

Cyclical-pressure Topical Wound Oxygen therapy emerges as a proven wound-healing device for diabetic foot ulcers, showing great promise in venous leg ulcers

Enrico Ascher, MD, and Natalie Marks, MD, currently combine their close to 60 years of vascular surgery practice experience in New York City's 3 million-strong populous borough of Brooklyn. Between them they see a steady stream of patients with various types of acute and chronic wounds—arterial, venous and mixed etiology nonhealing ulcerations not being properly treated.

Over the years, Ascher, a vascular surgeon with the Vascular Institute of New York, has established a wound care center, built expertise in the wound-healing space and developed hyperbaric oxygen therapy experience, seeking to fill a void in appropriate therapy for a sick population of patients with peripheral arterial disease (PAD).

More recently, Ascher and Marks, a vascular medicine and board-certified wound specialist in the same practice, have developed a “small but impressive” experience with Topical Wound Oxygen Therapy (TWO2) in treating not only diabetic foot ulcers (DFUs) but also venous leg ulcers (VLU). Ascher says the home-based TWO2 therapy—which combines supplemental oxygen with non-contact cyclical compression and humidification through a single-use extremity chamber system—is emerging as an effective alternative with independently proven advantages involving cost, simplicity and patient comfort.

He points to a recent systematic review of randomized controlled trials (RCTs) he says confirmed RCT evidence showing that topical oxygen therapy increased the likelihood of DFU healing compared to controls.

“We have a small experience—but significant in our initial interpretation—of the outcome of this therapy,” Ascher explains. “We did 29 limbs with patients who absolutely would not heal with anything, and for months we followed these patients. When we tried this new methodology, most of them did well.”

Introducing two cases in which TWO2 was used to treat two patients with VLU, Ascher expresses hope similar evidence will emerge showing effectiveness in the healing of ulceration with a venous etiology.

Case no. 1

Ascher and Marks describe the case of an 82-year-old male patient who first presented to their practice in 2021 with recurrent lower-leg circumferential ulceration, seo-san-

guinous discharge, severe itching, inflammation and venous stasis.

“He had some venous procedures in the past—he had had his veins closed, a stent placed in the iliac vein, several sessions of foam sclerotherapy of varicose veins—to decrease swelling in his leg and to promote healing,” explains Marks. “He had been going to different specialists, but was getting worse. We also found that in addition to his venous insufficiency, he had vasculitis, and we tried topical and oral steroids. After starting, TWO2 at home, in five months—there were a couple of hiccups in the middle to do with coverage issues—we were able to heal his wound completely, and it stayed healed.”

Case no. 2

Turning to a second case—that of an 84-year-old female who presented with a large lower leg ulcer of venous etiology in the setting of recurrent cellulitis—Ascher and Marks outline a lingering wound that had worsened over weeks.

The patient, who was housebound, had comorbidities that included hypertension and hyperlipidemia, and had sought treatment through her primary care doctor. Her symptoms included progressive swelling, skin hyperkeratosis and peeling, itching, dermatitis changes and increased discharge.

“After she came here, we were wrapping her with compression dressings,” says Marks then, after gaining coverage approval for TWO2 within a week, in just four weeks of oxygen therapy at home, the wound healed and has not recurred since.”

Home-based care

Ascher highlights TWO2's simplicity. “This is a methodology that is much simpler, less complicated, less burdensome to the patient and actually very comfortable,” he says. “The patient is sitting in their home watching TV, listening to some music or reading a book, and they put a boot on over existing compression dressings.”

Among its advantages, he lists how it helps reduce edema with the non-contact cyclical compression, addresses infection resistance, and aids the production of good collagen in the wounds, resulting in wound



Case one is depicted at different stages of healing with TWO2 at home: pictures 1a–d were taken at one, two, three and five months, respectively, after therapy initiation. Case two, shown in pictures 2a–d, results are pictured at zero, one, two and four weeks, respectively, after the therapy began



Enrico Ascher



Natalie Marks

coverage with healthy tissue. “There is evidence it also can increase angiogenesis,” Ascher adds. The topical mode of oxygenation to the tissue is delivered with a partial pressure of approximately 800mmHg.

Contrasting TWO2 with hyperbaric oxygen therapy, Ascher reflects that some had trouble tolerating the hyperbaric machine. “But most of the complaints were that they had to spend two hours inside the chamber, and some were claustrophobic. So TWO2 has been shown, so far mostly by our podiatry colleagues, in the literature that it is an alternative for these patients, and maybe for more patients if they want to have this kind of comfort with equally or almost equally good results.”

Marks notes how patients interact with the device, an extremity chamber, or boot, which extends up to and above the knee. “We have seen meaningful results in terms of patient comfort and willingness to stick with the treatment,” she says. “They see the results with each treatment as the wound gets a little bit better looking—less pain, less swelling, less discharge. So they persist because they see constant and gradual improvement.”

Combined with the evidence provided in the meta-analysis, Ascher says the “small but impressive experience” from his own practice encourages him to push on with TWO2 as a component feature of his wound-healing armamentarium. “I think

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NATALIE MARKS

we will try to treat these ulcers by fixing the cause of the ulceration: If it is an infection, we have to clean the wound—maybe administer antibiotics. If it is of arterial origin, we have to improve the circulation. If venous, we have to fix the vein issue as best we can. Then we give a chance for the ulcer to heal. If it does not heal, then I think that is the time to provide the option of having topical oxygen therapy.”

Marks also highlights a cost-savings dimension. “TWO2 provides not only patient comfort, healing of the wound and decreased chances of complications, I think financially it makes a lot of sense,” she says. “Give a little bit of extra resource up front for this topical oxygen therapy but provide faster healing, instead of having all of these wasted resources.” Ascher points to what chronic wounds cost the U.S. in dollar terms: “Anywhere from \$50 to \$60 billion,” he concludes. “It’s a big problem and has been forgotten for years. Only now, fortunately, people are much more tuned into it.”



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