Treatment of Venous Leg Ulcers with a Cellular Human Repair Matrix

Matthew Regulski, DPM; Russell D. Petranto, DPM; Vincent J. Migliori, DPM; Girish Nair, DPM; Darelle Pfeiffer, DPM Ocean County Foot and Ankle Surgical Associates, Toms River, NJ

Abstract

Introduction

Chronic vascular wounds of the lower extremities including venous leg ulcers (VLUs) comprise the largest group of lower extremity wounds accounting for nearly 75% of all chronic ulcers. VLUs remain a leading cause of morbidity and loss of productivity with few proven options available for those wounds that are refractory to standard compression therapy. Newer therapies, including a novel cellular human repair matrix*, may provide better VLU healing rates than currently available advanced therapies.

Methods

A total of 34 patients (22 female, 12 male) with VLUs were treated with the cellular repair matrix from April 2010 through March 2012 and underwent retrospective analysis to assess wound healing defined as complete re-epithelialization of the wound with no evidence of drainage. The mean wound size was 8.66 cm². Among the 34 patients, 22 (64.7%) had failed at least one advanced wound therapy. Patients received standard wound care, debridement, and compression dressings at each visit. Cellular graft placement was at the discretion of the treating healthcare provider, usually biweekly. Four examples are presented in this poster.

Results

Of the 34 patients treated with the repair matrix, 24 (70.6%) healed within 26 weeks, with 23 of those patients (95.8%) healing within 12 weeks. The mean time to closure among the 24 patients was 6.1 weeks (range 1-23 weeks) with an average of 3.4 graft applications (range 1-7). The grafts were well tolerated with no reported adverse reactions in any of the patients. There was no recurrence of any of the healed wounds with follow-up through one year.

Conclusion

A cellular human repair matrix demonstrated significant promise in a large, single arm retrospective review of patients with refractory venous leg ulcers and should be considered in patients who are not responsive to conventional or other advanced therapies.

1. Sen CK, Gordillo GM, Roy S, et al. Human skin wounds: a major and snowballing threat to public health and the economy. Wound repair and regeneration : official publication of the Wound Healing Society [and] the European Tissue Repair Society 2009;17:763-71.

*Grafix® PRIME Osiris Therapeutics, Inc. Columbia, MD

Case 1

Patient Information and Medical History

- 80-year old female.
- History of peripheral vascular disease, mild dementia.

Wound Description

- Presented with a 12.1cm² wound on left lower leg.
- Wound present for 16 weeks prior to application of cellular repair matrix.
- Failed compression dressing and silver containing products.

Treatment and Outcome

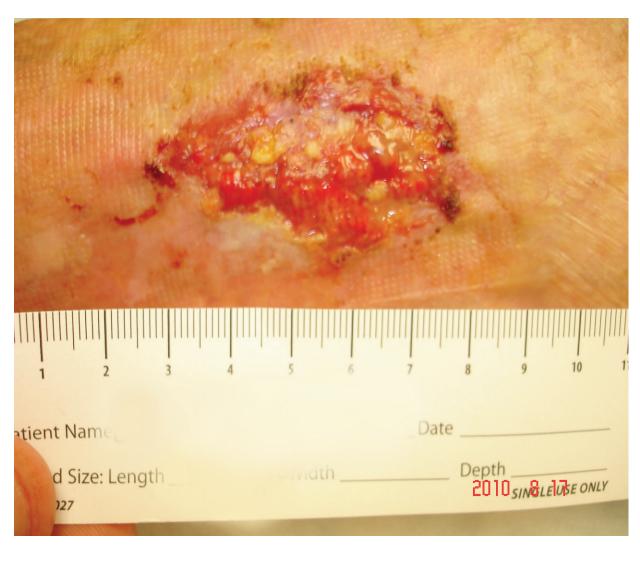
- Patient received 2 applications of the repair matrix.
- Wound closure achieved in 4 weeks.



Prior to Treatment



Week 1





Week 4 - Closure

Week 2

Case 2

Patient Information and Medical History

- 68-year old male.
- History of diabetes, venous insufficiency, hypertension, hypercholesterolemia.

Wound Description

- Presented with a 33.2cm² wound on right lower leg.
- Wound present for 8 weeks prior to application of cellular repair matrix.
- Failed wound vacuum prior to treatment.

Treatment and Outcome

- Patient received 7 applications of the repair matrix.
- Wound closure achieved in 9 weeks.









Week 6



Week 8



Week 9 - Closure

Case 3

Patient Information and Medical History

- 67-year old female.
- History of diabetes mellitus, psoriasis, venous insufficiency.

Wound Description

- Patient presented with 6.83cm² wound on left lower leg.
- Wound present for 2 years prior to application of cellular repair matrix.
- Failed porcine small intestine submucosa product, bilayered cell-based product, and human-fibroblast dermal substitute prior to treatment.

Treatment and Outcome

- Patient received 5 applications of the repair matrix.
- Wound closure achieved in 11 weeks.

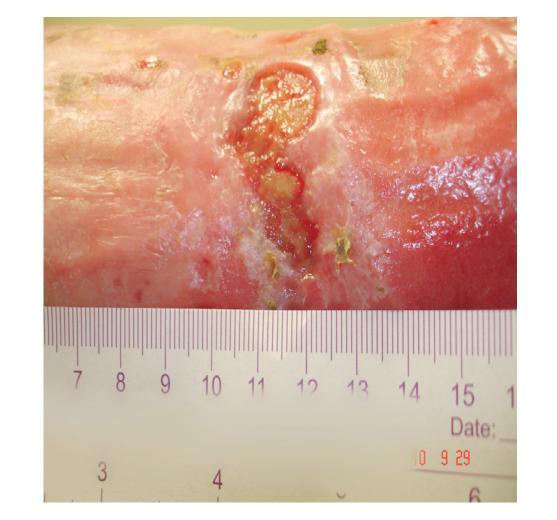


Prior to Treatment



Week 2







Case 4

Patient Information and Medical History

- 72-year old male.
- History of diabetes mellitus, obesity, hypertension.

Wound Description

- Patient presented with 4.5cm² on left lateral ankle.
- Wound present for 12 weeks prior to application of the cellular repair matrix.
- Failed porcine small intestinal submucosa product.

Treatment and Outcome

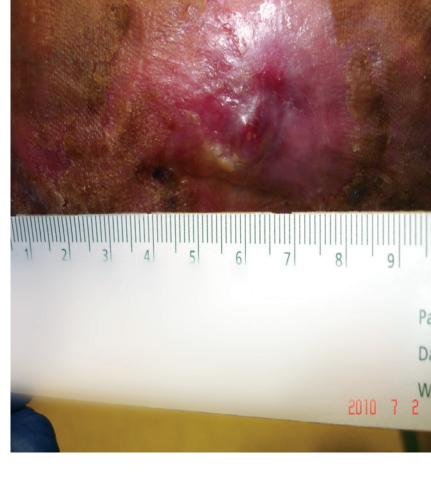
- Patient received 6 applications of the repair matrix.
- Wound closure achieved in 9 weeks.











Week 8 - Closure

Week 4