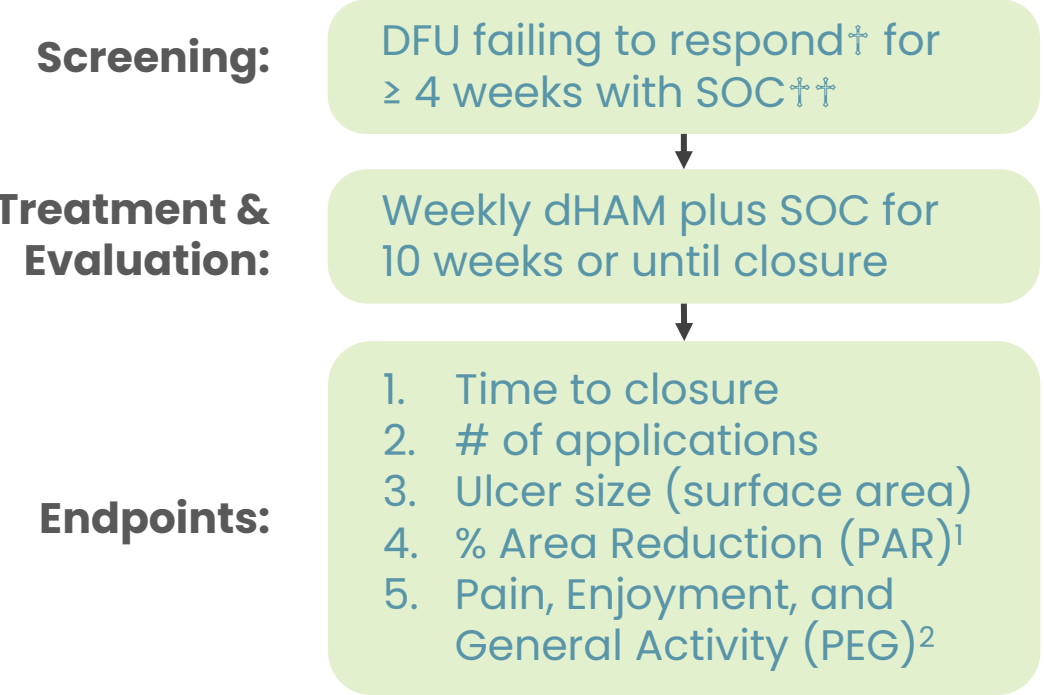
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INTRODUCTION

Diabetic foot ulcers (DFUs) pose a major clinical challenge, affecting up to 25% of patients with diabetes and accounting for most non-traumatic lower-limb amputations. This case study evaluates the efficacy of air-dried human amniotic membrane (dHAM*) in managing a chronic, non-healing DFU. The patient is an 86-year-old male with well-controlled type II diabetes, atrial fibrillation, GERD, venous insufficiency, and peripheral neuropathy. Given the risk of osteomyelitis and potential amputation, expedited healing was medically indicated.

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

METHODS



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

RESULTS

A patient presented with a 4.4 cm² full-thickness, Wagner Grade 2 DFU on the left medial malleolus, persisting for over 1 year despite SOC (**Fig. 1a**). At Baseline, the wound enlarged to 8.0 cm² and dHAM treatment was initiated (**Fig. 1b**). Within two weeks, the wound decreased to 3.6 cm², with evidence of granulation tissue (**Fig. 1c**).



Fig. 1a: 9/20/24 Screening
Wound Area: 4.4 cm²
SOC administered



Fig. 1b: 10/25/24 Baseline
Wound Area: 8.0 cm²
2 x 3 cm dHAM applied



Fig. 1c: 11/8/24 Week 2
Wound Area: 3.6 cm²
2 x 2 cm dHAM applied



Fig. 1d: 11/22/24 Week 4
Wound Area: 1.08 cm²
1 x 2 cm dHAM applied



Fig. 1e: 12/6/24 Week 6
Wound Area: 0.6 cm²
1 x 2 cm dHAM applied



Fig. 1f: 12/20/24 Week 8
Wound closed

A 4-week PAR > 50% is a surrogate predictor of long-term healing¹. By Week 4, the wound area reduced to 1.08 cm² (**Fig. 1d**), corresponding to a PAR of 86.5% (**Fig. 2**). Continued healing was observed at Week 6, with further reduction to 0.6 cm² (**Fig. 1e**). PEG scores increased from baseline through the treatment course, reaching 0 by Week 8 (**Fig 3**), when wound achieved full closure (**Fig. 1f**).

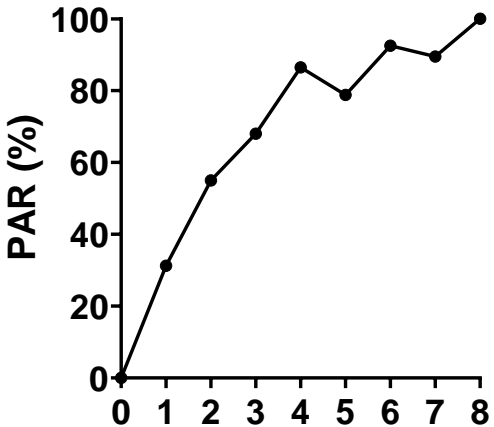


Fig. 2: Weekly PAR calculated at each treatment visit as % reduction in wound area from baseline.

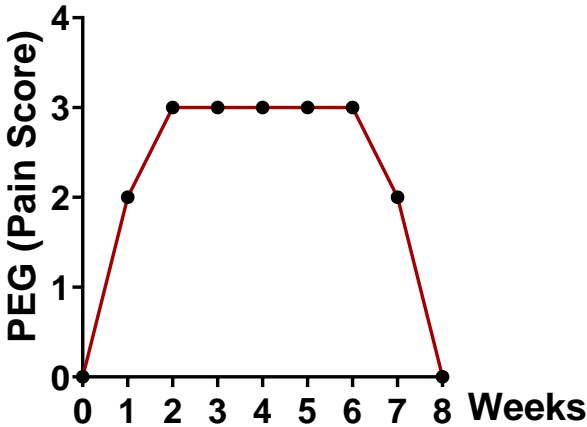


Fig. 3: PEG pain score reported by patient on a 0 – 10 scale, with 0 indicating no pain.

CONCLUSION

This case study demonstrates successful closure of a chronic DFU after 8 weekly applications of dHAM plus SOC, with no adverse events. The treatment proved safe and effective in resolving a complex, non-healing DFU present for over a year. dHAM's biological properties likely aided the accelerated response, supporting its potential as a noteworthy option for chronic ulcers, with benefits in healing time, quality-of-life, and return to functional recovery.

REFERENCES:
1. Sheehan P, et al. Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. Diabetes Care. 2003;26(6):1879-82.
2. Krebs EE, et al. Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference. J Gen Intern Med. 2009;24(6):733-8.