Venous leg ulcerations (VLUs) frequently represent a significant clinical challenge. Dehydrated human amnion and chorion allografts have shown great promise in the treatment of refractory VLUs when compared to standard wound care (SOC) alone which includes debridement followed by multilayer compression therapy with a primary absorptive dressing. Adding placental grafts into the treatment regimen is often successful as they are rich in extracellular matrix proteins, growth factors, and cytokines, and as such can induce angiogenesis and dermal fibroblast proliferation which can lead to accelerated healing. Asceptically processed grafts may have a benefit of being non-heat sterilized. The goal of this study was to compare asceptically processed dehydrated human amnion and chorion allograft (dHACA) applied weekly or biweekly combined with standard of care versus standard of care alone in facilitating wound closure in non-healing VLUs. The research was reviewed and approved by the Western Institutional Review Board and registered on ClinicalTrials.gov.

Patients with non-healing VLUs heal on SOC alone (appropriate debridement, primary absorptive dressing and multilayer compression) after a 2-week screening period were randomized to either receive SOC (20 patients) or wound-size-specific dHACA plus SOC applied weekly or biweekly (20 patients) for up to 12 weeks. Primary endpoint of this clinical trial was percent of patients healed (completely epithelialized) at 12 weeks. At study conclusion, both weekly and biweekly application of dHACA was statistically significantly better at healing VLUs than standard wound therapy and at a faster overall rate. In conclusion, asceptically processed dHACA should be considered as a viable option for the refractory venous leg wounds.

Lower extremity ulcers pose significant clinical, hematological, and economic burdens on society. Millions of Americans are affected with painful, open, draining sores on their lower extremities. These sores are referred to as venous leg ulcers and comprise approximately 70% of all lower extremity ulcers. Under the best of circumstances, these ulcers require weeks or months to heal. Not uncommonly wound care specialists see patients who have suffered for many years. An estimated 2.25 million Americans suffer from venous leg ulcers (VLUs) which are chronic, non-healing wounds that affect the lower extremities. VLUs require weeks or months to heal. Not uncommonly wound care specialists see patients who have suffered for years. An estimated 2.25 million Americans suffer from venous leg ulcers (VLUs) which are chronic, non-healing wounds that affect the lower extremities. VLUs often cause chronic pain, and many patients become severely disabled, with wound care costs estimated to exceed $1 billion per year in the United States alone.

A Prospective, Randomized, Controlled, Multi-Center Comparative Study of Two Application Regimens of Amniotic Membrane Wound Graft Versus Standard of Care in the Management of Non-Healing Venous Leg Ulcers

**ABSTRACT**

**RESULTS**

Results are summarized in Table 1 below, and Figures 1a and 2. The target ulcer has been treated with compression therapy for at least 3 months prior to initial screening, or who receive such medications during the course of the trial.

**CONCLUSIONS**

Patients with non-healing VLUs healed on SOC alone (appropriate debridement, primary absorptive dressing and multilayer compression) after a 2-week screening period were randomized to either receive SOC (20 patients) or wound-size-specific dHACA plus SOC applied weekly or biweekly (20 patients) for up to 12 weeks. Primary endpoint of this clinical trial was percent of patients healed (completely epithelialized) at 12 weeks. At study conclusion, both weekly and biweekly application of dHACA was statistically significantly better at healing VLUs than wounds treated with SOC alone in facilitating wound closure in non-healing VLUs. The research was reviewed and approved by the Western Institutional Review Board and registered on ClinicalTrials.gov.

**METHODS**

**Figure 1a. Percent wounds closed over 12 weeks.**

**Figure 1b. Percent wound area red.”

**Table 1. Inclusion/Exclusion Criteria**

**Table 2. Proportion of wounds healed statistics, chi-squared test (p<.05)**

**Figure 2. Representative case examples of patients healed with dHACA+SOC with either weekly or biweekly application**

**Results from this multicenter randomized controlled study in VLUs demonstrate that dHACA results in greater percentage of patients healed in 12 weeks when compared to standard multi-layer compression therapy, and significantly improves patients healing trajectory over time. These data suggest that dHACA serves to benefit patients previously failing to heal with the standard care in venous leg ulcers.**

**Table 1. Results summary table**

**Table 2. Proportion of wounds healed statistics, chi-squared test (p<.05)**

**Table 3. PROS and CONS of dHACA**

**Figure 1a. Percent wounds closed over 12 weeks.**

**Figure 1b. Percent wound area reduced over time.**

**Figure 2. Representative case examples of patients healed with dHACA+SOC with either weekly or biweekly application**

**Table 1. Results summary table**

**Table 2. Proportion of wounds healed statistics, chi-squared test (p<.05)**

**Table 3. PROS and CONS of dHACA**

**Figure 2. Representative case examples of patients healed with dHACA+SOC with either weekly or biweekly application**

**Results from this multicenter randomized controlled study in VLUs demonstrate that dHACA results in greater percentage of patients healed in 12 weeks when compared to standard multi-layer compression therapy, and significantly improves patients healing trajectory over time. These data suggest that dHACA serves to benefit patients previously failing to heal with the standard care in venous leg ulcers.**

**Methods**

**Table 1. Inclusion/Exclusion Criteria**

**Table 2. Proportion of wounds healed statistics, chi-squared test (p<.05)**

**Figure 1a. Percent wounds closed over 12 weeks.**

**Figure 1b. Percent wound area reduced over time.**

**Figure 2. Representative case examples of patients healed with dHACA+SOC with either weekly or biweekly application**

**Results from this multicenter randomized controlled study in VLUs demonstrate that dHACA results in greater percentage of patients healed in 12 weeks when compared to standard multi-layer compression therapy, and significantly improves patients healing trajectory over time. These data suggest that dHACA serves to benefit patients previously failing to heal with the standard care in venous leg ulcers.**

**Methods**

**Table 1. Inclusion/Exclusion Criteria**

**Table 2. Proportion of wounds healed statistics, chi-squared test (p<.05)**

**Figure 1a. Percent wounds closed over 12 weeks.**

**Figure 1b. Percent wound area reduced over time.**

**Figure 2. Representative case examples of patients healed with dHACA+SOC with either weekly or biweekly application**

**Results from this multicenter randomized controlled study in VLUs demonstrate that dHACA results in greater percentage of patients healed in 12 weeks when compared to standard multi-layer compression therapy, and significantly improves patients healing trajectory over time. These data suggest that dHACA serves to benefit patients previously failing to heal with the standard care in venous leg ulcers.**