

Clinical Experience with Oasis[®] Wound Matrix for the Treatment of Venous and Diabetic Ulcers: A Series of Four Cases



Diabetic and venous ulcers are prevalent, costly, and can be frustrating to treat. These wounds are typically slow to heal and may develop into chronic wounds that are nonresponsive to therapy. Although standard care is effective for some of these wounds, a substantial portion fail to heal despite 3 or 4 months of diligent care.¹ Evidence from a number of studies shows that wounds that do not progress adequately toward healing within the first 2 to 4 weeks of standard care are unlikely to heal given 3 or 4 months of care.^{2,3} These findings suggest that difficult-to-heal wounds should be re-evaluated after 4 weeks; if they have not progressed adequately toward closure, more aggressive treatment strategies should be initiated.²

Chronic wounds may display many abnormalities in the extracellular matrix⁴ that develops in difficult-to-heal wounds. This suggests that strategies designed to address extracellular matrix deficits may be beneficial for these wounds. The naturally occurring extracellular matrix consists of structural and functional molecules that coordinate the healing process and provide a scaffold to support cellular proliferation.⁵ With inadequate or absent extracellular matrix, healing is impaired.

Oasis[®] Wound Matrix is a cell-free, naturally derived extracellular matrix that retains its natural three-dimensional structure.⁶ Because Oasis[®] contains some key components of the dermal extracellular matrix such as collagen, elastin, glycosaminoglycans, glycoproteins, and proteoglycans, it acts as an extracellular matrix replacement.⁶ Oasis[®] is stored at room temperature and has a shelf life of up to 2 years.⁷ It has been found to significantly improve wound management⁸ and is resorbed by the body over the course of each weekly application as it facilitates wound closure. Given its practical features and efficacy in clinical trials, Oasis[®] may be a logical next step in the management of difficult-to-heal wounds that are not progressing adequately toward closure. The four cases of difficult-to-heal wounds presented in this publication were treated with Oasis[®].



Case 1

A 45-year-old man with venous insufficiency, lupus, anemia, and a history of deep vein thrombosis (DVT) presented with an ulcer on the medial portion of his right ankle (see Figure 1a) and bilateral edema of the lower extremities. The ulcer had been present for 3 months; it exhibited fibrin within the wound bed and periwound inflammation. The ulcer, measuring 1.0 cm x 1.5 cm, was associated with pain rated by the patient as 4 to 6 on a 10-point scale. Initially, the wound was treated with papain-urea-chlorophyllin copper complex (PUCCC) and a cadexomer iodine-based wound product. After 9 days, granulation tissue was present and PUCCC was discontinued. At that time, treatment with Oasis® was initiated (see Figure 1b). Oasis® was applied once weekly and covered with a non-adherent, open-mesh, fabric dressing and a cadexomer iodine-based dressing. The Oasis® was changed once weekly for 7 weeks and the secondary dressings were changed three times per week. Visco/Cotton/Coban wraps Coban (3M Health Care) were used for compression and fibrin was excisionally debrided as needed. Ulcer size and pain were evaluated at 1-week intervals during follow-up.

Across all follow-up visits, the patient's rating of pain associated with the ulcer ranged from 0 to 2 on a 10-point scale. After 4 weeks, ulcer size decreased to 0.6 cm x 0.9 cm, representing 64% closure (see Figure 1c). Endovenous laser treatment was performed at week 5 and after 6 weeks ulcer size decreased to 0.4 cm x 0.5 cm (87% closure). By week 7, ulcer area decreased to 0.2 cm x 0.2 cm, the wound base had become superficial, and the wound was almost completely (97%) closed; thus, Oasis® treatment was discontinued (see Figure 1d). No adverse events were reported during Oasis® treatment.

Figure 1. Case 1: A 45-year-old man with a venous leg ulcer



Figure 1A. At presentation



Figure 1B. Oasis® initiated



Figure 1C. After 4 weeks of Oasis®



Figure 1D. Complete closure after 7 weeks of Oasis® treatment.

