



Introduction

Venous Leg Ulcers (VLUs) are challenging wounds associated with healthcare costs estimated at >\$32 billion annually¹, given the delayed healing and high recurrence rates, with only 60% closing by 12 weeks and 75% reappearing within 3 weeks². Despite the severity of the issue and the recent advancements in wound care, VLUs remain an unmet clinical need requiring novel approaches. The objective of this study was to evaluate the safety and performance of an innovative **Biomimetic Matrix (BMM)** in chronic VLU management. Designed to promote tissue regrowth and prevent infection, BMM is a synthetic extracellular matrix (ECM)-like scaffold made of antibacterial self-assembling peptides that completely conforms to irregular, deep, and hard-to-access wounds.

Methods

Patients with multiple comorbidities presenting chronic VLUs that failed to respond to SOC / advanced treatments were selected to receive an **FDA-approved peptide-based BMM™ (G4Derm™ Plus, Gel4Med Inc.)**. All patients received standard of care following the Prepare to Repair Protocol³ before BMM treatment. BMM was applied topically to the wound according to the manufacturer's instructions. Wound healing progression, peri-wound skin condition, and adverse events were monitored throughout the study.

Patient #	Medical History	Wound type	Wound location	Wound age	Previous treatments
1	PVD, arterial disease, spinal stenosis, multiple spinal surgeries, endovenous ablations, angioplasties (both legs), fibrotic skin	VLU	Left Medial Ankle	8 mos.	SOC, Antimicrobials, Collagen Matrix
2	PVD, diabetes, rheumatoid arthritis, major prednisone lymphedema, walking difficulty	VLU	Left Leg	1.5 mos.	SOC, Antimicrobials
3	PVD, rheumatoid arthritis, chemotherapy, cuboid fusion, foot surgery, surgical dehiscence	VLU	Dorsal Foot	4 mos.	SOC
4	PVD, ischemic skin, traumatic injury to leg	VLU	Right Leg	1 mo.	SOC
5	PVD, diabetes, below the knee amputation, psoriasis, chemotherapy	VLU	Left Leg (Stump)	2 mos.	SOC, Antimicrobials, Enzymatic Debridement, Topical Steroids

Table 1: Patient medical history and wound characteristics

Results

Despite the wound chronicity, failure of previous treatments, and multiple risk factors for impaired healing, all VLUs in this case series responded positively to BMM treatment, showing **rapid healing progression**. A substantial reduction in wound area with healthy granulation tissue formation was observed after a single BMM treatment.

Results

Wound depth reduction was observed, particularly in the cases with deep tissue penetration / exposed muscle. In all cases, **complete wound closure** was achieved within a median of 5 BMM applications (2 to 7 BMM applications). An improvement of the **peri-wound skin appearance** was noted. No adverse events were observed.

