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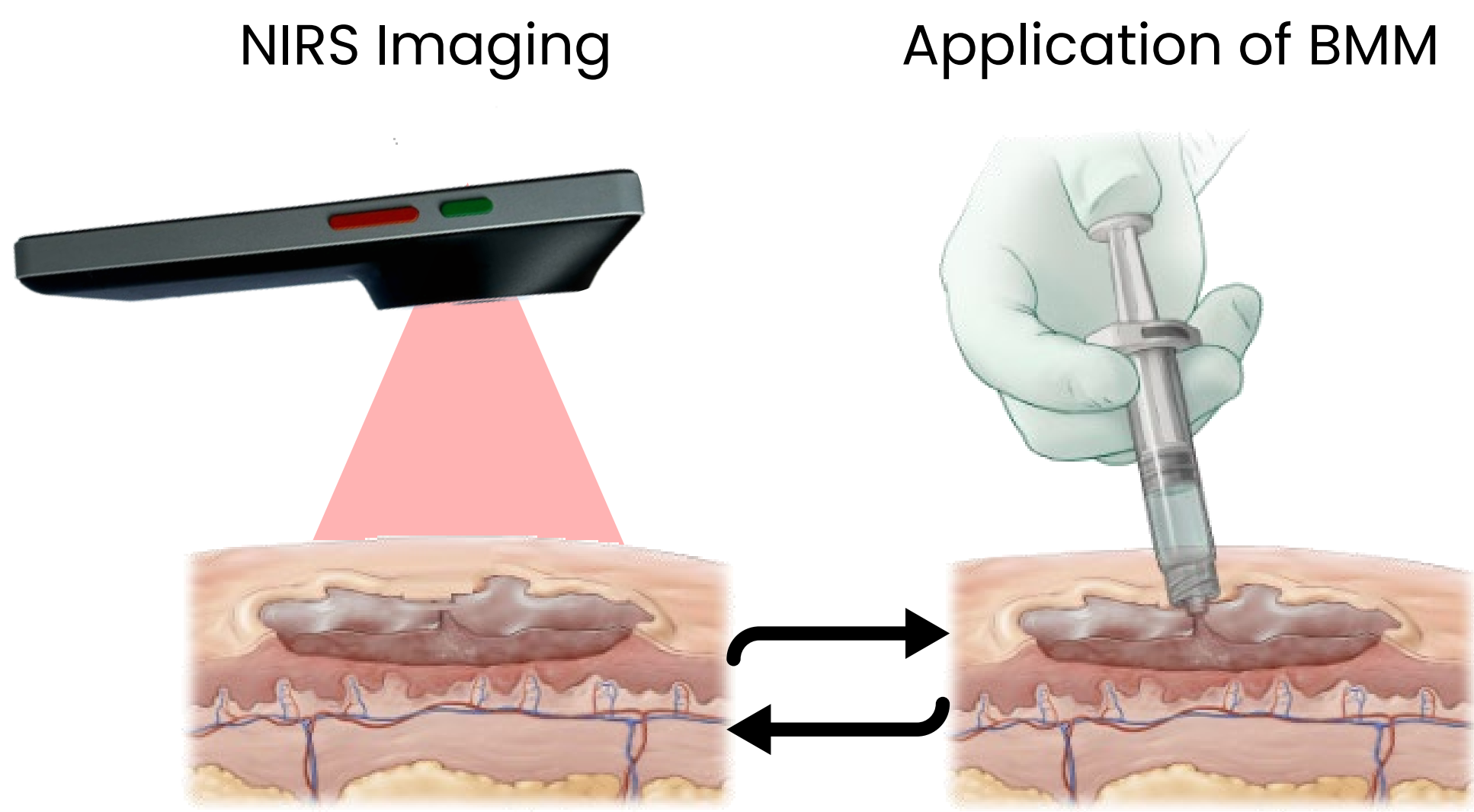
## Introduction

**Background** : Chronic wounds, which affect millions globally, substantially reduce the patients' quality of life and place significant burdens on healthcare systems.<sup>1,2</sup> 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<sub>2</sub>) 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.