Case 2

An 86-year-old woman with venous insufficiency, arterial insufficiency, myelodysplastic anemia, hypothyroidism, and a history of DVT presented with an ulcer on her right lateral ankle (see Figure 2a) and bilateral edema of the lower extremities. The ulcer had been present for 17 weeks, characterized by eschar, and fully granulated with a superficial wound base. At presentation, the ulcer measured 1.2 cm x 1.1 cm proximal and 0.4 cm x 0.3 cm distal and the patient rated pain associated with the ulcer as 4 on a 10-point scale. The patient had been managed sequentially for a total of 13 weeks with various treatments, including silver sulfadiazine for 3 weeks, silver sulfadiazine/PUCCC for 6 weeks, PUCCC/gentamicin for 2 weeks, and a topical silver dressing for 2 weeks. At this point, the silver dressing was

Figure 2. Case 2: An 86-year-old woman with a venous leg ulcer



Figure 2A. At presentation



Figure 2B. After 1 week of Oasis®



Figure 2C. After 2 weeks of Oasis®



Figure 2D. After 3 weeks of Oasis®



Figure 2E. Completely epithelialized at 4 weeks after presentation.

Case 2 continued

discontinued and treatment with Oasis[®] initiated. Oasis[®] was applied once weekly and covered with a non-adherent and cadexamer iodine dressing that was changed two times per week. Visco/Cotton/Coban (3M Health Care) wraps were used for compression and the wound was excisionally debrided as needed. Pain and ulcer area were evaluated at 1-week intervals during follow-up.

Across all follow-up visits, the patient's rating of pain associated with the ulcer ranged from 0 to 1 on a 10-point scale. After 1 week, the ulcer size was 1.8 cm x 1.1 cm (see Figure 2b), and after 2 weeks, the ulcer size had decreased to 1.5 cm x 1.1 cm (see Figure 2c). Following 3 weeks of Oasis[®] application, the size of the ulcer decreased to 0.2 cm x 0.2 cm and Oasis[®] treatment was discontinued (see Figure 2d). By 4 weeks, the wound was completely epithelized (see Figure 2e). No adverse events were reported during Oasis[®] treatment.

Case 3

A 75-year-old woman with peripheral neuropathy and a history of cancer treated with surgery plus radiation therapy presented with a diabetic ulcer on her left plantar foot (see Figure 3a). The ulcer had been present for 15 weeks, exhibited periwound callus, and measured 1.3 cm x 0.8 cm at baseline. No pain was associated with the ulcer. The patient had initiated dry dressing for 2 weeks and had been treated with Silvadene (Medline) for 3 weeks. At this point, previous treatment was halted and treatment with Oasis[®] initiated. Oasis[®] was applied once weekly and covered with a non-adherent dressing. In addition, a cover dressing was applied. The patient was offloaded in a DH shoe (Royce Medical) and the wound periodically debrided excisionally to remove fibrin and periwound callus as needed. Pain and ulcer size were evaluated at 1-week intervals during follow-up.

No pain was associated with the ulcer during follow-up. After 1 week of Oasis[®] treatment, ulcer size decreased to 0.7 cm x 0.3 cm (80% closure). After 2 weeks, the size was 0.9 cm x 0.3 x 0.2 cm (74% closure) and following 3 weeks, the size was 0.8 cm x 0.3 cm (77% closure; see Figure 3b). The ulcer size continued to decrease over the next few weeks and after 8 weeks, the wound measured 0.5 cm x 0.1 cm and Oasis[®] treatment was discontinued (see Figures 3c, 3d). The wound was fully closed and healed when evaluated at 1 week post- Oasis[®] discontinuation (see Figure 3e). No adverse events were reported during Oasis[®] treatment.

Figure 3. Case 3: A 75-year-old woman with a diabetic foot ulcer



Figure 3A. At presentation



Figure 3B. After 3 weeks of Oasis[®]



Figure 3C. After 5 weeks of Oasis[®]



Figure 3D. After 8 weeks of Oasis[®]



Figure 3E. Ulcer closed.

