Use of an Aseptically Processed Dehydrated Human Amnion and Chorion Membrane* Improves Likelihood and Rate of Healing in Chronic Diabetic Foot Ulcers: A Prospective, Randomised, Multi-Centre Clinical Trial in Eighty Patients

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ABSTRACT

Aseptically processed grafts have been shown to be effective in treating chronic diabetic foot ulcers (DFUs). The goal of this trial was to determine whether a randomised, controlled, multicentre clinical trial of Aseptically Processed, Dehydrated Human Amnion and Chorion Membrane (dHACMa) versus standard of care (SOC) in facilitating wound closure in non-healing DFUs could improve outcomes.

METHODS

Patients with DFUs treated with SOC (soft-tissue debridging, autograft, allograft and/or dermal substitute) were randomized to either SOC or dHACMa treated wounds at 8 weeks. The primary endpoint was the percentage of wounds healed at 8 weeks between groups.

RESULTS

At 8 weeks, 68% (124/180) of the dHACMa-treated DFUs were healed compared to 20% (46/180) treated with SOC (p-value < 0.001). Furthermore, at 12 weeks, 88% (164/180) of the DFUs in the dHACMa group healed compared to 33% (59/180) in the SOC group (p-value < 0.001), with a corresponding mean time to heal of 67.3 ± 17.8 days, respectively. At 12 weeks, the mean number of grafts used per healed wound for the dHACMa group was 4 ± 1.6, and mean weight of the tissue to heal a DFU was $17.71. Overall, the mean weight was 12 ± 3.5 weeks. Three adverse events and 1 serious adverse event occurred in the dHACMa group, none were graft related. Eight adverse events and 3 serious adverse events occurred in the SOC group.

CONCLUSIONS

The use of Aseptically Processed Dehydrated Human Amnion and Chorion Membrane in the treatment of chronic diabetic foot ulcers is associated with improved likelihood and rate of healing compared to standard of care. Further research is needed to determine the long-term outcomes and cost-effectiveness of this treatment option.