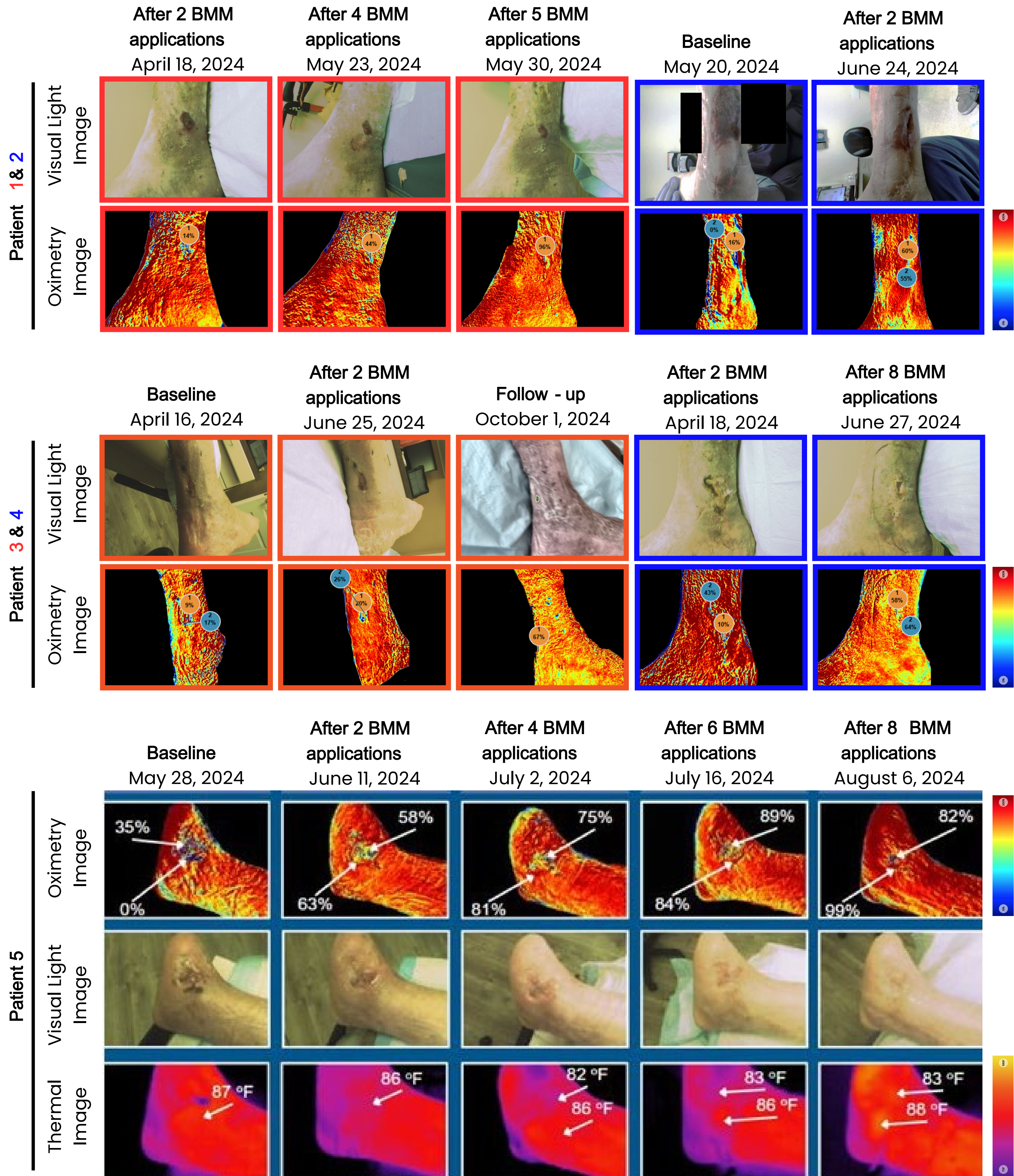
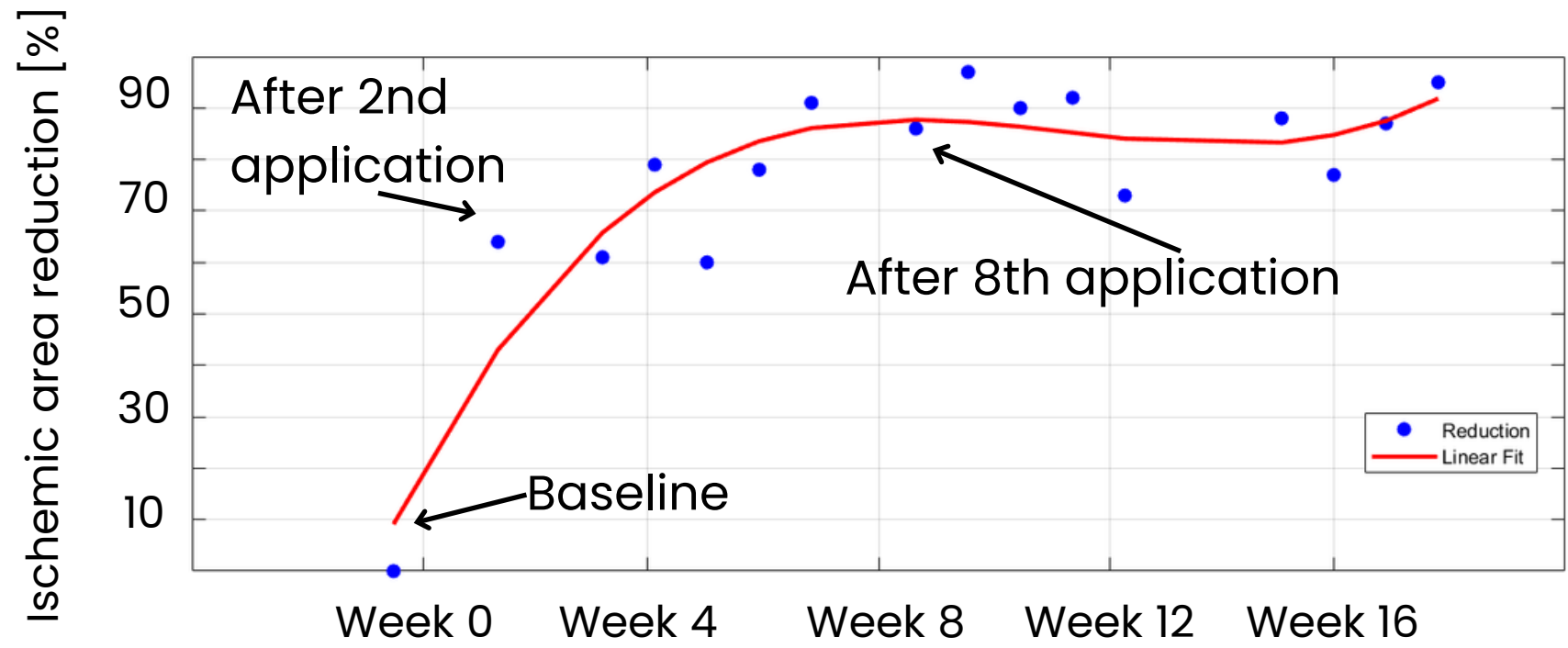
## Results

All patients responded positively to BMM treatment, showing ischemic area [defined as StO<sub>2</sub> <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 hard-to-heal wounds, unresponsive to SOC, by fostering an environment that promotes tissue regrowth and neovascularization. NIRS imaging provided an objective, non-invasive measure of 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:

- 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);
- Ebot, J. Managing Complex Wounds in Skilled Nursing Facilities (SNFs). Cureus 15, e47581 (2023).





