



Integrating Multispectral Near-Infrared Spectroscopy and Thermography Imaging in the Management of Diabetic Foot Ulcers and Venous Leg Ulcers Treated with Skin Substitutes



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Introduction

Diabetic Foot Ulcers (DFUs) and Venous Leg Ulcers (VLUs) pose significant healthcare challenges in the U.S.,¹ driven by an aging population and rising rates of diabetes and obesity.²⁻³ Skin substitutes play a crucial role in treatment, supported by growing evidence. Historically, Medicare Local Coverage Determinations (LCDs) only accepted the Ankle-Brachial Index (ABI) for vascular assessment in skin substitute documentation. However, many providers question its accuracy despite standard-of-care guidelines, best practices, and institutional policies. Long hospital wait times—up to three months for ABI—further hinder its use. In response to evolving clinical needs, recent LCDs have broadened the scope of acceptable vascular assessment methods to include tissue oxygenation measurements, complementing traditional techniques. This study examines the integration of multispectral near-infrared spectroscopy (NIRS) for non-invasive perfusion assessment, thermography for early infection identification, and automated wound area measurements to optimize ulcer management in patients receiving advanced treatment with skin substitutes.

Methods



A handheld, FDA 510(k)-cleared NIRS and thermal imaging device (MIMOSA Pro, MIMOSA Diagnostics Inc., Toronto, Canada) was used to measure tissue oxygenation and skin surface temperature. Wound images were taken at various stages: 1. pre- and post-debridement during the four-week standard of care (SOC) treatment period, 2. before the first skin substitute application, and 3. after each subsequent application (pre- and post-debridement, prior to placement). The key parameters of interest were wound size reduction and changes in tissue oxygenation with SOC and skin substitute application treatments.

Conclusion

Integrating NIRS and thermography imaging, and automated wound measurement into care protocols enhances patient outcomes, streamlines treatment access, and reduces administrative burden. This approach enables more precise decision-making and personalized care.

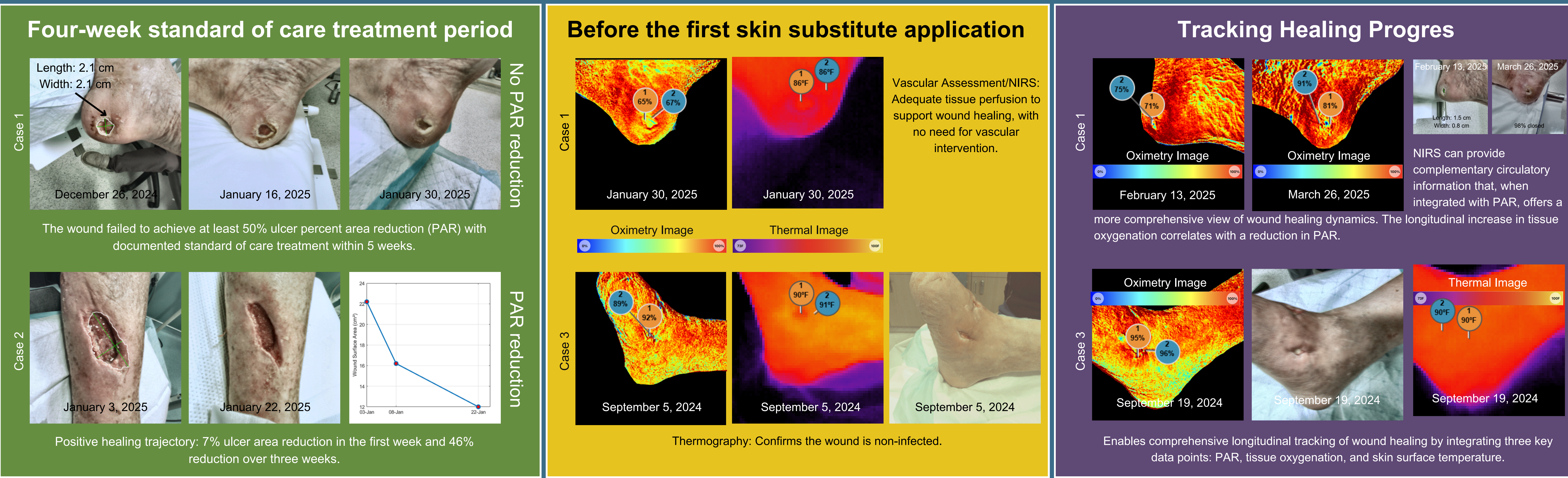
Key benefits include:

- Enhanced Patient Compliance through improved engagement and understanding
- Streamlined Skin Substitute Qualification & Documentation with timely, accurate assessments
- Real-Time Healing Progress Tracking to guide treatment adjustments and optimize outcomes

"At three maine sites, docs HATE ABIs and literally refuse to do it. NIRS imaging offers a solution, and we believe it will be a game changer."

Results

The integration of NIRS and thermography imaging, alongside automated wound size measurements, enabled comprehensive, objective documentation of wound progression. Tissue oxygenation levels confirmed sufficient perfusion necessary for wound healing, while thermography re-confirmed the absence of infection prior to skin substitute application. These combined technologies streamlined clinical workflows and provided the objective data necessary to meet the medical necessity criteria for skin substitute therapy.



The table compares two scenarios: 1. before integrating NIRS and thermography imaging into the management of diabetic foot ulcers and venous leg ulcers with skin substitutes (Pre-NIRS), and 2. after integration (NIRS).

	Pre-NIRS	NIRS
Total number of appointments booked (for skin substitute placement)	60	62
Compliance: Missed/attended appointments	81%	95%

Pre-NIRS vs. NIRS Scenario:

- The total number of appointments booked for skin substitute placement increased by 3%, highlighting improved patient management.
- Patient compliance improved by 17%.

Bibliography

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