

Multicenter, Randomized Controlled Trial Evaluating Ovine Forestomach Matrix-Hyaluronic Acid Graft vs Standard of Care in the Treatment of Chronic Diabetic Foot Ulcers: An Interim Analysis

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INTRODUCTION

A novel composite CAMP containing ovine forestomach matrix and hyaluronic acid (OFM-HA*) has recently been shown to have successful outcomes in management of DFUs and calciphylaxis ulcerations.¹⁻² A prospective, multi-center, randomized control trial is ongoing to compare outcomes between OFM-HA versus standard of care (SOC) in the treatment of chronic, complex diabetic foot ulcers (DFUs). The following presents the interim analysis of the first 128 DFUs enrolled in the study.

METHODS

In accordance with established protocols,³⁻⁵ a prospective, randomized controlled trial (RCT) is ongoing across 10 outpatient centers in the US. Wagner 1 or 2 DFUs unresponsive to SOC treatment for at least four weeks were enrolled and randomized to receive either OFM-HA or SOC (collagen-alginate dressing). The interim analysis included 128 patients in the intent-to-treat (ITT) group (n=64 OFM-HA; n = 64 SOC) and 103 who completed the study per protocol (PP) (n=55 OFM-HA; n=48 SOC). Patients received weekly treatment, for a maximum of 12 weeks. Closure of the index ulcer was validated by a blinded independent physician panel. The primary endpoint was incidence of closure at 12 weeks. Secondary endpoints included time to heal, percent area reduction (PAR), W-QoL, and pain. Tertiary endpoints included product wastage and cost to closure.

INTERIM RESULTS (Per Protocol Population)

| Treatment | Mean Days to Heal Within 12 Weeks | Healing Rate at 12 Weeks |
|-----------|-----------------------------------|--------------------------|
| OFM-HA | 65.5 (95% CI: 59.0-72.0) | 30/55 (55%) |
| SOC | 71.5 (95% CI: 65.5-77.3) | 20/48 (42%) |

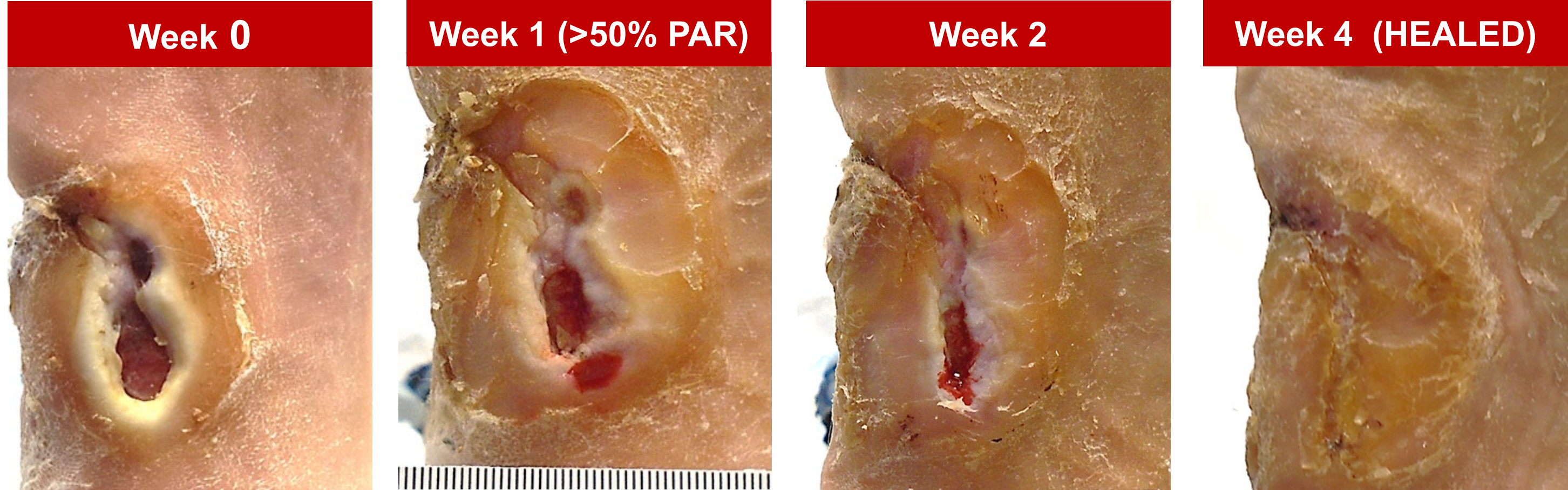
CONCLUSION

In comparison to the SOC, DFUs treated with OFM-HA had an increased 12-week incidence of healing and reduced time-to-heal. Rigorous statistical analysis will be presented on completion of the on-going controlled trial.

