The use of decellularized, dehydrated human amniotic membrane in the treatment of full thickness wounds: a case series

Jennifer L Mulhern, DPM, AACFAS, Nicole M. Protzman, BS, MS, Stephen A. Brigido, DPM, FACFAS
The use of decellularized, dehydrated human amniotic membrane in the treatment of full thickness wounds: a case series

Jennifer L Mulhern, DPM, AACFAS

My disclosure is in the final AOFAS mobile app. I have no potential conflicts with this presentation.
INTRODUCTION

- Phases of wound healing
  - Hemostasis
  - Inflammation
  - Maturation
- Chronic/non-healing wounds are stuck in the inflammatory phase
- Successful wound healing requires conversion of the wound beyond the inflammatory phase
INTRODUCTION

Human amniotic membranes:
- Reduce inflammation\(^1\-^2\)
- Decrease infection\(^1\-^2\)
- Enhance re-epithelialization\(^1\-^2\)
- Increase recruitment of mesenchymal stem cells to the wound bed\(^1\-^2\)
- Improve granulation tissue formation\(^3\)

Decellularized, dehydrated human amniotic membrane (DDHAM):
- Cellular components removed
- Biochemical components retained
- Intact matrix
- Scaffold for cell attachment/proliferation
HYPOTHESIS

Application of an amniotic membrane will be effective in closure of full thickness wounds without the need for multiple applications.

PURPOSE

To report our preliminary findings following treatment of full thickness wounds with a single application of an amniotic membrane.
Materials & Methods

Retrospective chart review (10/2011 through 10/2014)

Inclusion Criteria

• ≥18 years of age
• Underwent full thickness debridement with a single application of DDHAM
• Pain data recorded preoperatively and postoperatively at 8 weeks
• Wound granulation and wound size (length, width, depth) were measured preoperatively and postoperatively at 1 week and 8 weeks
• Surgery performed by one surgeon (S.A.B.)

Exclusion Criteria

• Absence of pain and/or wound data
• Inadequate follow-up
Materials & Methods

Outcome Data

- Pain (visual analog scale [VAS])
- Wound characteristics
  - Wound granulation (%)
  - Wound area (cm²)
  - Wound depth (cm)

Wound area was computed using the equation for an ellipse:

$$\pi \times \frac{\text{length}}{2} \times \frac{\text{width}}{2}$$
Results

Patient Demographics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>8 (100.0)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>54.9 ± 17.3</td>
</tr>
<tr>
<td>Body Mass Index (kg/m²)</td>
<td>32.4 ± 4.4</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>4 (50.0)</td>
</tr>
<tr>
<td>Women</td>
<td>4 (50.0)</td>
</tr>
<tr>
<td>Injury Side</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>5 (62.5)</td>
</tr>
<tr>
<td>Right</td>
<td>3 (37.5)</td>
</tr>
</tbody>
</table>

Patient Comorbidities

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>5 (71.4)</td>
</tr>
<tr>
<td>Gastroesophageal reflux disease</td>
<td>2 (25.0)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>4 (50.0)</td>
</tr>
<tr>
<td>Restless leg syndrome</td>
<td>2 (25.0)</td>
</tr>
<tr>
<td>Smoker</td>
<td>2 (25.0)</td>
</tr>
</tbody>
</table>

Wound Type

- Postoperative Dehiscense
- Diabetic Ulceration

Data presented as mean ± standard deviation or n (%).
Results

Wound Healing

Preoperative  1 Week Postoperative  6 Weeks Postoperative  8 Weeks Postoperative
# Results

## Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>Time main effect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1 week</td>
<td>8 week</td>
</tr>
<tr>
<td><strong>Pain (VAS)</strong></td>
<td>3.6 $\pm$ 3.3</td>
<td>2.6 $\pm$ 2.6</td>
<td></td>
</tr>
<tr>
<td><strong>Wound granulation (%)</strong></td>
<td>35.7 $\pm$ 12.7</td>
<td>61.9 $\pm$ 24.5</td>
<td>98.8 $\pm$ 3.5*</td>
</tr>
<tr>
<td><strong>Wound area (cm$^2$)</strong></td>
<td>5.3 $\pm$ 4.0</td>
<td>4.2 $\pm$ 2.7</td>
<td>0.0 $\pm$ 0.1*</td>
</tr>
<tr>
<td><strong>Wound depth (cm)</strong></td>
<td>0.3 $\pm$ 0.1</td>
<td>0.2 $\pm$ 0.1</td>
<td>0.0 $\pm$ 0.0*</td>
</tr>
</tbody>
</table>

**Post-hoc Analyses**

*Statistically significant at the 5% level (p ≤ 0.05), comparing preoperative and 1 week postoperative values.

†Statistically significant at the 5% level (p ≤ 0.05), comparing preoperative and 8 week postoperative values.

‡Statistically significant at the 5% level (p ≤ 0.05), comparing 1 week postoperative and 8 week postoperative values.
Discussion

- We have demonstrated success in obtaining closure of full thickness wounds with a single application of DDHAM allograft.

- The allograft DDHAM with epithelial basement membrane and collagen-rich extracellular matrix appears to provide a natural scaffold for cell attachment and proliferation in stalled wounds, allowing the wound to progress toward closure.
REFERENCES

