# A Newly Approved Piscine Acellular Dermal Xenograft Used for the Treatment of Diabetic Foot Wounds: A Case Series

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## Abstract

**PURPOSE:**
A case series is presented to demonstrate the efficacy of a piscine acellular dermal xenograft that is newly approved for the treatment of diabetic foot wounds.

**BACKGROUND:**
Over the past few years, the piscine dermal xenograft has been evaluated in several studies for efficacy and safety in treating patients with acute and chronic wounds. This graft has been recently approved by the FDA for use in the United States.

This piscine acellular dermal xenograft differs from other available products in the market. Since there is no known fish to human disease transmission risk, it requires only minimal processing thus allowing it to retain its Omega 3 fatty acid and collagen scaffolding. This is thought to aid healing by maintaining moisture balance, providing mechanical protection and strength to the dermal matrix, and by acting as a barrier to bacterial contamination.

**METHODS:**
Participants consisted of three diabetic male patients with foot wounds of varying etiologies. Prior to initial graft application, each patient had a foot wound of greater than 6 weeks in duration.

After sharp wound debridement and wound bed preparation, each participant received an application of the piscine acellular dermal xenograft. Graft reapplication was performed as needed. Patients were followed weekly for serial wound measurements. Termination period was set at complete wound closure.

**CONCLUSIONS:**
Initial results illustrate favorable outcomes with all wounds showing a rapid reduction in ulcer dimensions allowing for overlying epithelialization. Preliminary observations have demonstrated a high rate of patient satisfaction and favorable functional and cosmetic outcomes.

The authors recommend further investigation to achieve approval for further alternative treatment indications.

## Background

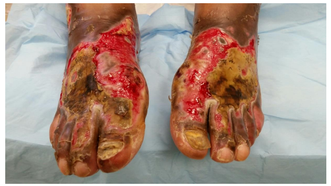
Diabetic foot ulcerations and lower extremity amputations continue to burden the US health care system. In 2012, more than 22.3 million people in the USA were diagnosed with diabetes, with $176 billion in direct medical cost and $69 billion in lost productivity.[1] Diabetic ulcers precede 85% of lower extremity amputations.[2] The healing time for diabetic ulcerations can be tedious and slow.
The Wound Healing Society guidelines recommend consideration of advanced wound therapies if a diabetic ulcer does not reduce in size by 40% or more after four weeks of standard therapy.[3] Application of biological dressings can potentially save health care dollars as they have been shown to decrease healing time.[1] Current literature recommends the use of biological dressings as an adjunctive therapy to standard wound care. Kerecis™ (Omega3, Kerecis, Isafjordur, Iceland) acellular dermal xenograft is an advanced biological wound dressing for the use of diabetic foot ulcerations. It is composed of Icelandic Cod fish skin that requires minimal processing due to low risk of disease transmission. This is advantageous as it maintains its natural structure and retaining its Omega-3 fatty acids. Literature has demonstrated superiority of piscine acellular graft in comparison to bovine skin substitutes, however research is limited.[4, 5] A case series is presented to demonstrate the efficacy of piscine acellular dermal xenograft in the outpatient wound care center setting.

## Materials and Method

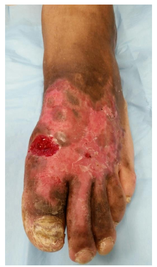
Three patients with a history of chronic diabetic foot ulcers were randomly selected for application of piscine acellular dermal xenograft. Prior to application, all patients received standard wound care for at least 6 weeks. Wound bed preparation was performed via sharp debridement utilizing a #15 surgical blade and a dermal curette. The recipient sites were copiously cleansed with sterile normal saline. Hemostasis was achieved by application of topical pressure. Following wound bed preparation, the piscine acellular dermal xenograft was rinsed with sterile normal saline and fenestrated with a #15 surgical blade. Following direct application to the wound, graft margins were secured with Steri-Strips. The graft sites were covered with a bolster dressing consisting of sterile 4 x 4 gauze, roll gauze and covered with a lightly compressive elastic bandage. Offloading measures were implemented to ensure protection of the graft site. The patients were followed weekly to document and observe uptake of graft material until complete wound closure.

