



A Breakthrough for Podiatrists Treating DFUs

An innovative technology fills a therapeutic and economic gap.

BY DONNA SAGE

By now, most podiatrists should be aware that the Centers for Medicare and Medicaid Services (CMS) and three Medicare Contractors' actions to pare back reimbursement for cellular tissue products (CTP) via a new Local Carrier Determination (LCD) is still uncertain. There are also limited options for topical oxygen therapy (TOT), which is not available via Traditional Fee for Service Medicare contractors. This has significantly reduced podiatrists'

the obvious first step for Vaporox before pursuing mass commercialization of VHT.

The 2023 JAPMA Study

Dr. Dustin Kruse, DPM, led the research team as Primary Investigator. Dr. Ken Morgan, DPM and Dr. Cade Christensen, DPM also treated with VHT in the study, expanding the research scope to a 3 center, multi-provider sample. All doctors kept their existing chronic wound care patients, maintaining the same Standard Wound Care (SWC) protocols as prior to the start of VHT. Study treatment protocol was to sharply debride the wound once per week and treat with VHT twice per week, in conjunction with SWC and offloading. No CTP, HBO, TOT or Negative Pressure Wound Therapy were used in the cohort. All patients had diabetes, and most had multiple comorbidities. Treatment compliance was high in this study, at 1.7 treatments average per week. 45% of the wounds were Wagner 2 and 55% were Wagner 3 and the average age of the wound in the study was 11.7 months. Exclusion criteria was: propagation of uncontrolled infection, neoplasm, untreated osteomyelitis, participation in another clinical trial, culture confirmed MRSA, failure to follow wound care instructions.

VHT delivers a low-frequency, non-contact, non-thermal, ultrasonic mist along with concentrated oxygen therapy.

options for treating chronic (> 30 days old) wounds. With patients' limbs and lives at stake, something is needed to address these new restrictions by the recent CMS actions.

Fortunately, a new technology that represents a breakthrough in both healing efficacy and practice economics became available earlier this year. Early adopters have seen diabetic foot ulcers (DFU) healing efficacy increase by 2x to 3x and per-patient revenue increase by 4x to 5x.

On March 23, 2023, Vaporox, Inc., received FDA 510(k) clearance for its Vaporox Hyperoxia Therapy (VHT®) wound-healing device. Vaporox is commercializing units to private practice clinics, making this advanced wound care technology accessible to doctors and patients across the United States. VHT delivers a low-frequency, non-contact, non-thermal, ultrasonic mist along with concentrated oxygen therapy. VHT has been clinically validated as a safe and effective adjunct treatment for healing nine different types of chronic skin wounds, including diabetic foot ulcers, Venous Leg Ulcers (VLU), and post-surgical wounds. The healing efficacy of VHT has been validated via Institutional Review Board (IRB) clinical studies in 2007, 2019, and 2022, and in commercial use from 2020-2021 (see Figure 1).

VHT demonstrated an impressive 84% closure rate on chronic DFUs in 2007. Validating the 2007 IRB study was

Results

- 83% DFU healing rate within 20 weeks
- Average time to wound closure 9.4 weeks
- ~2.85 times higher healing rate than standard wound care

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New Concepts and Studies

"Clinical Innovations" is PM's ongoing series of articles dedicated to introducing new concepts, technologies and studies to the podiatric community. Readers should be aware that Podiatry Management does not specifically endorse any of the technologies, concepts, or products being discussed.



RESULTS OF CLINICAL STUDIES

Treatment of Non-healing Diabetic Foot Wounds with Vaporous Hyperoxia Therapy in Conjunction with Standard Wound Care

DFUs (only)	2007 IRB Study	2019 IRB Study	2020-2021 Commercial Data Retrospective Study	2022 IRB Study
Number of wounds	31	29	59	8
Average Wound Age	19.6 months	11.6 months	9.3 months	12.1 months
Average Wound Size	0.9 cm ²	3.17 cm ²	5.33 cm ²	3.51 cm ²
Resolved at 12 Weeks	77%	56%	56%	75%
Resolved at 20 Weeks	84%	83%	66% *	87%

* 76% resolved at 28 weeks



japmaonline.org/view/journals/apms/113/2/20-259.xml

Figure 1

25-month-old DFU, Closed in 12 Weeks

The first photo was at intake for this patient. The provider was able to prevent an amputation, however, the wound had stalled for 8 months and was not responding to treatment. After the addition of VHT[®], the wound closed in 12 weeks and 16 VHT[®] treatments. The only variable that changed was adding VHT[®], exemplifying even the most diligent wound care providers can benefit from the VHT[®] assist. Remarkably, this 70%+ jump in just a few VHT[®] treatments is typical.



