Diabetes has become an epidemic in the United States of America with public health estimates showing 26 million people in roughly 9.3% of the population having diabetes. Current data has shown that one in three Americans is predicted to be diabetic by 2050. 

The ultimate goal of advanced wound therapies is to facilitate resumption of the normal healing process in order to prevent complications of limb and the threatening infections and amputations.

Human amniotic membrane has a long history of clinical use. Unique properties, matrix composition and endogenous growth factors that facilitate wound healing, have been shown to be maintained through aseptic processing used in production of dHACA. It has previously been shown in a cohort of 80 patients that dHACA is effective in diabetic foot ulcers (DFU) management.

This study evaluates dHACA effectiveness as compared to TESS, one of the most commonly accepted options for the treatment of DFU wounds.

### ABSTRACT

**BACKGROUND**

Diabetes care has been in the spotlight with public health estimates showing that one in three Americans is predicted to be diabetic by 2050. It is estimated that 25% of diabetes will develop an ulcer in their lower extremity over their lifetime. Studies show that these ulcerations precure nearly 85% of lower extremity amputations. The ultimate goal of advanced wound therapies is to facilitate resumption of the normal healing process in order to prevent complications of limb and the threatening infections and amputations.

**PURPOSE**

The purpose of this prospective, randomized, controlled, parallel, multicenter clinical trial was to compare the proportion of ulcers completely healed by use of dHACA versus TESS in diabetic patients with a DFU with adequate arterial pulsations.

The study was conducted in five outpatient wound centers and pre-registered in ClinicalTrials.gov (NCT02878976).

**METHODS**

#### STUDY GROUPS

<table>
<thead>
<tr>
<th>Study group</th>
<th>No. healed (%)</th>
<th>Mean time to heal (days)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>dHACA+SOC</td>
<td>27/30 (90%)</td>
<td>6.5 (5.6, 7.9)</td>
<td>0.0002</td>
</tr>
<tr>
<td>TESS+SOC</td>
<td>8/30 (27%)</td>
<td>12.0 (9.5, 15.2)</td>
<td>0.043</td>
</tr>
</tbody>
</table>

#### STUDY DESIGN

1. Patients demonstrating <20% wound area healing within 2 week of initial screening were randomized into either of the two treatment arms.

2. Weekly patient visits included sharp debridement, cleaning, graft application, dressing change, photography, and wound measurement via outline tracing and ruler measurement. Offloading was also employed.

3. Validation visit one week after 100% epithelialization of wound was required to confirm closure.

#### DATA ANALYSIS

1. Parametric or non-parametric tests as appropriate

2. Adjusted two-sided p-values < 0.05 were considered significant.

#### RESULTS

**CONCLUSIONS**

The confirmation of this randomized controlled multicenter study confirms positive outcomes previously reported for dHACA in published RCT data. The study also establishes that dHACA in conjunction with standard of care is superior to TESS with regard to healing efficacy and cost-effectiveness.

**REFERENCES**