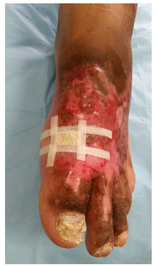
## Case Study

A 46 year old diabetic male with third degree burns to both feet. The right foot was used as a control and was treated with standard wound care. The left foot, which received piscine acellular dermal xenograft treatment, was noted to heal 2 months faster as compared to the control.

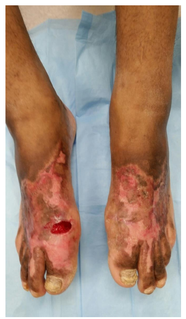


Initial presentation





Application of graft



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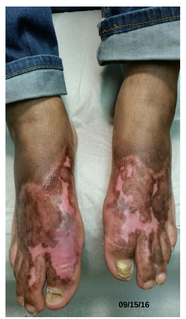
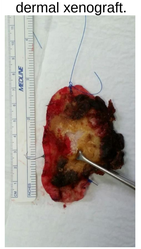
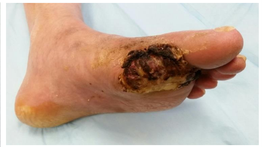



Resolved Ulcer

## Case Study

A 64 year old diabetic male status post resection of verrucous carcinoma, who had failed to heal with standard wound care, was treated with piscine acellular dermal xenograft.



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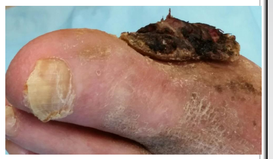
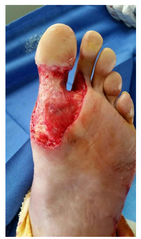
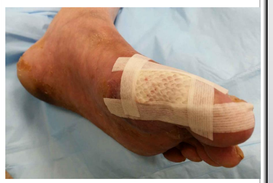
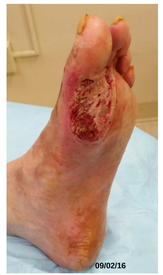




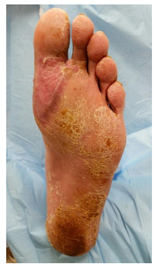
Post excisional biopsy of lesion



Application of graft



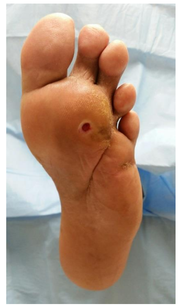

Improved granulation post application of graft



Resolved Ulcer

## Case Study

A 68 year old diabetic male presented to the wound care clinic with a non-healing chronic plantar diabetic foot ulcer.



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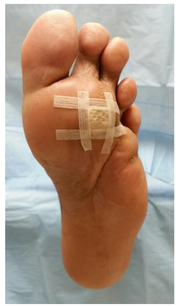
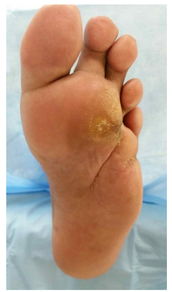


Application of graft



Resolved Ulcer

## Analysis & Discussion

Currently, the scientific community lacks a full understanding of the complete mechanism by which biological membranes can facilitate wound healing. Recent research has demonstrated clear benefits of the use of biological membranes in the field of wound healing.[6] A possible advantage for the use of biological membrane is an increased healing rate, particularly in chronic wounds that fail standard wound care treatment.[1] The use of biological membranes can reduce overall treatment costs.

Due to the limited number of cases, the authors cannot formulate any definitive conclusions, however favorable outcomes and favorable patient satisfaction was noted.

In all the presented cases, complete wound closure was achieved in an average of 6 weeks. None of the patients had any adverse reactions. The use of piscine acellular dermal xenograft is noted to be a safe and viable adjunctive tool for achieving wound healing when used in conjunction with standard wound care, including offloading, infection control and frequent debridement.

Further studies are suggested to evaluate the effectiveness of its use and to establish further treatment indications.

## References

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