

ADVERTORIAL | SPONSORED BY AOTI

Exploring the effectiveness of Topical Wound Oxygen therapy in diabetic foot and venous leg ulcers: ‘A new, different functionality that penetrates the wound’

Until about a decade and a half ago, vascular surgeon Alisha Oropallo, MD, could be counted among the skeptics. Back then, she says, topical wound oxygen therapy for nonhealing vascular wounds did not have much traction in the vascular surgery community. Skepticism was widespread. There was little data behind the technology of the time, and questions lingered over its effectiveness.

Then along came a new mechanism of oxygen delivery to the wound bed. Data followed, including results from a randomized controlled trial (RCT) showing durable healing in chronic diabetic foot ulcer (DFU) wounds.

The key difference maker, says Oropallo, who is professor of surgery at Zucker School of Medicine at Hofstra University/Northwell and director of the Comprehensive Wound Healing Center at Northwell Health in New Hyde Park, New York, is the cyclical pressurized oxygen applied directly to sites of wounds by Topical Wound Oxygen (TWO₂) therapy.

“It wasn’t cyclical before, there wasn’t 100% oxygen, there wasn’t proof that it was actually penetrating the tissues—I think they were just blowing in oxygen from the outside and there wasn’t really a pump mechanism for the most part,” she explains. “It’s new and different multi-modality func-

tionality in how it penetrates the wound with oxygen.”

For Oropallo, TWO₂ use is now routine. With DFU patients who qualify, she starts topical oxygen therapy almost immediately. For patients who she sees with radiation injuries, she almost always refers them for TWO₂. And then there are those patients with venous leg ulcers (VLUs), and particularly recurrent VLUs.

A real-world outcomes study, conducted on a very co-morbid diabetic population—similar to the population that Oropallo treats—showed that even in the face of dysvascular function, and in many cases dialysis, this technology can help this particular population achieve successful outcomes and expedite healing of these hard-to-heal wounds. As the data in the study—carried out by Jessica Izhakoff Yellin and colleagues, and published in *Advances in Wound Care* in 2021—demonstrates, the significance of being able to decrease hospitalizations that prevent amputations in this group of patients with diabetic foot ulcers is life changing for them, Oropallo points out. It also showed that it was economically beneficial for all concerned when this TWO₂ therapy can be implemented, she adds.

Oropallo cites a recent VLU case involving a 64-year-old man with a history of multiple deep vein thromboses (DVTs) and Factor V

Leiden deficiency. Prior, he had undergone left iliac vein stenting and radiofrequency ablation. The patient had residual deep venous reflux of the femoral vein and recurrent leg ulcerations, despite compliance with compression therapy, says Oropallo. “He received adjunctive therapy, such as skin substitutes,” she explains. “TWO₂ was applied with subsequent improvement from baseline [image 1] and over four months duration to closure [2 and 3].”

Oropallo says she deploys TWO₂ whenever feasible. “I use it throughout the treatment too,” she continues. “Because a lot of times the patients are only given a few weeks of hyperbaric oxygen therapy through insurance and that’s just not enough. So, I use it adjunctively and concomitantly. I don’t find that they’re mutually exclusive. I think that they can both help to enhance the wound healing, at least from a continuous basis.”

“Some do very well with TWO₂,” she adds. “It also depends upon the mental status of the patient too, because if the patient is cognitively impaired, that can change the role of how we use TWO₂, because they have to administer it themselves.”

Oropallo says the RCT that evaluated the efficacy of TWO₂ in the setting of DFUs represented a gamechanger in the level of

“The TWO₂ Study is one of the strongest manuscripts in the literature regarding Wagner grade 1 and 2 DFUs”

ALISHA OROPALLO



Alisha Oropallo

evidence behind the therapy. Known as the TWO₂ Study, led by Robert G. Frykberg, DPM, it demonstrated that at 12 weeks and 12 months, adjunctive cyclical pressurized TWO₂ therapy was superior in healing chronic DFUs compared with optimal standard of care alone. Oropallo believes a similar study carried out in the setting of VLUs and published in the vascular literature might eventually lead to topical wound oxygen therapy forming part of the guidelines.

“The TWO₂ Study is one of the strongest manuscripts in the literature regarding Wagner grade 1 and 2 DFUs,” she says. “So, I

