Human Placental Connective Tissue Matrix in the Treatment of Chronic Wounds

A Prospective Multi-Center Case Series

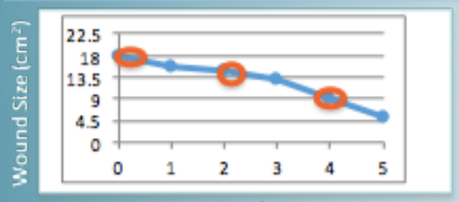
Heather Connell CCRP[1], Raphael Yaakov[1], Keyur Patel DO[2], Daniel DiMacro DO[3], Lam Le MD[4], Bryan Doner DO[2], Laura Serena LPN[1,2], Debbie Meyers LPN[3], Lindsay Saunders[4], Sharon McConnell CCRC[1], Thomas Serena MD[1]

[1]SerenaGroup - Cambridge MA, [2]The Wound Healing & HBO Center ACMH Hospital – Kittanning PA, [3]The Wound Center St. Vincent Hospital – Erie PA, [4]The Wound Center St. John's Health System – Tulsa OK

Day 0 – 17.7 cm²

Day 25 – 9.3 cm²

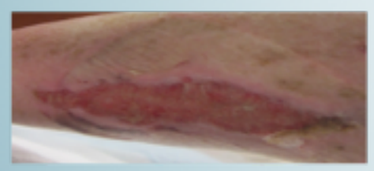
Age of Patient: 71
Wound Location: Left Foot Amputation Site
Age of Wound: 2.5 Months
Co-morbidities: Diabetes, Neuropathy, HTN, Previous Amputations
Previous Treatments: Debridement, HBO, NPWT, Hypochlorous Acid Wash
Current Treatments: 1 2x3 Dermavest per application, NPWT, Hypochlorous Acid Wet to Dry, Santyl, Granufoam



48% Area Reduction in 25 days

= Dermavest Application

Day 0 – 44.0 cm²



Day 49 – 18.2 cm²

Age of Patient: 87
Wound Location: Left Posterior Leg
Age of Wound: 5 months
Co-morbidities: Hypertension, Hypercholesterolemia, Lumbago
Previous Treatments: Oasis Ultra, Tubigrip Compression, Endoform, Xeroform, Prisma, Xtrasorb
Current Treatments: 1 2x3 cm Dermavest per application, Prisma, Alginate

58% Area Reduction in 49 days applying only three 6cm2 Dermavest total – one per week for the first three weeks

Introduction

In recent recent years, application of amniotic membrane has expanded to the treatment of diabetic and venous stasis ulcers, postsurgical wound dehiscence and chronic wounds. In this case series, we evaluated the efficacy of a Human Placental Connective Tissue Matrix Graft*.

Methods

This prospective, multicenter case series evaluated wound healing time and wound characteristics of fifteen patients with various etiologies. Up to two, six cm2 pieces of the Graft* were used per application on wounds ranging up to 44 cm2. The average number of applications was 2 with a max of 4. Length, width, and depth measurement as well as percent granulation tissue were measured at each weekly visit using a wound imaging camera. The wounds were cleaned and debrided based on the physician's discretion.

Acknowlegements

The SerenaGroup™ would like to thank AediCell, manufacturer of Dermavest, for an unrestricted grant as part of our case series initiative.

*Dermavest

Results

All patients demonstrated a decrease in wound size and depth. There were no graft-related adverse events. The age of the ulcers ranged from 3 weeks to 4 years. There was also a notable decrease in would exudate and odor in all ulcers treated.

For the diabetic and venous ulcer cases:

- The week 4 PAR (Percent Area Reduction) was 59% (71% diabetic and 50% venous).
- 62% (80% diabetic and 50% venous) of the cases had a week 4 PAR > than 40%.

For the diabetic and venous ulcer cases that started with a wound size < 20 cm2 and where one six cm2 Graft* was used per application:

- The week 4 PAR was 70% (82% diabetic and 62% venous).
- 80% (100% diabetic and 67% venous) of the cases had a week 4 PAR > than 40%.

Conclusions

The Graft* was effective in reducing wound size and improving wound bed characteristics in chronic wounds.