

Review of 3126 Patients Treated with Multi-Modality Topical Oxygen for Chronic Lower Extremity Wounds

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Introduction: Chronic wounds persist due to a self-sustaining cycle of hypoxia, inflammation, lymphatic dysfunction, and edema. By integrating topical oxygen delivery with non-contact cyclical compression, Multi-Modality Intermittent Topical Oxygen Therapy (ITOT)* addresses multiple interrelated barriers to wound repair, promoting durable healing and reducing complications.¹

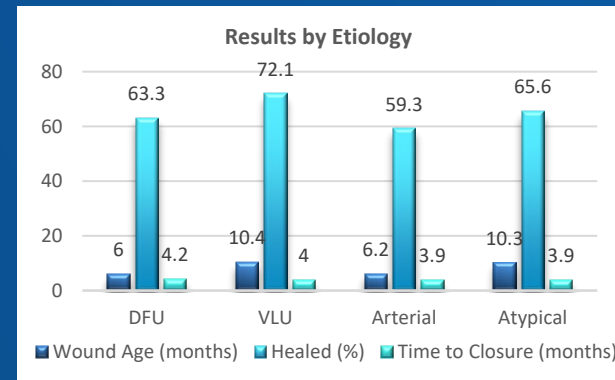
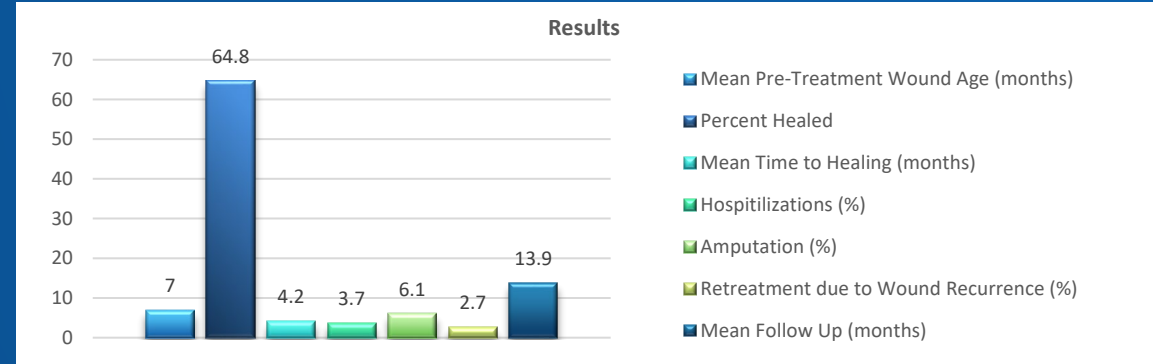
Objective: This multi-center, large cohort retrospective study evaluated the effectiveness of ITOT in the treatment of chronic lower extremity wounds.



Methods: Data from 5318 patients treated between January 2023 and December 2024 for lower extremity wounds were retrospectively analyzed. Patients who were still receiving therapy and did not have outcome data (n=1408), had incomplete data (n=423), or who discontinued therapy for non-medical reasons (n=361), were excluded, resulting in a final cohort of 3126 patients. Demographics are shown in Table 1. Outcomes assessed included healing rates, retreatment rates, and complications.

Table 1: Patient/Wound Demographics	
Female: % (n)	10.6% (332)
Male: % (n)	89.4% (2794)
Patient Age: years (SD)	69.6 (±12.3)
Pre-Tx Wound Age: months (SD)	7.3 (±15.7)
Wounds/Patient: n (SD)	1.1 (±0.4)
Diabetic: % (n)	72.2% (2257)
Venous: % (n)	20.1% (628)
Arterial: % (n)	6.7% (209)
Atypical: % (n)	1% (32)

Results: 64.8% (n=2027) of the wounds achieved complete healing in 4.2 (SD±2.5) months, despite a mean pre-treatment wound age of 7 (±15.9) months. The need for retreatment due to wound recurrence was low, 2.7% (n=54), with a mean follow up time of 13.9 (±4.9) months. The rates of hospitalization and amputation were 3.7% (n=115) and 6.1% (n=191) respectively, with subgroup analyses showing consistent healing rates. ITOT therapy significantly reduced amputation and hospitalization rates compared to historical standards.



Real-World Comparison

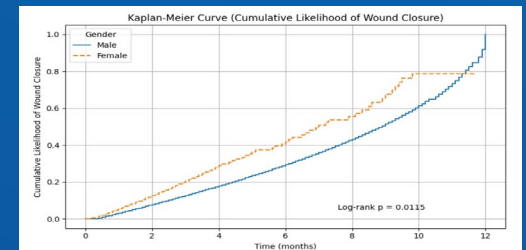
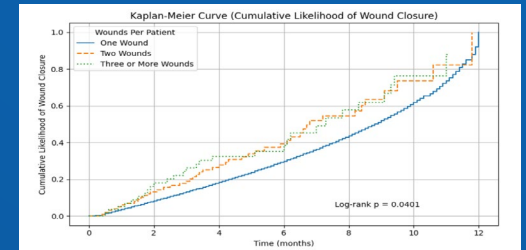
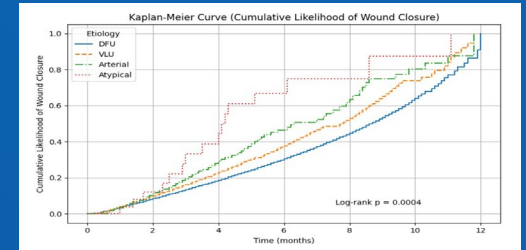
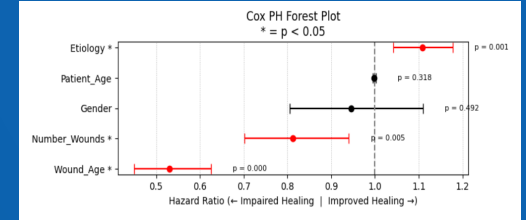
Healing rates in the US Wound Registry² (included 62,964 DFU's and 97,420 VLU's, treated with both standard and advanced therapies):

- DFU: 45% in a mean time of 20 weeks
- VLU: 57% in a mean time of 16 weeks

Healing rates in this study:

- DFU: 63% in a mean time of 18 weeks
- VLU: 72% in a mean time of 17 weeks

Conclusions: Multi-modality ITOT is an effective, noninvasive, patient-applied therapy that synergistically addresses the root causes of chronicity seen in nonhealing wounds: inflammation, edema, and tissue hypoxia. In this large cohort study, ITOT demonstrated superior wound healing outcomes in complex, comorbid populations, compared to those reported in population based real world studies. The results of this study support the durable healing outcomes demonstrated in previously published ITOT randomized controlled trial and real-world evidence studies.



References

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2. Fife CE, et al. Publicly Reported Wound Healing Rates: The Fantasy and the Reality. *Adv Wound Care (New Rochelle).* 2018 Mar;7(3):77-94. doi:10.1089/wound.2017.0743