

Early Experience Using Novel Ovine Forestomach Matrix and Hyaluronic Acid Composite Graft in the Outpatient Treatment of Real-World Chronic Lower Extremity Wounds

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INTRODUCTION

In 2020, the burden of chronic wounds impacted the quality of life of approximately 2.5% of the United States population and continues to climb[1]. Chronic wounds include those that are unresponsive to appropriate initial therapy or remain persistent for greater than 3 months in the face of appropriate additional care. The occurrence of these wounds leaves patients frustrated and searching for additional options. The goal of this study was to document use of a novel "Cellular, Acellular, Matrix-like Product" (CAMP), ovine forestomach matrix-hyaluronic acid (OFM-HA*) graft, on complicated wounds and patients. This composite CAMP (OFM-HA) is designed to facilitate cellular infiltration and migration to drive improved wound closure.

METHODS

This multi-center, retrospective case series included five (n=5) patients with chronic diabetic foot ulcers (DFU) treated with OFM-HA in the outpatient setting following at least 4 weeks of conservative care. Endpoints include time to complete closure, percent area reduction (PAR), responders at 4-weeks, time to closure, and number of product applications. All data was gathered retrospectively via electronic medical records. Patients were not excluded due to complex comorbidities in an effort to reflect real world patient outcomes.

RESULTS

All five patients achieved at least 50% PAR and complete closure during the study interval with no device-related adverse events. All patients responded to treatment and achieved complete closure with no more than 5 (five) OFM-HA applications during the treatment period.

REFERENCES

[1] Sen CK. Human Wound and Its Burden: Updated 2020 Compendium of Estimates. *Adv Wound Care* (New Rochelle). 2021 May;10(5):281-292. doi: 10.1089/wound.2021.0026. PMID: 33733885; PMCID: PMC8024242

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CASE 1: 76--Year-old female with DM and prior TMA presents with chronic sub-metatarsal Wagner 2 DFU

Week 0: Initial Defect



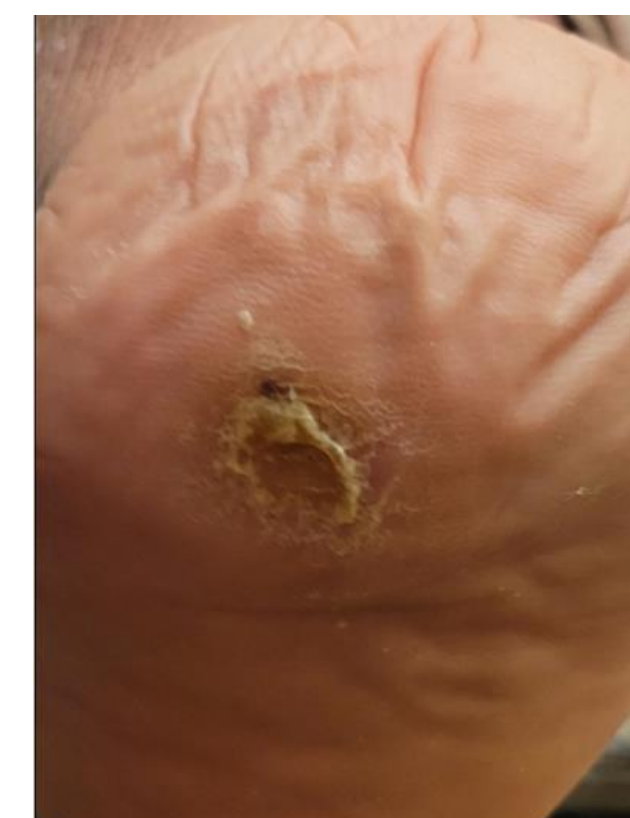
Week 0: OFM-HA application



Week 3: Significant reduction in wound size



Week 8: 100% epithelialization, 3 applications of OFM-HA



CASE 4: 56-year-old female with DM and history of Charcot presents with chronic Wagner 2 DFU.