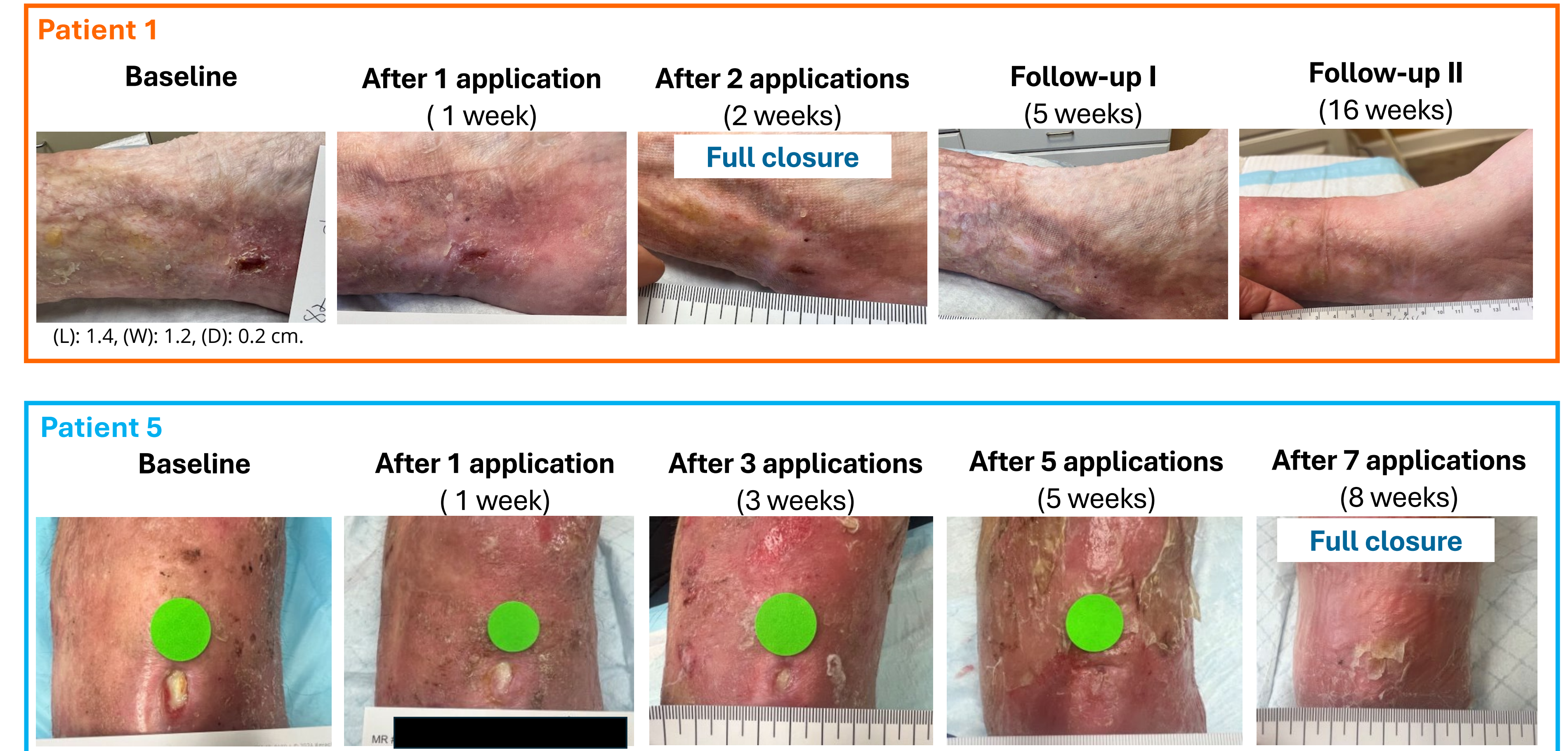
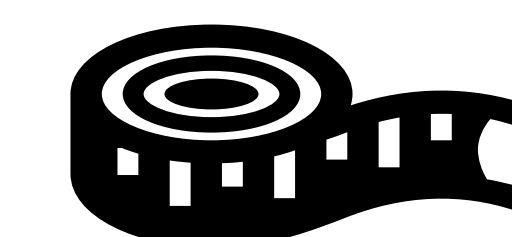


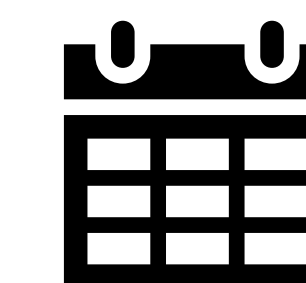
Fig. 1: Representative images of chronic VLUs before and after BMM treatment.

Discussion

BMM successfully facilitated healing of chronic VLUs in five patients with several comorbidities, achieving complete wound closure within only two to seven applications. BMM also improved the overall appearance and integrity of the peri-wound skin. BMM is easy to use, apply, and spread onto the wound bed, supplied in a ready-to-use shelf-stable pre-filled syringe with an optional flexible applicator tip.



Significant **reductions in wound size and depth** were noted after a **single BMM application**.



Complete **wound closure** was achieved with a **median of five BMM applications**, within 2 to 8 weeks.

References

- ¹Fania L, et al. Cutaneous Squamous Cell Carcinoma: From Pathophysiology to Novel Therapeutic Approaches. Biomedicines. PMID: 33572373.
- ²Kim P, et al. Guidelines of care for the management of cutaneous squamous cell carcinoma. J Am Acad Dermatol. 2018. PMID: 29331386.
- ³Regulski, M. Preparing to Repair in Diabetic Wound Care: Insights from an Expert | Podiatry Today (hmpgloballearningnetwork.com)

