## Treatment of Venous Leg Ulcers with a Cellular Human Repair Matrix

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### Abstract

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 wounds. 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 epithelialization of the wound without evidence of drainage. The mean wound size was 8.66 cm². Healing rates were compared to standard care alone used for the repair matrix. Long-term follow-up data was recorded for patients treated with the repair matrix from April 2010 through March 2012 and underwent retrospective analysis to assess wound healing defined as complete re-epithelialization of the wound without evidence of drainage.

### Results

- Of the 34 patients treated with the repair matrix, 24 (70.5%) healed within 32 weeks, with 22 of these patients (64.7%) healing within 12 weeks. The mean time to closure among the 34 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.

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### Case 1

**Patient Information and Medical History**
- 68-year-old female
- History of peripheral vascular disease, stout deformed.

**Wound Description**
- Partial thickness 5.2 cm² wound on left lower leg

**Treatment and Outcome**
- Patient received 3 applications of the repair matrix
- Wound closure achieved in 6 weeks

**Graft prior to Treatment**
- Week 2
- Week 4
- Week 6
- Closure

**Graft during Treatment**
- Week 1
- Week 3

**Graft prior to Treatment**
- Week 4
- Week 6
- Week 8
- Week 11
- Closure

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### Case 2

**Patient Information and Medical History**
- 66-year-old male
- History of diabetes, venous insufficiency, hypertension, hypoxic trophic ulcers.

**Wound Description**
- Present with a 1.85 cm² wound on right lower leg

**Treatment and Outcome**
- Patient received 4 applications of the repair matrix
- Wound closure achieved in 4 weeks

**Graft prior to Treatment**
- Week 1
- Week 2
- Week 4
- Week 8
- Closure

**Graft during Treatment**
- Week 1
- Week 3

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### Case 3

**Patient Information and Medical History**
- 72-year-old male
- History of diabetes, venous insufficiency, hypertension, hypercholesterolemia.

**Wound Description**
- Failed wound vacuum prior to treatment.

**Treatment and Outcome**
- Patient received 2 applications of the repair matrix
- Wound closure achieved in 9 weeks

**Graft prior to Treatment**
- Week 2
- Week 4
- Week 6
- Week 8
- Week 12
- Closure

**Graft during Treatment**
- Week 1
- Week 8

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### Case 4

**Patient Information and Medical History**
- 72-year-old male
- History of diabetes mellitus, obesity, hypertension.

**Wound Description**
- Failed porcine small intestinal submucosa product, bilayered cell-based product, and human-fibroblast dermal substitute prior to treatment.

**Treatment and Outcome**
- Patient received 4 applications of the repair matrix
- Wound closure achieved in 9 weeks

**Graft prior to Treatment**
- Week 1
- Week 8
- Week 12
- Week 16
- Week 20
- Week 24
- Week 28
- Closure

**Graft during Treatment**
- Week 1
- Week 8

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