

# Limb Preservation and Functionality Utilizing Perfusion Decellularized Porcine Hepatic 3-Dimensional Wound Matrix\* for Deep Complicated Diabetic Ulcerations

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## INTRODUCTION

The annual incidence of diabetic foot ulcer worldwide is between 9.1 to 26.1 million. Around 15% to 25% of patients with diabetes mellitus will develop a diabetic foot ulcer during their lifetime<sup>1</sup>. The total medical costs for the management of diabetic foot disease in the U.S. ranges from \$9-\$13 billion and it is estimated that 85% of all amputations are caused by foot ulceration which further deteriorates to chronic infection and severe forms of gangrene<sup>2</sup>. As a result, these high-risk diabetic patients present with multiple clinical issues that require urgent attention. The surgeon or health care professional faces many potential challenges as they outline a strategic care plan for healing these complex patients. Ultimately, the primary goal is to obtain closure of the wound and restore a functional limb. One would also desire to have the wound filled with a matrix that covers and protects vital structures and conforms to deep, tunneling and undermining areas to achieve conversion to human dermis that is sustainable. If wound healing, and ultimately functional restoration is not achievable, then it is not unreasonable to consider amputation that may provide a higher level of function for the patient.

## METHODS

This is a retrospective review of four patients with challenging lower extremity wounds that were deep, tunneling or undermining. All patients underwent sharp debridement and were treated with an application of a perfusion decellularized porcine hepatic three-dimensional wound matrix in conjunction with negative pressure wound therapy due to the nature of the wound depth. Protocol included pre and postoperative care and treatment recommendations across the continuum of care.

### Perfusion Decellularization Technology

Perfusion decellularization is a proprietary method for removing native cells through the existing vasculature of whole or partial organs. The result is a preserved collagen scaffold with the appropriate native vasculature and microenvironment for cellular integration. It is through this technology that the porous three-dimensional wound matrix can be manufactured from a highly vascular porcine liver.

### References:

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\*Miro3D wound matrix, Reprise Biomedical, Inc. Plymouth, MN.  
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## DISCUSSION

All four patients in this case series had complex diabetic wounds of the foot and/or ankle and each individual's comorbidities further complicated the potential outcomes. All patients healed their complex wounds completely and without the need of a skin graft for final closure. Further, a functional foot and ankle was maintained to ensure mobility and allow for a higher quality of life.

### CASE #1

47 year old male with history of type 2 diabetes with neuropathy and HTN who presented to ED with cellulitis and abscess of left foot. Patient underwent incision and drainage followed by NPWT. Prior to 3D wound matrix, wound measured 22 cm x 4 cm x 1.5 cm. Post 49 days with one application of 3D wound matrix and wound VAC at 125 mmHg, wound size was 8 cm x 1 cm x 0.1 cm. Post 68 days from the initial application and continued NPWT, the wound size was 0.8 cm x 0.4 cm x 0.1 cm. At day 131, wound was fully closed.



### CASE #2

60 year old male with history of type 2 diabetes with neuropathy, HTN, OSA, CKD, morbid obesity status post lap gastrectomy, and hyperlipidemia who presented with chronic ulceration of right anterior ankle with associated cellulitis and abscess. Patient underwent drainage of abscess and excisional debridement with wound VAC placement at 125 mmHg. Eight days later, wound measured 8 cm x 6 cm x 0.5 cm with 2.5 cm tunnel at 12 o'clock and 3D wound matrix applied with continued NPWT. After one application of 3D wound matrix, wound measured 3.4 cm x 1.9 cm x 0.1 cm at 65 days postop and 0.5 cm x 0.5 cm x 0.1 cm at 123 days postop. At day 137, wound was fully closed.



