# Efficacy of Three-Dimensional Acellular Xenograft* in Promoting Healing of Challenging Chronic Diabetic Foot Ulcers Penetrating to Underlying Tissues: Two Case Studies

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## INTRODUCTION

Diabetic foot ulcers (DFUs) represent one of the most complex and costly chronic wound types, especially when penetrating to underlying tissues such as tendon, muscle, or bone. These wounds often occur in patients with significant comorbidities, including peripheral vascular disease, neuropathy, and immune compromise. Healing is further complicated by factors like poor adherence to care protocols, smoking, or inadequate offloading.

The use of advanced biologics—specifically, a three-dimensional (3D) acellular xenograft*—has shown promise in overcoming these barriers. The 3D acellular xenograft* used in this study is derived from porcine liver tissue, processed to remove cellular components while preserving an intact extracellular matrix and the organ's inherent vascular architecture. This scaffold facilitates cellular infiltration, neovascularization, and granulation tissue formation, offering a biologically conducive environment for healing even in challenging wound settings.

This poster presents two case studies that demonstrate the practical clinical application and effectiveness of this novel xenograft* in promoting wound closure in complex, chronic DFUs.

## METHODS

**Case 1:** A 64-year-old African American male presented with a chronic DFU (15.81 $cm^2$) on the plantar surface of the left foot, exposing tendon. The wound had been present for 55 days before enrollment. Weekly applications of the 3D acellular xenograft* were administered for the first four weeks, followed by biweekly applications through week 13. Throughout treatment, the patient adhered to prescribed offloading protocols and standard dressing changes per protocol.

**Case 2:** A 33-year-old African American male presented with a smaller but older DFU (2.24 $cm^2$) on the left heel. The wound had been present for 24 weeks and was complicated by the patient's history of tobacco use and poor adherence to offloading. Weekly applications of the xenograft* were performed during the first four weeks. Despite non-ideal clinical conditions, the wound was monitored closely, and standard of care (SOC) procedures were implemented throughout, including regular debridement and peri-wound skin assessments.

Both patients were treated in accordance with protocols derived from ongoing clinical studies evaluating the porcine liver-derived xenograft*, including regular wound measurements and documentation of quality of life and pain scale metrics.

*Miro3D® wound matrix, Reprise Biomedical, Inc., Plymouth, Minnesota.

Miro3D wound matrix is indicated for the management of wounds, including: partial and full-thickness wounds; pressure ulcers; venous ulcers; chronic vascular ulcers; diabetic ulcers; tunneled, undermined wounds; trauma wounds (abrasion, lacerations, partial thickness burns, skin tears); drainage wounds; and surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence).

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## RESULTS

These case studies illustrate the promising potential of a porcine liver-derived 3D acellular xenograft* in accelerating healing of chronic DFUs, even in high-risk situations. In both cases, robust granulation tissue and significant percentage area reduction (PAR) were observed, leading to near or complete healing within 8 to 13 weeks.

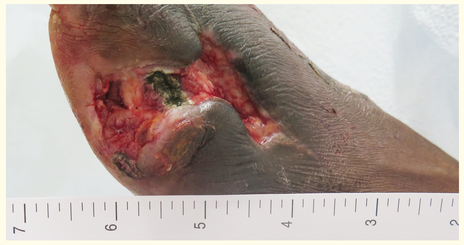
**Case 1** exemplifies an optimal healing trajectory when SOC is combined with a regenerative scaffold provided by the xenograft* and patient adherence to offloading protocols. Importantly, healing occurred despite tendon exposure—often a predictor of poor outcomes—suggesting the scaffold's capacity to facilitate cellular ingrowth and tissue remodeling in deep, complex wounds.

**Case 2** in contrast, demonstrates the xenograft's* efficacy under suboptimal conditions. Despite poor compliance and the presence of contributing risk factors (e.g., smoking, moisture imbalance), the wound achieved over 96% PAR. This highlights the product's potential to perform in real-world outpatient scenarios where perfect adherence is not always achievable.

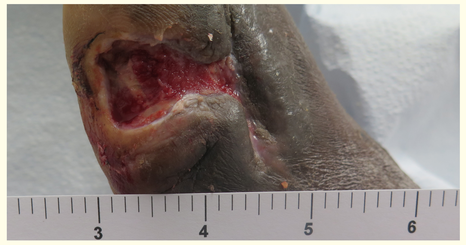
These findings align with guidelines from the accompanying clinical protocols, which emphasize structured weekly and biweekly applications and measure both objective (e.g., PAR, granulation) and subjective (e.g., pain, QOL) endpoints. The porous, vascular scaffold of the xenograft* may contribute to a more favorable healing microenvironment, promoting both epithelialization and resolution of chronic inflammation.

