

Vibrato Medical Announces Positive Results for Early Feasibility Study of Wearable, Non-Invasive Therapeutic Ultrasound to Treat Chronic Limb-Threatening Ischemia (CLTI)

The first-on-podium data were presented as a late-breaking clinical trial during VIVA 2023

Newport Beach, Calif. (Nov 1, 2023) - Vibrato Medical, an innovator in the treatment of peripheral arterial disease (PAD), announced today that data from an early feasibility study of Non-Invasive Therapeutic Ultrasound (TUS) to treat Chronic Limb-Threatening Ischemia (CLTI) has successfully met its endpoint. The study evaluated patients with infrapopliteal PAD and measured changes in foot perfusion and oxygenation as well as therapy tolerance, compliance and perception.

The data from the 12-patient Prelude study were presented by Mahmood Razavi, MD, Director of Clinical Trials and Research Center at the Vascular & Interventional Specialists of Orange County, as a podium presentation during the annual VIVA conference at Wynn Las Vegas on October 31, 2023.

Patients in the trial had Rutherford class 3, 4 or 5 PAD, meaning severe claudication, ischemic rest pain or tissue loss including nonhealing ulcers. The trial participants received 30-40 TUS treatment sessions over two months. At the end of the treatment:

- Each individual patient demonstrated a statistically significant improvement in perfusion
- Toe perfusion increased acutely by 180 ± 34 percent ($p < 0.001$)
- Tissue oxygenation increased by +17 percent ($p = .02$)
- Patients showed excellent therapy tolerance, compliance and feedback

“It is hard to believe that even with so many medical advancements, almost 20 percent of patients with chronic limb-threatening ischemia will eventually need an amputation,” said Dr. Razavi. “While the findings from this study are still very early, I am impressed by the clinical improvements, compliance and patient tolerance, and think therapeutic ultrasound may prove itself to be an important treatment for patients with reduced tissue perfusion, such as those with PAD and CLTI.”

Over 18 million people in the United States have PAD, a disease that occurs when the peripheral arteries narrow, making it more challenging to carry blood away from the heart to other parts of the body.¹ It is estimated that two million people with PAD have blockages so extreme they have advanced to CLTI, a chronic condition that can cause extreme pain, sores and wounds that do not heal and can result in the amputation of the affected limb.² The unmet clinical needs for this population are extremely high.

“These early findings are promising for the future of non-invasive therapeutic options to treat chronic limb-threatening ischemia,” said Juliana Elstad, CEO at Vibrato. “We’re looking forward

¹ The Sage Group. Critical Limb Ischemia. Volume 1 US Epidemiology, 2010. Accessed at <http://thesagegroup.us/>. October 14, 2016.

² Duff, et al. Vascular Health and Risk Management 2019.

to building on these findings as we begin our next prospective multi-center randomized clinical trial.”

Based on decades of therapeutic ultrasound research and the latest technological advancements, Vibrato’s technology is the first wearable therapeutic ultrasound device designed to promote vasodilation and vessel growth.

About Vibrato Medical

Vibrato Medical is a private company located in Newport Beach, California. The company has developed the first wearable therapeutic ultrasound device for the noninvasive, outpatient treatment of peripheral arterial disease (PAD) and chronic limb-threatening ischemia (CLTI). It is designed to promote vasodilation, collateral vessel growth and angiogenesis, and restore perfusion. Its leadership team brings deep experience in developing and commercializing medical devices and is supported by an experienced board of directors as well as recognized clinical leaders in the field of PAD. Vibrato Medical’s mission is to be the preferred therapeutic system for patients with reduced tissue perfusion.

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