A Prospective, Randomized Comparative Study of Weekly versus Biweekly Application of Dehydrated Human Amnion/Chorion Membrane Allograft in the Management of Diabetic Foot Ulcers

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Objectives: To determine if weekly application of dehydrated amnion/chorion membrane (dHACM) allograft reduces mean healing time in diabetic patients (DFU) compared to biweekly application.

Methods: A Western Institutional Review Board approved, registered, prospective, randomized, controlled, multi-center study to compare time to healing in diabetic patients with a DFU treated with dHACM.

Results: Overall, 61 patients were randomized to receive weekly (n=20) or biweekly (n=20) application. Complete healing occurred after 3 applications of dHACM. Wound reduced in size by 90.1% after 3 applications of dHACM.

Conclusions: These results validate previous studies showing that dHACM is an effective treatment for DFU. Although similar numbers of grafts were used, wounds treated with weekly application of dHACM healed more rapidly than those with biweekly application. Rapid healing may reduce early care costs and prevent further medical complications including infection and amputation associated with chronic wounds.

Abstract

Background

• Diabetic ulcers are often slow to resolve; a large meta-analysis reported a weighted healing rate of only 24.2% after 12 weeks of treatment.

• Approximately 25% of diabetic patients will develop a foot ulcer over their lifetime.

• When applicable, measurements and photographic evaluation were done after 12 weeks in each group, and number of dHACM allografts used receiving biweekly, despite a greater mean HbA1c.

• Overall, after 1 dHACM application, mean wound size reduction was 76.4 ± 16.9 mm².

• Patients were randomized to receive weekly (n= 20) or biweekly (n=20) application of dHACM allograft.

• DFU treated with weekly application of dHACM heal more rapidly than those treated with biweekly application. Rapid healing may reduce early care costs and prevent further medical complications including infection and amputation associated with chronic wounds.

• Parametric and non-parametric statistics were used as appropriate to compare healing characteristics between those receiving weekly applications of dHACM to biweekly controls.

• These results validate previous studies showing that dHACM allograft is an effective treatment for DFU. Although similar numbers of grafts were used, wounds treated with weekly application of dHACM healed more rapidly than those with biweekly application. Rapid healing may reduce early care costs and prevent further medical complications including infection and amputation associated with chronic wounds.

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