### CASE #1

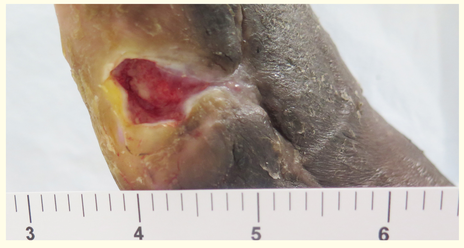
Despite tendon exposure—a known risk factor for non-healing—the wound showed steady granulation tissue formation and progressive closure, aided by the patient's consistent compliance and the regenerative scaffold provided by the xenograft*.



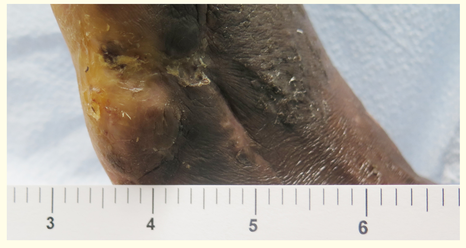
**Week 0 (Baseline):** 5.1 × 3.1 × 0.3 cm



**Week 4:** 3.6 × 2.0 × 0.2 cm → ***54.5% PAR***



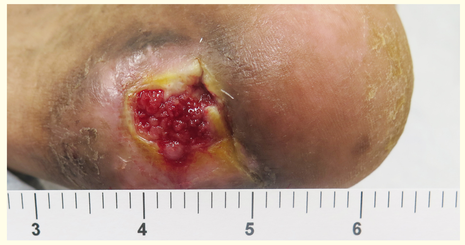
**Week 8**: 1.4 × 1.1 × 0.1 cm → ***90.3% PAR***



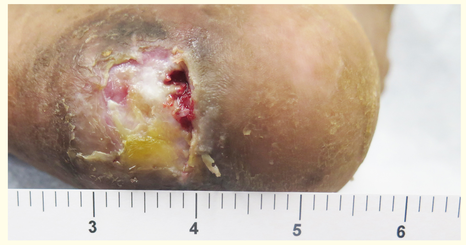
**Week 13:** Complete closure

### CASE #2

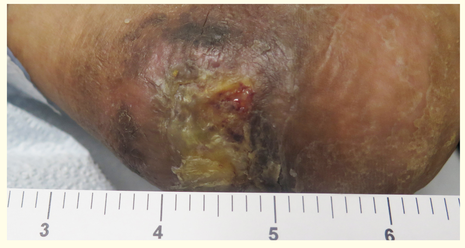
Although this patient was less compliant with offloading and experienced wound maceration due to environmental moisture and dressing challenges, the wound still demonstrated significant improvement. By week 8, the wound had nearly closed, and peri-wound maceration and exudate levels had diminished considerably.



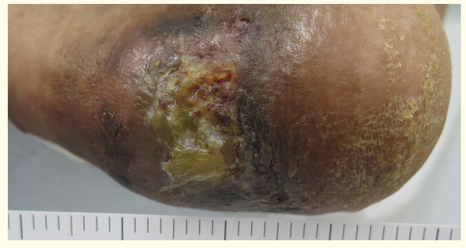
**Week 0 (Baseline):** 1.6 × 1.4 × 0.1 cm



**Week 4:** 0.5 × 1.7 × 0.1 cm → ***80.4% PAR***



**Week 8:** 0.4 × 0.2 × 0 cm → ***96.4% PAR***



**Week 9: - Near complete closure**

## DISCUSSION

In the first case, the wound area reduced by 54.5% by week four, despite the wound's penetration to exposed tendon. This improvement promoted a transition to biweekly applications, leading to a 90.3% percent area reduction (PAR) by week eight, with the wound area decreasing to 1.5 sq. cm. The consistent use of the three-dimensional acellular xenograft*, alongside standard of care and adherence to offloading protocols, played a critical role in achieving complete wound healing by week 13.

In the second case, the three-dimensional acellular xenograft* facilitated significant healing despite suboptimal clinical conditions. By week four, the wound area had decreased by 80.4%. Although fluctuations occurred due to maceration and lack of offloading, the wound area reached 0.08 sq. cm by week eight, representing an 96.4% PAR. The second case demonstrated improved peri-wound conditions, including reductions in maceration, while both cases exhibited reductions in exudate over time.

## CONCLUSIONS

These two case studies demonstrate that a porcine liver-derived 3D acellular xenograft* can significantly accelerate healing in chronic DFUs, including wounds with exposed tendon or those complicated by poor patient compliance. The scaffold's ability to support granulation tissue formation and reduce wound area under both ideal and challenging conditions underscores its clinical utility. Further studies are warranted to establish efficacy across broader patient populations and wound types. Nonetheless, these initial cases support the integration of 3D acellular xenografts* as a valuable addition to the DFU treatment paradigm, particularly for difficult-to-heal wounds.