A Prospective, Randomized, Controlled, Multi-center, Clinical Trial Examining Healing Rates, Safety, and Cost to Closure of A Dehydrated Ammon and Chorion Grant* Versus Standard of Care in the Treatment of Chronic Diabetic Foot Ulcers

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ABSTRACT

Amniotic membrane grafts are effective for healing chronic diabetic lower extremity wounds. To date, we studied an acellular dehydrated human amniotic membrane allograft (DHAMA) comprised of amnion and chorion layers that reduce the structural properties of extracellular matrix and contains various growth factors necessary for wound healing.

In a 12-week trial, 40 patients with nonhealing diabetic ulcers (1.25 cm) were enrolled and randomized to receive standard of care (SOC) or weekly applications of specific DHAMA after a 4-week screening period if the wound failed to reduce in size by 30%. Patients were followed for 12 weeks or until one week after healing.

Final results of 12 weeks show 17/20 patients (85%) healed completely with the DHAMA versus only 2/20 (10%) with SOC (adjusted p<0.0053). Mean grafts used to closure was 3/4 for DHAMA. There were no increased adverse or serious adverse events between groups.

METHODS

Study population: 40 patients with non-healing diabetic ulcers (1.25 cm) were enrolled and randomized to receive standard of care (SOC) or weekly applications of specific DHAMA after a 4-week screening period if the wound failed to reduce in size by 30%. Patients were followed for 12 weeks or until one week after healing.

Study exclusion criteria: 2/20 (10%) with SOC (adjusted p<0.0053). Mean grafts used to closure was 3/4 for DHAMA. There were no increased adverse or serious adverse events between groups.

RESULTS

The study shows that acellular dehydrated DHAMA is as effective as standard of care in the treatment of chronic DFUs. The DHAMA is cost-effective and safe for use in chronic DFUs.