



# INJECTABLE HUMAN STEM CELLULAR MATRIX FOR PLANTAR DIABETIC FOOT ULCERATIONS JEFF DIKIS, DPM<sup>1</sup>, RICK SCANLAN, DPM<sup>2</sup>

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### **INTRODUCTION & PURPOSE**

To our knowledge, no study has evaluated the use of injectable human cellular repair matrix specifically for diabetic plantar foot ulcerations.

A novel approach of injectable human cellular matrix (Osiris Ovation<sup>®</sup>), which contains mesenchymal stem cells, neonatal fibroblasts, growth factors, and extracellular matrix, was utilized. The target population included plantar diabetic foot wounds in patients who had difficulty with nonweightbearing status, or who had failed standard grafting techniques.

# **MATERIALS & METHODS**

Two consecutive patients with nonhealing plantar foot wounds were grafted with injectable human repair matrix (Osiris Ovation<sup>®</sup>), harvested per standard protocol.<sup>1</sup> Each patient had failed standard nonsurgical treatment for a minimum of 6 weeks. Patient 1 (blue line) received Ovation at Weeks 13, 15, and 17. Patient 2 (green line) received Ovation<sup>®</sup> at Weeks 10 and 12. Following injection, the wounds were covered with foam dressing, sterile gauze and roll bandage.

Note: (Patient 2 received human matrix sheet grafts prior to Ovation<sup>®</sup>, however these were complicated by shearing off during weightbearing.)

# DISCUSSION

Ulcerations of the plantar foot are commonplace in the diabetic population. An estimated 8% of the more than 16 million Americans with diabetes have some type of lower extremity ulceration.<sup>2</sup> Application of advanced biohealing grafts to the plantar foot may be complicated by shearing forces encountered during weightbearing, disrupting the graft. The use of an injectable graft avoids this inherent complication.

The use of human cellular matrix stem cell grafts as adjuvant therapy for diabetic foot ulcerations has gained popularity recently. The injectable graft utilized (Osiris Ovation®) contains components necessary for natural tissue repair. The extracellular matrix allows cellular adhesion and migration. Naturally occurring growth factors and cytokines mediate cell proliferation and differentiation, angiogenesis, and remodeling. Endogenous mesenchymal stem cells aid tissue repair through down regulation of inflammation.





**INITIATION OF OSIRIS OVATION** 



#### RESULTS

Injectable stem cell therapy was utilized in two consecutive patients. Each patient went on to complete closure 5 weeks after initiation of treatment.

Plantar foot ulcerations are challenging to treat. Grafting of the plantar foot involves strict nonweightbearing following application. The use of injectable stem cells was utilized in two cases of plantar foot ulceration. The patients either had difficulty with weightbearing status or had complications from shearing of standard grafting previously. Following injectable grafting with Osiris Ovation<sup>®</sup>, each patient went on to complete closure.

#### CONCLUSION

The use of injectable human stem cellular matrix in the plantar foot is a viable treatment option, considering the difficulties encountered with standard grafting techniques. The use of injectable matrix provided complete closure in a series of two patients with non-healing ulcerations. Further considerations towards modification of treatment modalities must be considered.

#### RESOURCES

1. Osiris Therapeutics <u>http://www.osiris.com/tech\_omp.php</u> 2. Margolis DJ, Malay DS, Hoffstad OJ, et al. Incidence of Diabetic Foot Ulcer and Lower Extremity Amputation Among Medicare Beneficiaries, 2006 to 2008: Data Points #2. 2011