The Use of Dehydrated Human Amnion/Chorion Membrane (dHACM) Allografts to Expedite Healing in Patients with Five Major Types of Refractory Non-Healing Wounds: A Cohort Study
Darshan Nagesh, DPM; Robin Lenz, DPM; Hannah Park, DPM; Patrick Sanchez, DPM; Sarah Park, DPM; Jake Ruff, DPM; Matthew Garoufalis, DPM, FASPS, FACFAOM, CWS
Jesse Brown Veterans Affairs Medical Center, Chicago, IL
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Background
- Chronic non-healing wounds including diabetic foot ulcers (DFU), venous stasis ulcers (VUS), pressure ulcers (PU), ischemic ulcers (IU), and surgical wounds (SW) pose a significant economic burden on the society.
- Human amniotic membrane has been used in a variety of surgical procedures and in wound healing for many decades.
- Amniotic membrane is a non-vascular tissue consisting of epithelium cells, basement membrane, a thick compact layer and fibroblast layer.
- The fibrous layer contains cells anchoring collagen types: I, III, IV, V, and VII.
- Biochemical properties of the membrane help to reduce inflammation and enhance soft tissue healing.

Dehydrated Human Amnion/Chorion Membrane (dHACM)
- Dehydrated human amnion/chorion membrane (dHACM) allografts have become a popular commercially available skin substitute.
- The material is cleansed, dehydrated, and sterilized by the proprietary PURION® Process that produces an easy to use allograft with a 5-year shelf-life at ambient conditions.
- PURION® Processed dHACM has been shown to retain biological activities related to wound healing, including the potential to positively affect four distinct and pivotal physiological processes intimately involved in wound healing: cell proliferation, inflammation, metalloproteinase activity, and recruitment of progenitor cells.
- Randomized controlled trials and clinical studies have established dHACM as an effective treatment for diabetic foot ulcers and venous leg ulcers.

Purpose
- The main purpose of this study is to show the effectiveness of dHACM in treating refractory non-healing wounds of various etiologies.

Methods

Study design
- Retrospective chart review from a podiatric surgery clinic of a single medical center.
- Included: 66 patients with lower extremity wounds (DFU, VUS, IU, PU, SW) who failed (>50% reduction) with Standard of Care for 4 weeks.
- Treatment: Weekly application of dHACM after sharp/mechanical debridement as deemed necessary in conjunction with offloading (PU, DFU, SW), compression therapy (VUS), and vascular surgical intervention/ArtAssist® as deemed appropriate for IU.
- Weekly dressing change and graft application was performed in our outpatient center and enhanced soft tissue healing.

Analysis
- Weekly wound measurements were obtained post debridement in the clinic during follow-up visits.
- Rate of closure using dHACM was calculated for the five major types of wounds.
- Percent area reduction to current date was calculated for wounds not completely epithelialized.

Results
- Overall, the average wound size was 4.41 cm².
- Of the 66 patients, 6 patients were not included secondary to either loss to follow-up or complications. One patient with a PU was being treated with dHACM at the time of chart review and showed a 91.7% size reduction after 5 consecutive weekly applications.
- There were statistical differences in the average size of the wounds between the major wound types in our cohort (p=0.0015), and a statistically significant difference in the number of applications to wound closure between the groups of major wound types (p=0.0004).

Conclusion
- dHACM can significantly expedite healing in different types of refractory wounds concomitantly while addressing the underlying etiology of the wounds.

Table 1. Summary of healing in patients with 5 major types of wounds.

<table>
<thead>
<tr>
<th>Wound Type</th>
<th>Total # of Patients</th>
<th># of Patients with Complete Data</th>
<th>Average Wound (wks)</th>
<th>Average Wound Size</th>
<th>Average % of dHACM to Heal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurovascular (DFU)</td>
<td>18</td>
<td>14</td>
<td>22.9</td>
<td>.75 cm²</td>
<td>4</td>
</tr>
<tr>
<td>Venous stasis ulcers (VUS)</td>
<td>17</td>
<td>16</td>
<td>21.3</td>
<td>3.94 cm²</td>
<td>5.19</td>
</tr>
<tr>
<td>Pressure Ulcers (PU)</td>
<td>7</td>
<td>6</td>
<td>9.1</td>
<td>8.35 cm²</td>
<td>8.66</td>
</tr>
<tr>
<td>Ischemic Ulcers (IU)</td>
<td>3</td>
<td>3</td>
<td>5.3</td>
<td>23 cm²</td>
<td>3</td>
</tr>
<tr>
<td>Surgical wounds (SW)</td>
<td>21</td>
<td>20</td>
<td>11.2</td>
<td>7.22 cm²</td>
<td>6.1</td>
</tr>
</tbody>
</table>

Overall
- 66 patients | 59 | 16.9 | 4.41 cm² | 5.4 |

References