

Self-Assembling Peptide Biomimetic Matrix Promotes Rapid Closure of Difficult-to-Heal Venous Leg Ulcers

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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

Five patients with multiple comorbidities [including peripheral vascular disease, diabetes, rheumatoid arthritis, limited mobility, lymphedema] presenting chronic VLUs were selected to receive an FDA-approved flowable BMM. BMM was used after proper wound bed preparation per the manufacturer's instructions. Wound size measurements were captured at baseline and at each following visit using an artificial intelligence (AI) based imaging software. Clinical observations were recorded at each visit, including wound and peri-wound skin appearance.

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

All patients in this case series responded positively to BMM treatment, showing fast wound healing progression with healthy granulation tissue formation noted after a single application. Substantial reductions in ulcer size and depth were observed after just one to two applications.

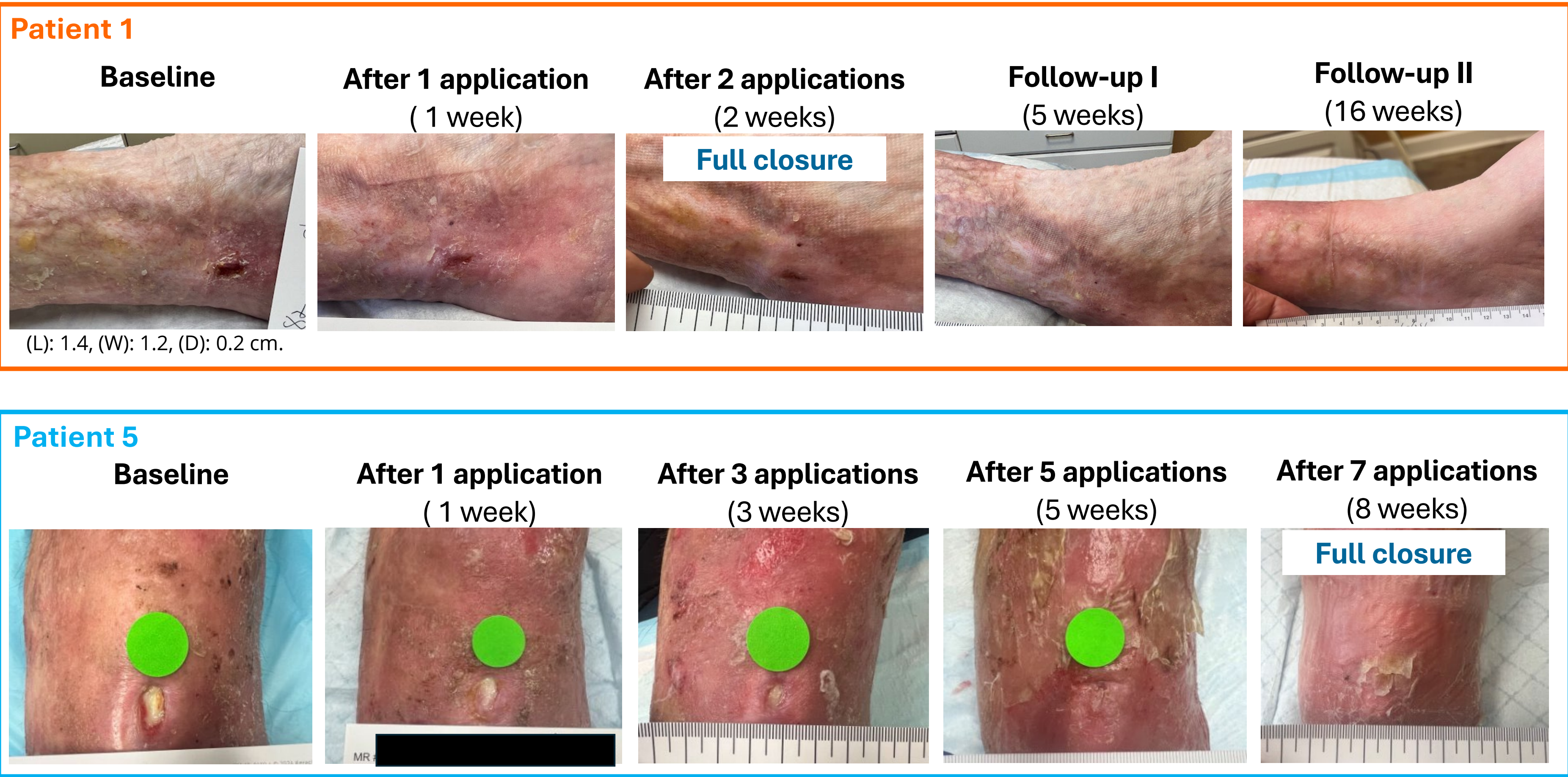


Fig. 1: Representative images of chronic VLUs before and after BMM treatment.

In two cases, approximately 50% surface area reduction was observed after a single application, with **100% re-epithelialization achieved within five applications** of BMM. In three other cases, while the first application did not result in such a marked surface wound area reduction [percent area reduction (PAR) ranging between 7% and 38%], full wound closure was still achieved within three to five BMM applications. **Complete wound closure** was achieved within the study period in all five ulcers. In all cases, **early formation of healthy granulation tissue** and an **improvement in peri-wound skin** appearance were noted with BMM treatment. No recurrence and no adverse events were observed during the study period.

Discussion

This case series demonstrates the safety and efficacy of BMM in treating difficult-to-heal, refractory VLUs. BMM promoted **early granulation tissue formation (after a single application)** and **rapid wound closure (within five applications)** of **challenging VLUs**. Future studies in a larger population are needed to confirm these findings.

References

¹Nussbaum SR, et al. An economic evaluation of the impact, cost, and Medicare policy implications of chronic nonhealing wounds. Value Health. 2018.
²Probst S, et al. Prevalence and incidence of venous leg ulcers—a protocol for a systematic review. Systematic Reviews. 2021.
***BMM:** G4Derm™ Plus, Gel4Med Inc. MA, USA.