A Long-term Follow-up Study of Chronic Diabetic Foot Ulcers Healed with Dehydrated Human Amniotic/Chorionic Membrane Allografts

Identification and implementation of an ideal treatment regimen for diabetic foot ulcers (DFU) is a common issue faced by clinicians. Therapies that promote rapid and complete healing reduce the risk for infection and amputation, can substantially improve quality-of-life while decreasing financial burdens.

IRB approved randomized clinical trial comparing rates of primary healing with dHACM versus a standard protocol of wound care.

Examples of Subjects healed with dHACM

We conducted a follow-up study of patients with chronic DFUs previously enrolled in an IRB approved randomized clinical trial comparing rates of primary healing with dHACM versus a standard protocol of wound care. The study was conducted in a single center in Southwest Virginia under the direction of a senior clinician with expertise in diabetic foot care. All patients signed an IRB approved consent form prior to enrollment in the initial study and provided additional IRB approved consent for the current review of subsequent data and outcomes.

Inclusion
- Patients from the initial randomized trial that were randomized to the dHACM treatment group and healed within 12 weeks (n=12)
- Patients that were randomized to standard treatment with moist wound care that subsequently received dHACM and healed after initial study completion (n=10)

Study Outcome
- Rate of ulcer recurrence in patients 6-12 months after primary healing with the use of dHACM

Data Analysis
- 22 patients with chronic DFUs that healed with the use of dHACM were eligible for inclusion
- Follow-up examinations were conducted at 9 months after primary healing with dHACM
- Complete healing was defined as a total epithelialization of the open area of the wound

Results
- 25 patients were enrolled in the initial randomized trial
- Of those 25, 13 were randomized to receive dHACM and 12 of 13 (92.3%) healed (mean of 2.5 ± 1.9 weeks)
- Of the 12 patients randomized to receive standard wound care treatment, 11 (91%) healed completely within 12 weeks of starting dHACM treatment (mean 4.3 ± 3.1 weeks)
- Twenty-two of 25 DFUs (88%) completely healed after dHACM treatment, and these patients were eligible for inclusion in the follow-up study. Follow-up examinations were conducted 9-12 months after healing. Eighteen of 22 patients returned for follow-up examination. Only one had recurrent DFU with 12.94%) remained fully healed. These findings support the effectiveness of dHACM for treatment of DFU. dHACM is a clinically viable and economically feasible treatment option.

Our purpose is to evaluate the rates of recurrence of chronic DFUs healed with the use of dHACM.

"EpiFix" - MiMedx®, Marietta, GA

Study sponsored by: MiMedx®, Marietta, GA

EpiFix®, PURiFi®, and Amnion are registered trademarks of MiMedx Group Inc., Marietta, GA

References

Conclusion
- In the present study of 18 patients with chronic DFUs that healed within 12 weeks after treatment with dHACM, all but one treated ulcer (94.4%) remained healed approximately one year later.
- Findings from this long-term follow-up study support the results of the original randomized trial and the second crossover study showing that dHACM is an effective treatment for both rapid and sustained healing of DFUs.

These results illustrate that the addition of dHACM to routine wound management can enhance wound healing in patients with DFUs.

Limitations of the current study are inherent to those of a retrospective study design and small sample size. These findings should be confirmed and expanded with subsequent clinical trials.