



Vibrato Medical: Ultrasound Offers a Healing Approach to Critical Limb Ischemia

Patients with critical limb ischemia desperately need treatments to stave off gangrene and the amputation of their lower limbs. Current revascularization methods buy time by unblocking arteries, but don't really heal the sites of disease. With a noninvasive leg wearable that delivers therapeutic ultrasound, Vibrato Medical aims to increase blood flow that supports the body's healing process.

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Patients with critical limb ischemia (CLI), which is the worst form of peripheral artery disease, face a dire prognosis, starting with a one-year mortality rate of 25%. Because narrowed, hardened arteries deprive the lower leg and foot of blood flow, 45% of patients will experience nonhealing ulcerations of the lower extremity, causing them immobility, pain, social isolation, and infection that can give rise to gangrene. Within one year of a CLI diagnosis, 15-20% of patients will suffer an amputation, and things go quickly downhill from that point. Following the amputation, 40% of patients will die within two years. Although one doesn't hear as much about critical limb ischemia, which affects two million people in the US, its mortality rate is worse than that of heart failure, stroke, and most cancers.

It's also a costly disease; the annual per-patient cost of major amputation is \$56,000 annually. As noted, amputation carries a high near-term mortality rate but even those who survive will require significant care. Medicare attributes a yearly cost of \$12 billion to CLI.

Amputation is the last resort in a treatment armamentarium that includes surgical or endovascular techniques. These go only so far toward saving lives; an analysis by Eric A. Secemsky, MD, presented in October at the annual VIVA (Vascular Interventional Advances) Conference in Las Vegas found that in a cohort of almost 8,000 Medicare patients with CLI who had undergone amputation, 31.1% had previously received high-intensity care, defined as revascularization by surgery, endovascular devices, or

a hybrid of both. Despite the efforts of innovative medical device and pharmaceutical companies working in critical limb ischemia, outcomes haven't improved since *MedTech Strategist* last wrote about the space almost five years ago. (See "New Interventions for Critical Limb Ischemia," *MedTech Strategist*, November 27, 2017.)

Vibrato Medical is entering the space with a different approach. The start-up believes it can help CLI patients with a noninvasive wearable wrap that delivers therapeutic ultrasound. After an initial visit to their prescribing clinician, they treat themselves at home, and software would help clinicians and the company monitor compliance.

Vibrato was founded in 2016 by medical device entrepreneur Bobak

Azamian, MD, PhD, and Babak Nazer, MD, a cardiologist, electrophysiologist, and expert in therapeutic ultrasound. Currently on the faculty of the Knight Cardiovascular Institute at Oregon Health & Science University, Nazer directs its multidisciplinary ventricular arrhythmia program. He also runs his own National Institutes of Health (NIH)-funded laboratory, which develops novel arrhythmia ablation devices, many based on ultrasound.

CEO Juliana Elstad has spent 20 years in executive business development roles for the medical device industry, at Medtronic, NDI Medical, Intelect Medical, Impleo Medical, and her own medical device consultancy. Elstad says she joined the start-up because of the severity of the unmet medical need. “The patients have pain, they suffer from ulcers, then amputation. For some there is absolutely no option. To bring a technology that might work for these people who are so desperate became my mission.”

Therapeutic ultrasound (in the form of laboratory-grade or research devices) has been shown in the coronary arteries to dilate vessels and, in animal models, to contribute to vessel growth and thickening. Vibrato Medical’s challenge was to create a therapy based on this technology that would be wearable as a leg wrap and delivered in a range of parameters comfortable for patients.

The company’s patents are pending, so Elstad can’t go into detail about the technology, but she notes that it involves a configuration of 16 transducers, angled to create a certain field of effect. The device delivers pulsed therapeutic ultrasound according to parameters the skin can tolerate while ensuring that it doesn’t go deep into the bones, at the same time accomplishing two therapeutic mechanisms: vessel

dilation, an immediate effect upon turning the therapy on, and vessel regrowth, which has been shown to occur in animal models two weeks or so after initiation of the therapy. The parameters can be adjusted to account for a number of variables, including different diameters of the leg.


Critical limb ischemia has been difficult to solve. While balloons and stents only address a single artery, the unmet need is diffuse disease involving more than one artery.

In September, Vibrato raised a \$4 million Series A round, led by the Horowitz Group, a family office with a successful track record in life sciences investing, and received a \$1.5 million Phase II Small Business Innovation Research (SBIR) grant from the NIH. The latter will allow the company to begin its CLI study—it has arrived at its target dose of therapy, received institutional review board approval, and will enroll 30 patients.

The target population for the therapy includes patients in stages 3, 4, and 5 of the Rutherford classification of ischemia, where 6 is the most severe

form of CLI, and 3 is peripheral artery disease verging to CLI. Once the therapy is validated and approved, Elstad envisions it being used for disease below the knee on a standalone basis or, potentially as an adjunct to endovascular or surgical therapy to improve outcomes, since reintervention rates are high—20% at 30 days, according to one literature review. Each endovascular or surgical reintervention is associated with \$50,000 in costs, notes Elstad. “Vibrato could help reduce that by enabling noninvasive treatment at home,” she says.

In early November, Vibrato proudly announced the appointment to its board of directors of someone well-known throughout medtech, Paul LaViolette. Currently a managing partner at the venture capital firm SV Health Investors, LaViolette has 40 years of operating experience in the medical device industry, including a 15-year tenure at Boston Scientific where he held several C-suite positions, most recently chief operating officer. LaViolette announced that he was pleased to “support this disruptive, noninvasive therapy for advanced peripheral arterial disease.”

Elstad believes Vibrato can have a meaningful impact on CLI. “It has been difficult to solve, perhaps because it is a complex disease, and balloons and stents only address a single artery.” But there is not just one artery, she notes, the unmet need is diffuse disease involving more than one artery. “We are taking a more systematic approach to try to affect all the arteries in the acoustic field to offer a noninvasive, convenient and cost-effective treatment where it is desperately needed.” 

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