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RESTORIGIN™

Human Amniotic Membrane (HAM)

Its Effective Use in the Management of Chronic or Acute Diabetic Wounds and Venous Leg Ulcers - A Case Study

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Case study report of chronic non-healing foot ulcers treated with dehydrated human amniotic membrane sheet

Background

Chronic non-healing wounds should initially be treated in accordance with standard care protocols[1,2], however, the wounds that did not achieve 53% area reduction by 4 weeks healed in only 9% of the cases ($p<0.001$).[3] Current treatment options are often insufficient to achieve complete wound closure. Dehydrated human amniotic membrane (HAM) is non-immunogenic biological material with anti-microbial, anti-inflammatory and anti-fibrotic properties that function as a scaffold to facilitate tissue regeneration.[4]

Study Objective

The purpose of this study was to evaluate the efficacy of a sterile, dehydrated HAM sheet (Restorigin™) for treating non-healing wounds of the lower extremities.

Study Design

Patient population and inclusion criteria

- 10 patients with Ulcer Wagner Grades 1 and 2:
  - Five patients with Type I or Type II Diabetes mellitus;
  - One patient with peripheral vascular disease
- Failure to improve after 4 weeks standard of care

Treatment

- Restorigin™ weekly or bi-weekly application

Results

- The baseline ulcer area was 2.3 ± 0.9 cm^2
- Median number of Restorigin™ applications was 3.5 (from 1 to 7)
- In two patients (20%), wounds were completely healed only two weeks after initial application of the Restorigin™ membrane sheet
- On average, 94.6% of wound area reduction was observed after 8 weeks of HAM therapy.

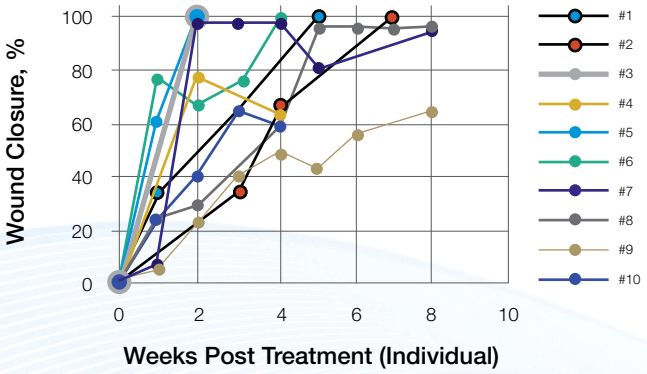

Figure 1. Individual wound closure results for each case.

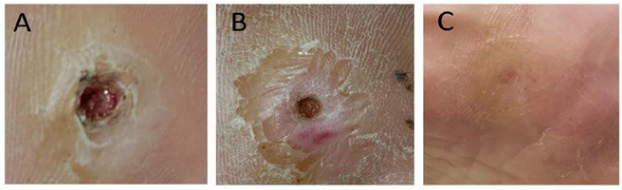

Figure 2. Healing progression is shown for a 42-year-old female patient from before the treatment (A) to complete closure after 4.5 weeks of HAM therapy and a single graft application) (C).

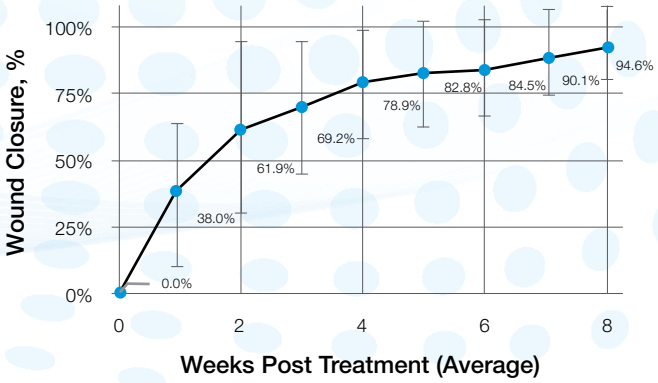

Figure 3. An average of 94.6% of wound area reduction was observed after 8 weeks of HAM sheet therapy.

Conclusion

The study demonstrated that human amniotic membrane (HAM) graft therapy is a safe and effective treatment for chronic non-healing ulcers.

1. Frykberg R, et al. J Foot Ankle Surg. 2006 Sep-Oct;45(5 Suppl): S1-66.
2. Bakker K, et al; Diabetes Metab Res Rev. 2012 Feb;28 Suppl 1:225-31.
3. Sheehan P, Jones P, et al. Diabetes Care. 2003 Jun; 26(6):1879-82.
4. Hao Y, Ma D, et al. Cornea. 2000 May;19(3):348-52.

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