Previous treatments used over 25 months:

- Standard wound care
- Surgical debridement
- 24/7 wound vac
- 60 HBO sessions
- Skin grafts

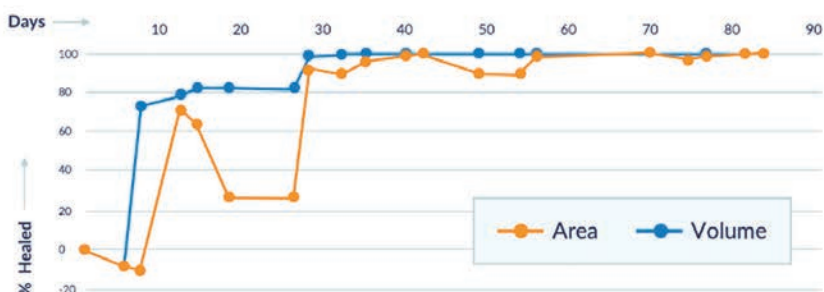


Figure 2



- ~1.3 times higher healing rate than HBO
- ~2 times higher than TOT
- ~1.8 times higher healing rates than non-contact ultrasound therapy

The JAPMA study achieved results that were nearly identical to those of the 2007 study on wounds that were 3.5 times bigger.

Conclusion: VHT is a viable adjunct therapy to aid in DFU healing. For more detail, refer to the 2023 peer reviewed JAPMA study.

Commercial Treatment Protocol

The VHT commercial treatment protocol included debridement and an average of about 2 VHT treatments per week. There were 10 sites and the cohort included much larger wounds and more severe comorbidities. Commercial providers use Vaporox's proprietary wound registry system, VapApp. VapApp analyzes the patient's healing journey and can produce granular analytics at the touch of a button. This data can be converted into a PDF file and uploaded into a provider's EMR system and used to support reimbursement for claims submitted to third party payers. A prominent industry influencer is in the process of publishing the 2020-2021 IRB real-world com-

mercial data that reflects a 76% wound resolution rate at 28 weeks.

Behind these study numbers are some life-changing miracles (see Figure 2).

**VapApp analyzes
the patient's healing journey
and can produce granular analytics
at the touch of a button.**

The Treatment

VHT is an adjunct therapy used in conjunction with SWC. VHT does not preclude other treatment modalities.

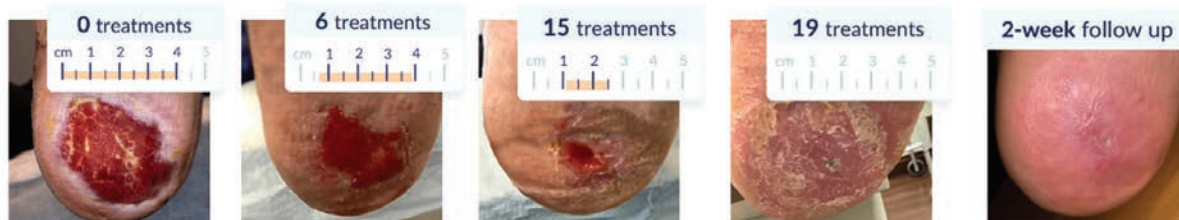
Integrating VHT into private practice is simple. The VHT device arrives at a provider's office in a few boxes. It can be unpacked and set up quickly, and the staff trained in about an hour. The patient's limb is placed into the treatment chamber and gentle hydrating vapor and concentrated oxygen surround the limb, allowing these

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8-month-old DFU, Closed in 11 Weeks

This patient was originally admitted to the hospital where she was told her she would likely need an amputation. The on-call podiatrist accepted her as a patient and made great strides with 8 months of diligent wound care, but the wound was recalcitrant. Fortunately, this provider entered the VHT® IRB study and was able to administer VHT® to this compliant patient. This wound healed in 11 weeks with 19 VHT® treatments.



Previous treatments used over 8 months:

- Slow progressing heel wound
- 8 months of diligent standard wound care
- Compliant CAM boot offloading