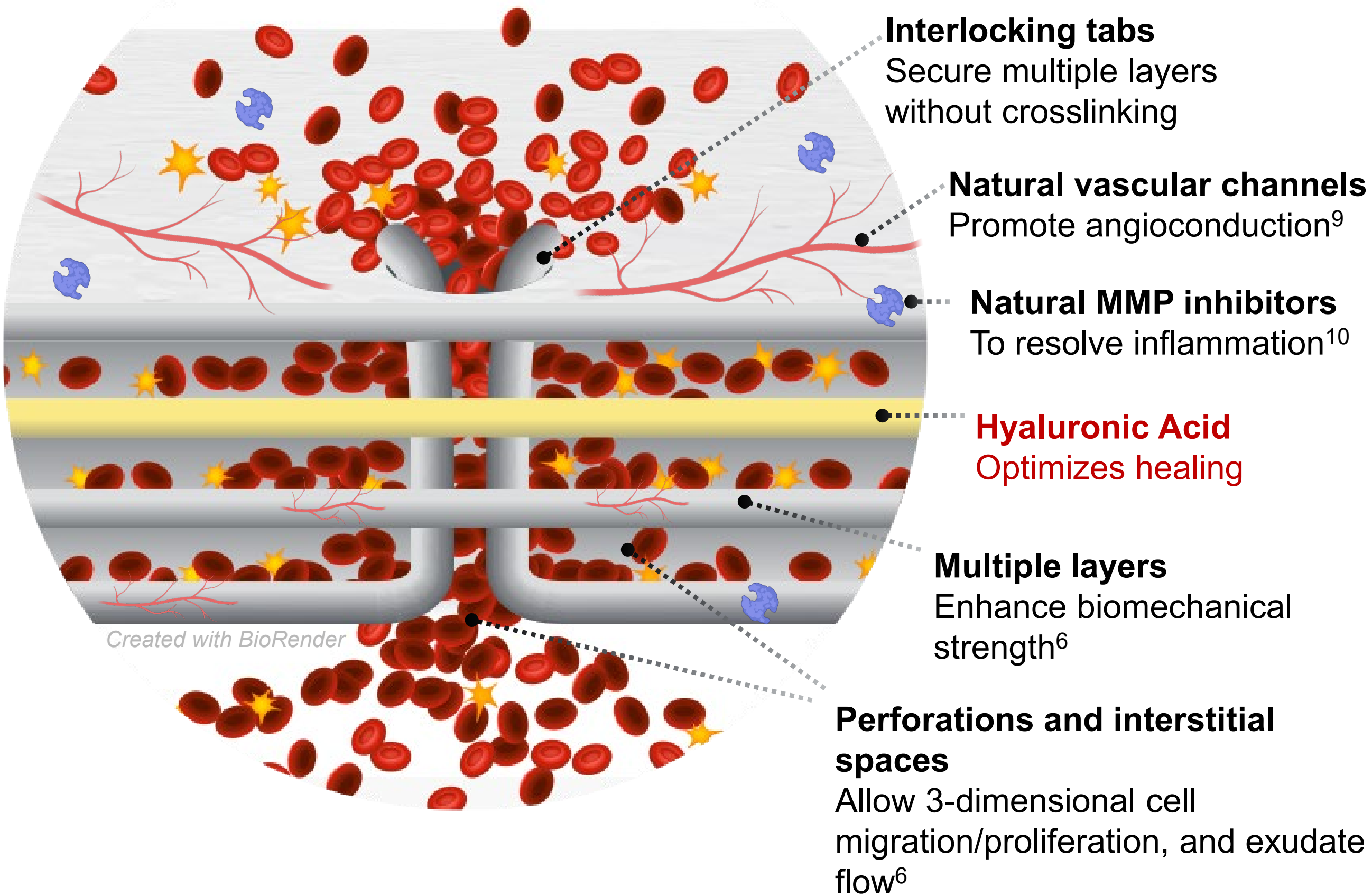
REFERENCES AND DISCLOSURES

1. Le et al., *Adv Skin Wound Care*, 2025. 2. Tettelbach et al., *J Wound Care*, 2025. 3. Tettelbach et al., *Int Wound J*, 2019. 4. Armstrong et al., *Int Wound J*, 2022. 5. Serena et al., *Plast Reconstr Surg*, 2022. 6. Smith et al., *J Biomater Appl*, 2022. 7. Schant'e et al., *Carbohydr Polym*, 2011. 8. Prosdocimi et al., *Panminerva Med*, 2012. 9. Irvine et al., *Biomaterials*, 2011. 10. Negron et al., *Int Wound J*, 2012. *OFM-HA: Symphony(TM) (Aroa Biosurgery LTD, Auckland, NZ). This independent research was funded by Aroa Biosurgery LTD.

CASE EXAMPLE: 58-Year-old male with Wagner 2 DFU (plantar midfoot)



Composite OFM-HA Device



Why Hyaluronic Acid?

- Promotes angiogenesis, cell proliferation, and migration⁶
- Can sequester 1000x its weight in water⁷
- Optimizes moisture balance⁸
- Accelerates wound healing and improves neo-tissue quality⁷