Efficacy of a Peptide Biomimetic Matrix in Lower Extremity Ulcers by Tissue Regrowth and Revascularization: Monitoring with Near-Infrared Spectroscopy Imaging

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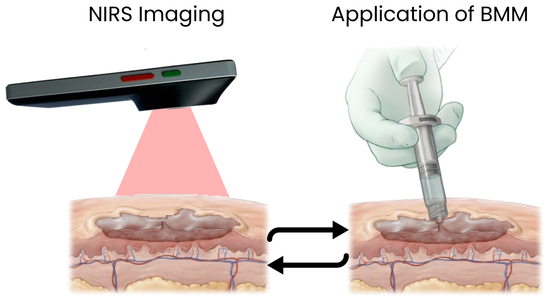
Introduction

Background: Chronic wounds, which affect millions globally, substantially reduce the patients' quality of life and place significant burdens on healthcare systems.[1,2] Effective management of chronic lower extremity wounds requires strategies that enhance tissue regrowth and revascularization.

Aim: This study evaluates the performance of a polypeptide BioMimetic Matrix (BMM) designed to support chronic wound healing via an extracellular matrix-like scaffold and antibacterial protection, using multispectral near-infrared spectroscopy (NIRS) imaging.

Methods

Five patients with multiple comorbidities presenting lower extremity wounds that failed to respond to previous treatments - diabetic foot ulcers, pressure ulcers, venous leg ulcers - were treated with an FDA-approved flowable BMM (G4Derm™ Plus, Gel4Med) . Multispectral NIRS, infrared (IR) thermal, and digital imaging were captured using a handheld mobile device (MIMOSA Pro, MIMOSA Diagnostics). Tissue oxygen saturation (StO_2) was assessed at baseline and continuously monitored during following visits.



Clinical Characteristics of Study Participants

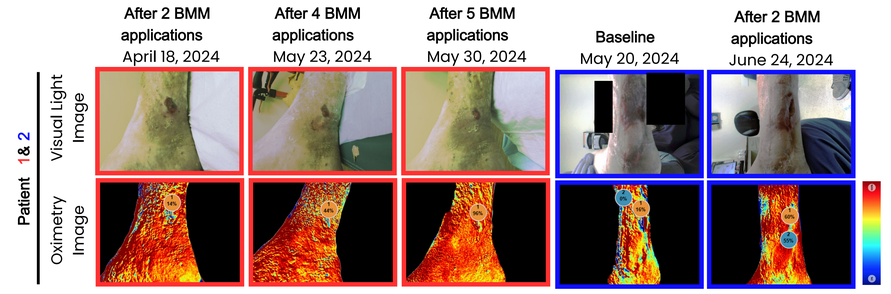
#	Wound	Patient Comorbidities	Previous Interventions	Wound Age at Baseline	Group
1	Pressure Ulcer on back of leg	ALPS	Muscle Flap, SOC	8 weeks	**rapid**
2	Venous Leg Ulcer (right)	Diabetes, KTS, PWS, PVD	SOC	5 months	**rapid**
3	Venous Leg Ulcer (Right Ankle)	Pre-Diabetes, L, PVD	TMA, LER, TCC, SOC	6 months	**slower**
4	Venous Leg Ulcer (Right)	PVD	SOC	6 months	**slower**
5	DFU on Transmetatarsal amputation (Right)	Diabetes	Bilateral TMA, SOC	8 months	**depth**

Comorbidities : ALPS: Autoimmune Lymphoproliferative Syndrome; KTS: Klippel-Trenaunay Syndrome; PWS: Parkes-Webber Syndrome; PVD: Peripheral Vascular Disease; L: Lymphedema. **Previous Interventions** : SOC: Standard of Care; LER: Lower Extremity Revascularization; TCC: Total Contact Casting; TMA: Transmetatarsal Amputation.