Case 4

A 71-year-old woman with coronary artery disease, diabetes mellitus, hypertension, hypercholesterolemia, and a history of cerebrovascular accident and transient ischemic attacks presented with a right plantar diabetic foot ulcer on the first metatarsal phalangeal joint (see Figure 4a). The ulcer had been present for 9 weeks and measured 1.6 cm x 1.0 cm. The patient rated the pain associated with the ulcer as a 2 on a 10-point scale.

The ulcer had shown signs of infection (erythema, drainage, and periwound warmth) 1 week earlier and the patient had been placed on levofloxacin (Levaquin®, Ortho-McNeil), 500 mg, for 7 days. At that time, treatment with PUECC and silver sulfadiazine was initiated. This treatment with PUECC and silver sulfadiazine was subsequently halted and treatment with Oasis® initiated. Oasis® was applied once weekly, covered with a non-adherent dressing followed by a cover dressing. The patient was offloaded in a DH shoe (Royce Medical) and the periwound callus debrided as necessary.

Ulcer size and pain were evaluated at 1-week intervals during follow-up. No pain was associated with the ulcer during follow-up. After 1 week, the ulcer size decreased to 1.0 cm x 0.8 cm (38% closure; see Figure 4b). The wound continued to decrease in size over the subsequent weeks (45% closure at 2 weeks; 88% closure at 4 weeks). After 6 weeks, the size had decreased to 0.3 cm x 0.1 cm (98% closure) and Oasis® treatment was discontinued see (Figure 4c). The wound was fully closed when evaluated 1 week after stopping Oasis® treatment. No adverse events were reported during Oasis® treatment.

Figure 4. Case 4: A 71-year-old woman with a diabetic foot ulcer



Figure 4A. At presentation



Figure 4B. After 3 weeks of Oasis®



Figure 4C. Almost complete closure after 6 weeks of Oasis®.

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Discussion

In all four cases, the venous or diabetic ulcers had persisted for at least 2 months before Oasis[®] treatment and were chronic. In all cases, treatment with Oasis[®], combined with standard care, resulted in wound closure within 4 to 9 weeks. Treatment with Oasis[®] was discontinued approximately 1 week before complete wound closure in each case. The two patients with venous ulcers and one of the patients with a diabetic ulcer complained of pain before treatment with Oasis[®]; in all three cases, pain was reduced after initiating Oasis[®] treatment. Furthermore, Oasis[®] was well tolerated and no adverse events occurred in any of the four patients.

Deficits in the extracellular matrix may contribute to a failure of healing in patients with diabetes and/or venous insufficiency. Diabetes is associated with an increased glycosylation of collagen and fibronectin, which may interfere with attachment and migration of epithelial cells.⁹ Venous ulcers are characterized by fibrin cuffs (organized structures of extracellular matrix proteins around wound edges and trapped leukocytes and fibrin) as well as a lack of fibronectin in the ulcer tissue (a glycoprotein that mediates cell attachment, proliferation, and migration).¹⁰ Thus, attempting to replace extracellular matrix in these conditions is a logical treatment strategy and one that proved successful in this series of patients.


One advantage of Oasis[®], in addition to its documented benefits in the treatment of venous and diabetic ulcers,^{8,11} is its practicality. For instance, its 2-year shelf life and room temperature storage requirement facilitate routine use. Additionally, the cost of Oasis[®] is reasonable based on several randomized trials. In these studies, the average cost of 12 weeks of Oasis[®] was \$320 to treat venous leg ulcers and \$250 to treat diabetic foot ulcers.^{8,11} These clinical and practical features may make Oasis[®] a logical next step in treatment for patients with non-responsive venous or diabetic ulcers.

Conclusion

The four cases described demonstrate the safe and effective use of Oasis[®] for venous and diabetic ulcers that are at risk of becoming chronic wounds. Because venous and diabetic ulcers may have a defective extracellular matrix that contributes to delayed healing, replacing the extracellular matrix is a logical next step in therapy when adequate progress is not made with standard care.

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