

Advanced Oxygen Therapy, Inc. Reports Clinical Data Supporting Multi-Modality Extremity Chamber Therapy

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Managing chronic non-healing wounds such as diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) presents an ongoing challenge in modern healthcare, as compromised tissue recovery often correlates with recurrent hospital admissions and surgical interventions. To address these complex wound environments, Advanced Oxygen Therapy, Inc. manufactures multi-modality extremity chamber systems designed to administer localized therapy in clinical and home settings. Grounded in published randomized controlled trials, real-world observational studies, and updated clinical practice guidelines, topical wound oxygen therapy provides care teams with an adjunctive treatment option intended to support tissue closure and complement standard wound management protocols.

The multi-modality extremity chamber platform known as the TWO2® system combines cyclical localized oxygen delivery, non-contact cyclical compression, and continuous mist humidification. Under cyclical pressure delivery, localized oxygen is administered to increase tissue oxygen tension at the wound site. Non-contact cyclical compression is designed to assist in edema reduction and promote microvascular circulation, while a continuous fine particulate mist helps maintain the moist wound environment necessary for epithelial cell migration. While these combined mechanisms are intended to support tissue repair processes, individual clinical responses depend on baseline vascular status, systemic comorbidities, and patient adherence to prescribed daily treatment regimens.

Clinical outcomes supporting the TWO2® extremity chamber platform specifically have been evaluated across distinct peer-reviewed trials. In a multinational, double-blind, sham-controlled randomized trial evaluating 146 patients with chronic DFUs (Frykberg et al., Diabetes Care, 2020), the TWO2® treatment arm demonstrated a 42.4% complete healing rate at 12 weeks compared to 13.5% in the sham control group ($p = 0.002$). During a 12-month post-healing follow-up of this trial population, ulcers healed with TWO2® therapy exhibited a 6% recurrence rate compared to 36% in the control arm ($p = 0.0001$).

Real-world observational data reflect outcomes across broader patient populations, though observational study designs carry inherent methodological limitations compared to prospective randomized trials. A

retrospective real-world evidence cohort study of 283 patients with refractory DFUs published in *Advances in Wound Care* (Yellin et al., 2022) observed an 88% reduction in hospital admissions ($p < 0.0001$) and a 71% reduction in total amputations compared to pre-treatment historical baselines for the cohort. In VLU populations, a prospective evaluation of 132 patients (Tawfick et al., *Journal of Vascular Surgery*, 2013) reported 12-week closure rates of 76% for TWO2® combined with compression versus 46% for compression alone ($p < 0.0001$), with a 36-month recurrence rate of 6% versus 47% ($p < 0.0001$).

Medical association guidelines recognize topical oxygen administration as a broader therapy class. In its *Standards of Care in Diabetes?2023*, the American Diabetes Association (ADA) issued an "A-grade" evidence recommendation stating: "Topical oxygen therapy can be considered as an adjunctive therapy for chronic, non-healing diabetic foot ulcers to improve wound healing." The Grade A classification indicates support from randomized controlled trial data evaluating topical oxygen therapies as a class, distinguishing localized administration from systemic hyperbaric oxygen protocols. Medical consensus guidelines emphasize that topical oxygen therapy functions as an adjunctive measure alongside established standard-of-care practices, including offloading, surgical debridement, infection control, and vascular assessment.

The TWO2® platform is cleared by regulatory authorities for administration in both clinical facilities and home environments. Designed to accommodate total contact casts, UNNA boots, and standard secondary dressings, the chamber allows patients to undergo daily 90-minute treatment sessions at home under clinical prescription. Observational data associate home-based access with consistent treatment compliance over extended care periods. While health economic evaluations suggest that reducing hospital readmissions and secondary surgical procedures may lower overall episode-of-care costs, actual financial impacts vary depending on patient risk profiles, institutional care settings, and local reimbursement frameworks.

For healthcare professionals and patients seeking published trial documentation, regulatory indications, and technical system specifications, visit the Advanced Oxygen Therapy, Inc. website.

Advanced Oxygen Therapy, Inc. manufactures medical devices focused on chronic and acute wound care. The company produces topical wound oxygen therapy systems cleared for use in clinical and home care settings, intended to serve as an adjunctive treatment to support tissue healing and complement standard wound care protocols worldwide.

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