

Treatment of Diabetic Foot Ulcers

Using Hydrated, Sterile, Ultra-thick Human Amniotic Membrane Allograft

Lawrence Chen, DPM

San Jose, CA

Introduction

Diabetic foot ulcers (DFU) present a substantial clinical and economic burden to healthcare systems, significantly reducing the quality of life of those affected. Despite aggressive treatment with debridement, infection control, dressings, and offloading, 55% of DFUs fail to heal.¹ This is alarming as delayed wound healing is the single most common cause of lower extremity amputation among the diabetic population.²⁻⁵ When DFUs fail to respond to standard of care, skin substitutes and regenerative treatments can be used to support the wound healing process. Ultra-thick human amniotic membrane is one treatment modality that can be used due to its anti-inflammatory and anti-scarring properties, with a key advantage of being readily available without necessitating refrigeration storage.⁶⁻⁸

Methods

A case series of 3 patients with DFUs who were treated with a fully hydrated, sterile, ultra-thick human amniotic membrane derived from the umbilical cord (AM) allograft† in the wound clinic. In brief, the wound was irrigated, and an AM allograft† was applied without sutures followed by a dressing to maintain moisture control and prevent allograft dislocation.

Results

CASE 1

A 55-year-old male with end-stage renal disease, Peripheral Arterial Disease (PAD), Diabetes Mellitus (DM), and prior transmetatarsal amputation presented with a DFU (FIG. 1A). Following a single application of AM, robust granulation tissue was noted at 9 weeks, with remanent AM graft still visible in the wound bed (FIG. 1B). Four additional applications of AM were applied at 12 weeks (FIG. 1C), 13 weeks, 15 weeks (FIG. 1D), and 16 weeks (FIG. 1E). Complete epithelialization was noted at 24 weeks (FIG. 1F).

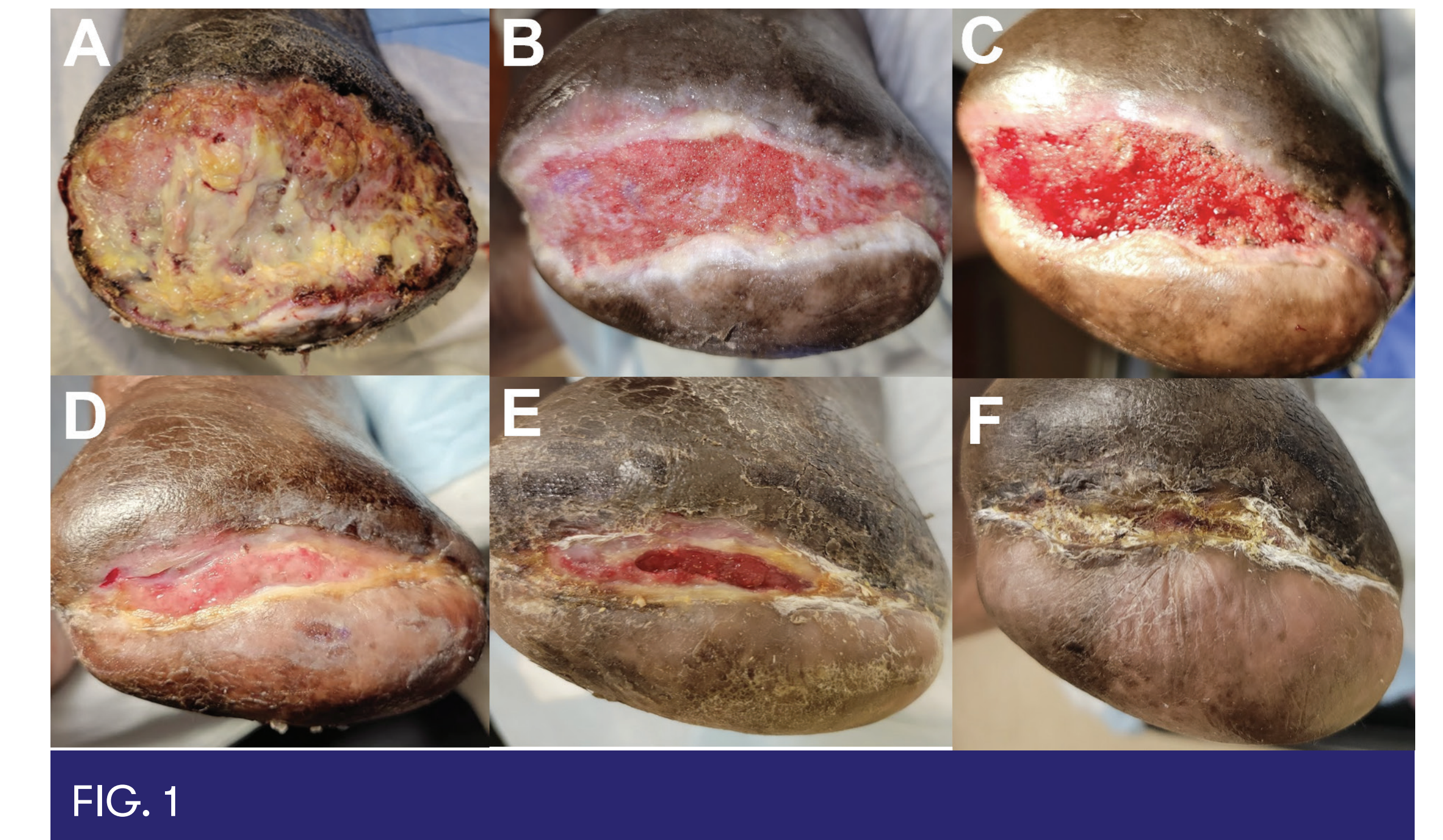


FIG. 1

CASE 2

A 64-year-old male with hypertension, DM, and sepsis presented with a DFU (FIG. 2A) and was planning to return to Vietnam in 2 months. Debridement was performed (FIG. 2B) with application of AM. By week 4, the wound was filled with robust granulation tissue (FIG. 2C), with complete healing noted at 7 weeks (FIG. 2D).