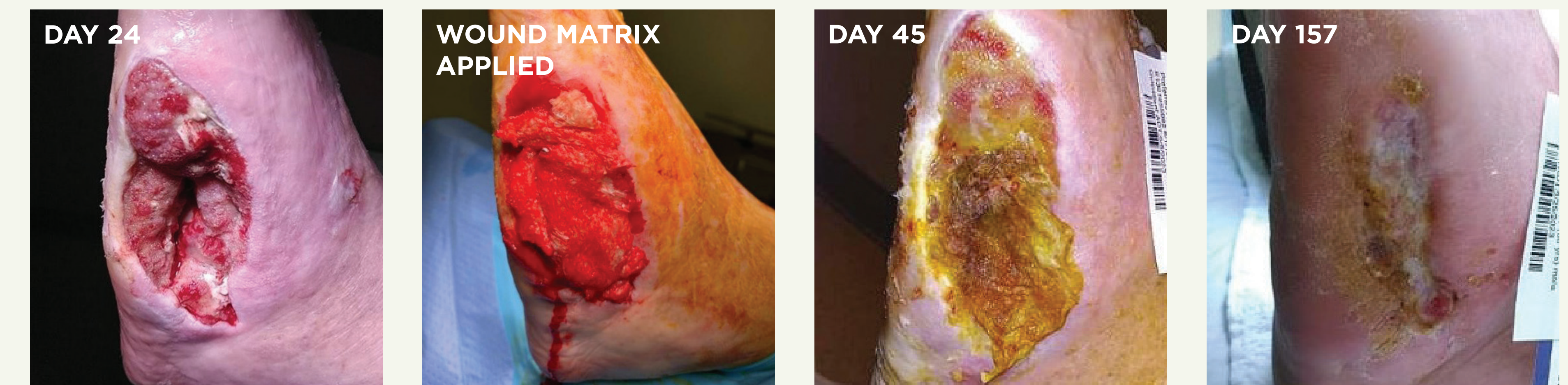
### CASE #3

50 year old female with history of type 2 diabetes with neuropathy, residual charcot foot on right, HTN, hypothyroidism, and hyperlipidemia who presented to ED with DFU of right plantar foot complicated by cellulitis/abscess, necrosis, and undermining. Patient underwent incision and drainage of right foot abscess with right lateral sesamoidectomy. Wound VAC was applied for 24 hours during hospitalization. 21 days later, 3D wound matrix was applied with NPWT at 125 mmHg. Wound measured 2 cm x 2.2 cm x 2 cm. 35 days postoperatively, wound measured 1.5 cm x 1.5 cm x 0.5 cm and a 2nd application of 3D wound matrix was applied. 84 days following the initial application of 3D graft (49 days from the 2nd application), wound was fully closed.



### CASE #4

65 year old male with history of type 2 diabetes with neuropathy, hyperlipidemia, CAD, OSA, and iron deficiency anemia who presents with DFU of left lateral foot for greater than one year and complicated by osteomyelitis. PSH significant for multiple foot surgeries including I&D, left 5th metatarsal amputation and left 5th toe amputation and recently underwent left 5th metatarsectomy with tendon transfer and wound VAC application. 21 days postoperatively, wound size was 10 cm x 4 cm x 2.4 cm and 14 days later, 3D wound matrix applied and continued NPWT. On postop day 10, there was a significant depth reduction of 85% noted with wound measuring 9.5 cm x 3.4 cm x 0.3 cm. 56 days following 1st application of 3D, patient underwent debridement and application of 2nd 3D wound matrix with wound measuring 7 cm x 2 cm x 1 cm postop. Patient started HBOT postoperatively and continued to progress with almost 100% epithelialization noted 63 days following 2nd application.



## CONCLUSION

Health care professionals have many choices when deciding the proper treatment plan for complicated patients in limb preservation. Perfusion decellularized porcine hepatic three-dimensional wound matrix is a novel technology that separates itself from all other grafts for wounds that are deep, tunneling or undermining. The three-dimensional porcine wound matrix has shown to close these challenging wounds with one or two applications. Creating a functional outcome for the patient is paramount and essential to maintain quality of life.