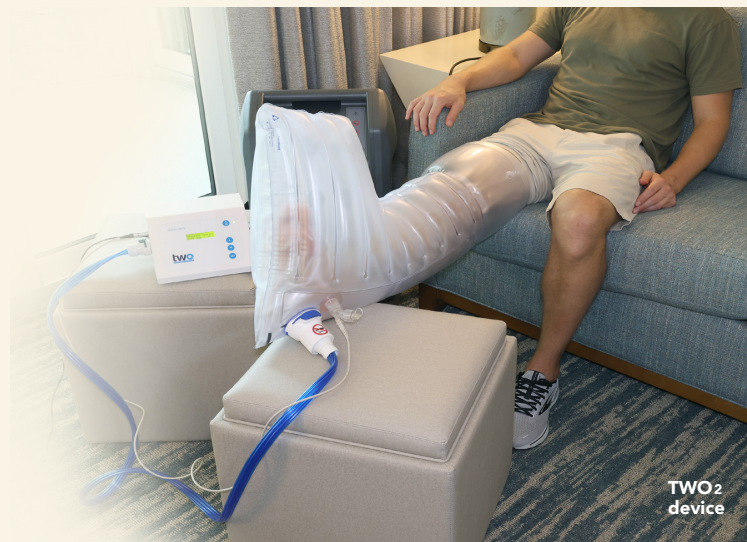
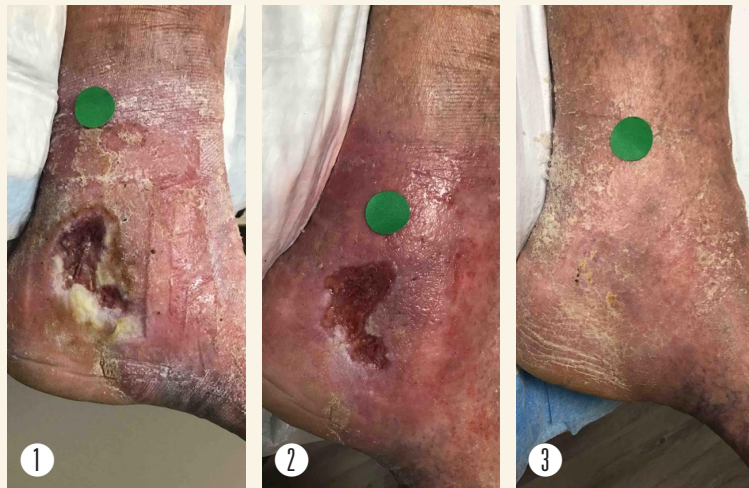
think that pans out really well for vascular surgery in general. If a DFU is a 3 or a 4, then it is more challenging, but the application may still be there—especially concomitantly with an adjunctive therapy.

“Probably the bulk of vascular surgeons’ work is in the field of foot ulcers, because that’s where they do a lot of the revascularization. Most of those patients are admitted in the hospital; they’re going to be under the vascular surgery service line; they’re not going to be under podiatry. The podiatrist might be seeing them ancillary, but the vascular surgeon is really making all the decisions and seeing the patients every day.”

Oropallo contrasts how vascular surgeons face DFU patients with the current VLU treatment landscape.

“Unfortunately, not many patients with venous leg ulcers get admitted too often at the hospital anymore, but they are routinely seen about 80% of the time,” explains Oropallo. “There’s not a lot of good literature out there on topical oxygen in VLUs. But for patients with hard-to-heal wounds who have been recurrently coming back to the office, I wrap the wounds and apply TWO₂ on those patients who really have some challenging wounds that are difficult to heal.”

CASE IN FOCUS: VENOUS LEG ULCER



TWO₂ device



SAVING LIMBS
SAVING LIVES



Delivering Exceptional Outcomes for VLU¹

2X

FASTER TIME TO HEALING FOR VLUs

8X

LOWER RECURRENCE RATE FOR VLUs after 36 Months

76%

HIGHER HEALING RATE at 12 Weeks

46%

MRSA ELIMINATION

PAIN SCORE

dramatically dropped from 8 to 3 in 13 days



A Unique Multi-Modality Therapy For DFUs

6X

MORE LIKELY TO HEAL² DFUs in 12 weeks

6X

LOWER RECURRENCE² rate at 12 months

88%

REDUCTION IN HOSPITALIZATIONS³ at 12 months

71%

REDUCTION IN AMPUTATIONS³ at 12 months

REFERENCES:

1. Tawfik W, Sultan S. Technical and clinical outcome of topical wound oxygen in comparison to conventional compression dressings in the management of nonhealing venous ulcers. *Vascular and Endovascular Surgery* 2013; 47: 30-37.
2. Frykberg R, Franks P, et al. A multinational, multicenter, randomized, double-blinded, placebo-controlled trial to evaluate the efficacy of cyclical Topical Wound Oxygen (TWO2) therapy in the treatment of chronic diabetic foot ulcers: the TWO2 study. *Diabetes Care*, 2020.
3. Yellin J, et al. Reduced Hospitalizations and Amputations in Patients with Diabetic Foot Ulcers Treated with Cyclical Pressurized Topical Wound Oxygen Therapy: Real-World Outcomes. *Advances in Wound Care*, 2021.

Disclaimer: Any person depicted is an actor portrayal and not an actual patient.



3512 Seagate Way, Suite 100, Oceanside, CA 92056, USA
P: 1-760-431-4700 • F: 1-760-683-3063

Visit www.AOTInc.net for more information



MKT-011 Rev. A