FIG. 2

CASE 3

A 65-year-old male with DM and PAD presented with a DFU that failed to improve with prior debridement and dressings by an outside physician (FIG. 3A). AM was applied at 2 weeks (FIG. 3B), with healing noted at 6 weeks (FIG. 3C). After another AM application at 8 weeks (FIG. 3D), the wound markedly reduced in size by 12 weeks (FIG. 3E), with complete healing achieved at 17 weeks (FIG. 3F).

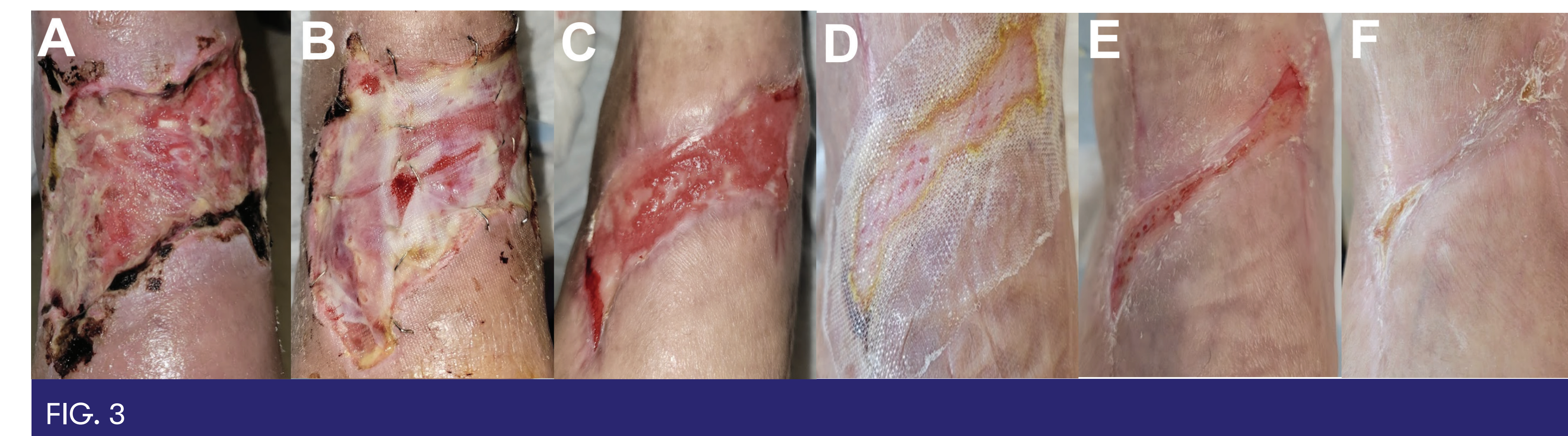


FIG. 3

†Neox® RT, BioTissue Holdings Inc, Miami, FL

Discussion

Treatment of DFUs with fully hydrated, sterile, ultra-thick human AM allograft† in the wound clinic resulted in complete wound closure in 7-24 weeks without need for sharp debridement in the operating room.

1. Fife CE, Eckert KA and Carter MJ. Publicly Reported Wound Healing Rates: The Fantasy and the Reality. *Advances in wound care*. 2018; 7: 77-94.
2. Singh N, Armstrong DG and Lipsky BA. Preventing foot ulcers in patients with diabetes. *Jama*. 2005; 293: 217-28.
3. Jones SA, Scheller J and Rose-John S. Therapeutic strategies for the clinical blockade of IL-6/gp130 signaling. *JClinInvest*. 2011; 121: 3375-83.
4. Sen CK, Gordillo GM, Roy S, et al. Human skin wounds: a major and snowballing threat to public health and the economy. *Wound repair and regeneration : official publication of the Wound Healing Society [and] the European Tissue Repair Society*. 2009; 17: 763-71.
5. Sheehan TP and Gondo GC. Impact of limb loss in the United States. *Physical medicine and rehabilitation clinics of North America*. 2014; 25: 9-28.

6. Raphael A. A single-centre, retrospective study of cryopreserved umbilical cord/amniotic membrane tissue for the treatment of diabetic foot ulcers. *Journal of wound care*. 2016; 25: S10-S7.
7. Tseng SC, Espana EM, Kawakita T, et al. How does amniotic membrane work? The ocular surface. 2004; 2: 177-87.
8. Marston WA, Lantis JC, 2nd, Wu SC, et al. An open-label trial of cryopreserved human umbilical cord in the treatment of complex diabetic foot ulcers complicated by osteomyelitis. *Wound repair and regeneration : official publication of the Wound Healing Society [and] the European Tissue Repair Society*. 2019.