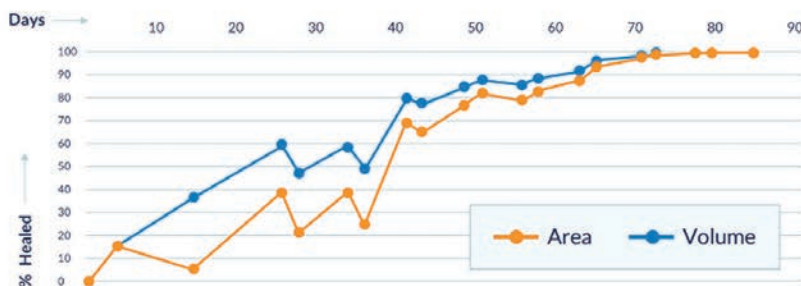
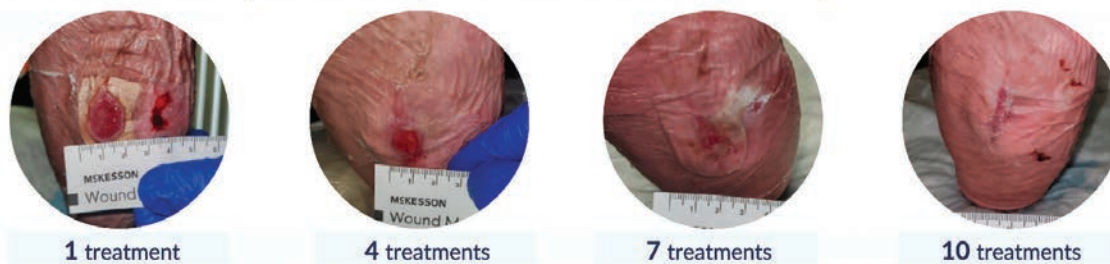


Figure 3

13-year-old Charcot Foot Ulceration, Closed in 7.7 Weeks

This neuropathic and vascularly compromised cattle rancher in Montana had given up hope of healing and headed to Phoenix to be with her daughter to recover from a below the knee amputation. As a last-ditch effort, while waiting for surgery, her new doctor started her on VHT. Her wound responded immediately to VHT and has remained closed for over 3 years.



Previous treatments used over 13 years:

- Total contact casts
- CROW boots
- Multiple surgeries with amniotic graft applications



Figure 4



elements to be passively absorbed into the tissue. This process hyper-saturates the tissue, reduces bioburden, and stimulates angiogenesis. VHT technology is reliable, and its status is monitored continuously by Vaporox via an “internet of things” (IoT) connection. Other than wiping down the device and replacing the disposables after each treatment, the only thing that a user must do is to clean the vaporizer at the end of a treatment day, something that takes about two minutes.

It is obviously best if a treatment is easy on patients. A VHT patient can sit comfortably with limbs elevated, and the treatment is painless and soothing.

Meeting Economic Needs

Although efficacy is the most important thing about any medical intervention, there is more to filling the gap created by CMS’ recent reimbursement restrictions than healing performance alone. If wound care specialists (DPM/DO/MD) are to employ a new technology, it must also meet the many economic needs of clinical private practice.



Figure 5: APMA 2023 Nashville: L to r: Dr. Paul Kesselman; Alan Sage, CEO of Vaporox; and Dr. Jon Purdy, DPM, an early adopter of VHT

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Wound care providers are business owners as well as healers. Reimbursement is crucial. A treatment that is not reimbursed by insurance is effectively unavailable to most patients. VHT has a “Category 1” CPT Code that is reimbursed by Medicare at a national average rate of \$451 per treatment.

Because Vaporox uses a “pay-per-treatment model” for treatments and supplies, there is no upfront cost or investment. A practice takes no risk and VHT is profitable from the first treatment.

“As a doctor in private practice, I like that Vaporox’s business model requires no provider capital investment. Other advanced wound care options often require hefty upfront provider investments while providing underwhelming healing efficacy and questionable prospects for reimbursement or patient payment.”—Dustin Kruse, DPM

VHT is more than a highly efficacious treatment; it reduces total healthcare costs by shortening the treatment period and preventing costly amputations. VHT’s extraordinary cost-effectiveness will help support long-term reimbursement.

Two Additional Case Studies

Figure 3 outlines another case study of the healing performance of VHT in a podiatry practice setting.

VHT reliably produces exceptional commercial results. Figure 4 reports the progress of a patient who is not diabetic but was facing amputation.

Summing Up

Here is a quote from Paul Kesselman, DPM:
“VHT is a revolutionary new procedure now available to wound care providers, allowing them to provide advanced wound care services within their own office. As

Because Vaporox uses a “pay-per-treatment model” for treatments and supplies, there is no upfront cost or investment.

the government and third-party payers demand increasing value while simultaneously decreasing costs, VHT can achieve both those goals.”

Full Disclosure

Dr. Kruse integrated commercial VHT therapy into his practice and accepted the role of Medical Director at Vaporox after witnessing the impressive healing results and successful reimbursement.

Dr. Kesselman is a paid reimbursement consultant to Vaporox. **PM**



As Vaporox’s Clinical Specialist, **Donna Sage** explains VHT to diverse audiences and helps providers successfully integrate VHT into their practices.