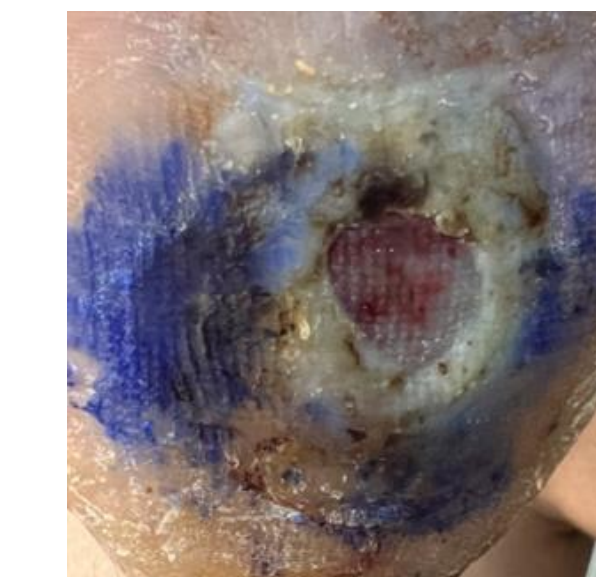
Week 0: Initial defect.



Week 0: Application of OFM-HA



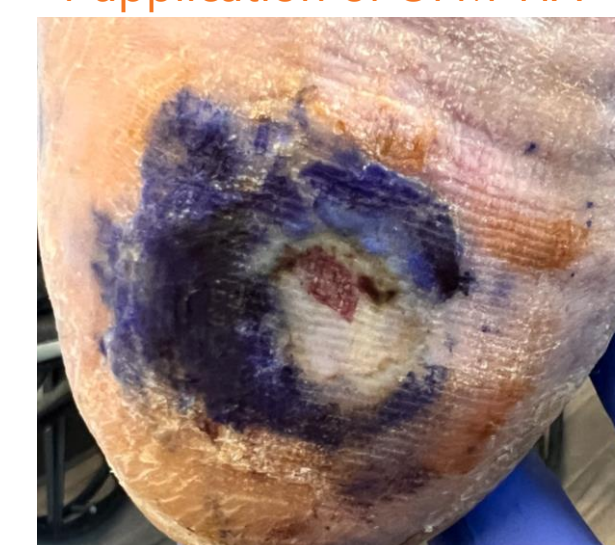
Week 1: Noted improvement in wound bed



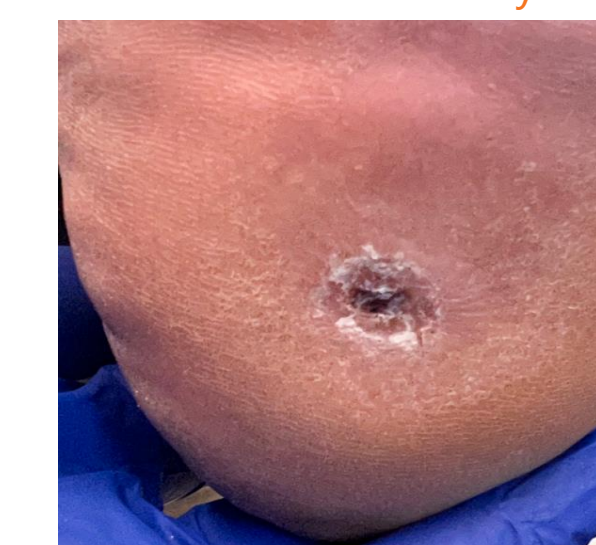
Week 3: Significant reduction in wound area



Week 6: Near full epithelialization, 1 application of OFM-HA



Long-Term: 100% epithelialized by **Week 7** and remains healed by 5 months (pictured)



CASE 2: 65-Year-old male with Wagner 4 DFU and initially treated surgically with OFM graft to cover exposed bone following partial amputation of gangrenous lateral rays

Week 0: Initial Outpatient Presentation



Week 1: Improved depth and reduced wound area



Week 4: Significant epithelialization



Week 9: 100% epithelialization, 5 applications of OFM-HA



CASE 5: 62-Year-old with DM, PAD, HIV, bladder cancer, history of Charcot presents with full-thickness Stage IV pressure injury of the posterior heel with exposed calcaneus

Week 0: Initial Defect following serial debridement with exposed bone



Week 4: Exposed bone now covered with tissue



Week 8: 100% depth filled



Week 17: 100% epithelialization, 3 applications of OFM-HA



CASE 3: 72-Year-old female with DM and PAD presents with Wagner 3 DFU to joint capsule and previous hallux

Week 0: Initial Defect



Week 4: Reduced area and improved wound bed



Week 10: ~80% reduction in wound area



Week 13: 100% epithelialization, 5 applications of OFM-HA



CONCLUSION

OFM-HA demonstrated to be safe and effective in challenging lower extremity wounds frequently encountered in outpatient wound healing facilities. The number of applications required in this small case series is in line with the proposed limit of CAMP applications as defined by CMS in April 2024. The promising results of this early experience should be further validated by larger prospective studies.