INTERNATIONAL CONSENSUS: TOPICAL OXYGEN THERAPY

2023 ADA EVIDENCE RATING A

Frykberg R, Andersen C, et al. Use of topical oxygen therapy in wound healing. Journal of Wound Care. 2023;32(S8B):S3–S30.

Executive Summary

This consensus document represents the collective expertise of a panel of 9 key opinion leaders from the US and Europe. It serves as a critical update to the 2017 EWMA document, synthesizing evidence from over 45 peer-reviewed articles to establish best practices for Topical Oxygen Therapy (TOT) in hard-to-heal wounds.

ADA Grade A
Evidence Rating (2023)

8.2 Million
Medicare Beneficiaries

$96.8 Billion
Projected Wound Costs

Purpose: To define mechanisms, review clinical evidence, and provide actionable recommendations for incorporating TOT into standard of care.

The Critical Role of Oxygen in Healing

Chronic wounds are inherently hypoxic. Oxygen is essential for cell metabolism, collagen synthesis, and antimicrobial defense. Without sufficient pO2, the healing cascade stalls.

100 mmHg (Healthy) → **~10** mmHg (Wound)

Impact of Hypoxia on Enzymes

Enzymatic activity falls to **10–30%** of max efficiency at low oxygen tension.

TOT reverses local hypoxia, restoring the microenvironment and upregulating angiogenic factors (VEGF, FGF-2).

Summary of TOT Modalities & Evidence

MODALITY	MECHANISM & DELIVERY	ADA EVIDENCE GRADE
Continuous Delivery of Oxygen (CDO)	Continuous low flow of pure oxygen (24/7). *Wearable, silent, ambulatory device.*	**A**
Higher Cyclical Pressure Oxygen (HCPO)	Humidified oxygen under cyclical pressure (10-50 mbar). *90 mins/day, 5 days/week (Extremity chamber).*	**A**
Haemoglobin Spray	Facilitates oxygen diffusion into wound bed. *Liquid spray applied at dressing changes.*	**B**
Other Modalities	Disposable CDO, Low Constant Pressure Oxygen (LCPO), Oxygen Dressings.	**C**

Clinical Evidence Highlights

Key Findings from Randomized Controlled Trials & Systematic Reviews

CDO in Diabetic Foot Ulcers

Significantly Higher Healing Rates
46% vs 22% complete healing at 12 weeks compared to placebo (p=0.016).

Accelerated Closure
Time to 50% healing was nearly **halved** in the CDO group. Relative performance increased with larger, more chronic wounds.

HCPO in Diabetic Foot Ulcers

Reduced Hospitalizations
Real-world data showed an **82% reduction** in hospitalizations (p<0.0001) and 73% fewer amputations.

Long-term Durability
12-month closure rate: **56% vs 27%** for standard of care (p=0.013).

HCPO in Venous Leg Ulcers

Superior Closure Rates
76% vs 46% complete healing at 12 weeks (p<0.0001) in refractory non-healing VLUs.

Faster Healing Time
Median time to full closure: **57 days** (HCPO) vs 107 days (Conventional Compression).

Cost-Effectiveness

Economic Impact
CDO vs NPWT: Saves ~$4,800 per patient.
CDO vs HBOT: Saves up to $14,060 per patient.

Simulation Results
79% of economic simulations demonstrated that CDO was a cost-effective intervention for chronic wounds.

Clinical Recommendations for Implementation

- **Primary Trigger:** Consider TOT when wounds fail to reduce in size by **≥50% after 4 weeks** of standard of care.
- **Broad Applicability:** Appropriate for most non-neoplastic hard-to-heal wounds (DFU, VLU, Pressure Injuries).
- **Early Intervention:** Earlier use is better; consider for early treatment of ischaemic DFUs.
- **Administration:** Self-administration is possible after brief training; multidisciplinary approach recommended.

Key Takeaway & Guideline Updates

TOT is safe, clinically effective, and cost-efficient. The substantial body of high-quality evidence has led to major guideline updates in 2023.

ADA Standards of Care (2023) Gave TOT its highest-ever evidence rating (**Grade A**) for chronic diabetic foot ulcers.

IWGDF Recommendation (2023) Made its first-ever recommendation to consider adjunctive TOT for hard-to-heal DFUs.

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