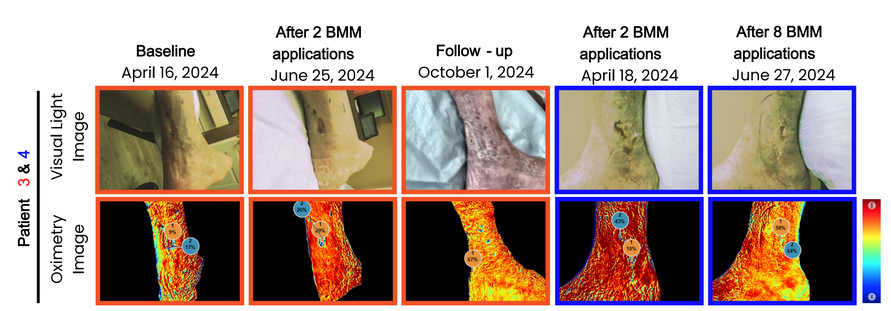
Results

All patients responded positively to BMM treatment, showing ischemic area [defined as StO_2 <39%] reduction and wound healing progression. **Complete closure was achieved in all cases** . In all five cases, an increase in tissue oxygenation was observed with BMM treatment and predicted healing, suggesting healthy tissue regrowth and revascularization, which ultimately resulted in complete wound closure.

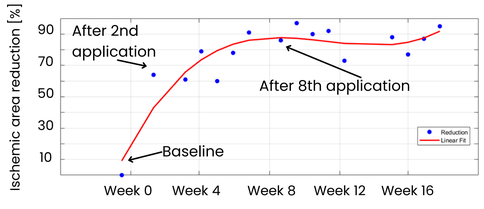
In two cases, **rapid ischemic area reduction** (>65% reduction after 2-4 applications) was observed, achieving >99% ischemic area reduction within 3 to 5 BMM applications and full wound closure within 7 to 8 BMM applications.

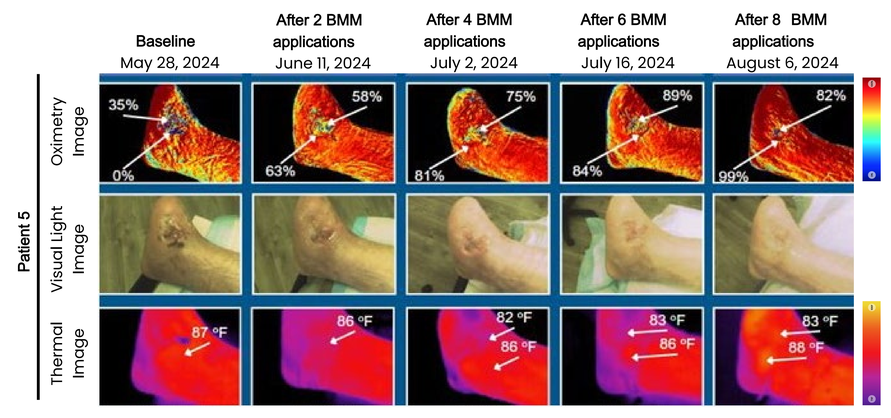


In two other cases, **slower ischemic area reduction** was noted (>65% reduction after up to 9 BMM applications), achieving full wound closure within 10-16 weeks.



In one case, while there was not such a marked reduction in wound surface area after 8 BMM applications, a substantial **wound depth reduction** with granulation tissue formation was observed and accompanied by 86% reduction in ischemic area.





Conclusion

This case series highlights the potential of BMM in treating chronic, unresponsive lower extremity wounds by fostering an environment that promotes rapid healthy tissue regrowth and revascularization. The new BMM technology may open avenues to reshape practice in the clinical management of difficult-to-heal wounds, particularly when ischemia is present. NIRS imaging provided an objective, non-invasive measure of tissue oxygenation, helpful in predicting ulcer healing trajectory and treatment effectiveness. The reduction in ischemic area emerged as a potential marker for assessing tissue regeneration and revascularization.

References:

1. Nussbaum, S. R. et al. An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health 21, 27–32 (2018); 2. Ebot, J. Managing Complex Wounds in Skilled Nursing Facilities (SNFs). Cureus 15, e47581 (2023).