# Clinical Outcomes of Lyophilized Human Amnion Chorion Membrane in Treating Hard-to-Heal Wagner Grade III Diabetic Foot Ulcers in Complex Cases

# Introduction

Diabetic foot ulcers (DFUs) are a serious complication of diabetes, leading to high rates of disability and mortality. Approximately 15–25% of adults with diabetes will develop DFUs, placing a significant burden on public health and the economy.

These ulcers increase the risk of infection, gangrene, and amputation, with 20% of moderate-to-severe cases resulting in amputation. The longer an ulcer remains open, the higher the risk of infection and tissue damage. Patients with DFUs often experience chronic pain that interferes with daily activities and sleep, greatly affecting their quality of life. Additionally, the 65% recurrence rate within five years contributes to long-term disability. Lyophilized Human Amnion Chorion Membrane (LHACM) is a tri-layer allograft composed of placental amnion, intermediate, and chorion layers. It contains over 300 regulatory proteins and a biocompatible extracellular matrix ECM, forming a protective barrier that supports the natural healing cascade. This retrospective case series examines the effectiveness of LHACM, combined with Standard Care (SoC), in managing hard-to-heal DFUs in clinically complex patients.

## **Methods**

This retrospective, multicenter case series examined the management and outcomes of hard-to-heal DFUs unresponsive to SoC. Patients with Wagner Grader 3 DFUs, complicated by multiple comorbidities and diabetic foot complications such as peripheral neuropathy, Charcot foot deformity, or osteomyelitis, were selected for this case series. The primary outcome was the time to achieve complete wound closure, while secondary outcomes included infection control and the ability to resume daily activities, such as walking and driving.

## Results

Cases included had been unresponsive to prior treatments and dressings for <u>1->2 years</u> before LHACM application. The mean wound size reduction across the two cases was 62.5%, with a median reduction of 68% after three weeks of treatment. Both LHACM-treated wounds closed with a mean time to closure of 45.5±10.5 days (Fig. 1). Individual cases are detailed below.



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**Case Presentation** 

## Case 1

A 65-year-old male with diabetes, Charcot neuroarthropathy, hypertension, and hyperlipidemia presented with a chronic Wagner Grade 3 DFU with an exposed fat layer on the left plantar foot, which had been unresponsive to prior treatments (including previous SoC, other allografts, alginate dressings, compression wraps, and offloading) and persisted for over a year. Following debridement, the wound was treated with LHACM, advanced dressings, compression therapy, and offloading with a PegAssist shoe. The wound closed fully in 56 days with no complications or signs of infection. The patient resumed normal activities and was fitted with diabetic shoes to prevent recurrence.



## Case 2

A 66-year-old male with type 2 diabetes, chronic kidney disease (post-renal transplant), hypertension, coronary artery disease, peripheral neuropathy, obesity, a history of smoking, and polypharmacy (13 medications) presented with a Wagner Grade 3 DFU on the left first metatarsal head, which persisted for over 2 years, despite prior wound management. The ulcer was complicated by osteomyelitis and was a full-thickness wound, which increased the risk of infection and delayed wound closure. Treatment included cleansing, debridement (including bone), advanced dressing, LHACM, and a Total Contact Cast (TCC) for off loading. After four LHACM applications over 35 days, the wound fully closed with no complications



## Conclusion

This case series highlights the effectiveness of LHACM as an adjunctive therapy for managing hard-to-heal DFUs that remain unresponsive to SoC in clinically complex patients. Patients in this series presented with Wagner Grade 3 DFUs and multiple comorbidities and complications such as Charcot deformities, peripheral neuropathy, and osteomyelitis, which contributed to delayed wound closure despite 1->2 years of SoC. However, despite these complexities, complete wound closure was achieved in all patients within a mean of 45.5 days, demonstrating the effectiveness of LHACM when combined with SoC.

Hard-to-heal wounds, particularly those complicated by Charcot deformities and osteomyelitis, often require advanced interventions beyond SoC to achieve closure and prevent recurrence.

LHACM accelerated wound closure, reduced complications, and addressed a critical gap in the treatment of hard-to-heal wounds. Its ease of application and ability to support the wound healing cascade make it a valuable tool in advanced wound management. These findings support the broader adoption of LHACM in clinical practice to improve patient outcomes and quality of life for those with challenging DFUs. Further studies will be essential to validate these results and expand the evidence base for its broader implementation.

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