

Bilateral focused ultrasound shown to be safe, effective for patients with lingering or severe essential tremor

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Credit: Mark James Schornak.

In a study [published](#) in *JAMA Neurology* co-authored by Vibhor Krishna, MD, associate professor of neurosurgery at the UNC School of Medicine, researchers found that a staged bilateral focused ultrasound

treatment for essential tremor is safe and effective. Essential tremor, a neurological condition that causes involuntary and rhythmic shaking, can be so profound that typical life tasks become difficult to accomplish.

Since 2016, neurosurgeons have been able to perform a highly technical, incisionless focused [ultrasound procedure](#) to ablate (or inactivate) the diseased tissue in the brain. The results are instantaneous, with many patients walking out of the procedure room without a tremor. However, for patients who have significant tremors or a tremor originating from both sides of the brain, one course of this [treatment](#) is not enough to keep their symptoms under control.

To help further improve the lives of patients with residual tremors, researchers at seven academic medical institutions around the United States performed a trial to evaluate the safety and effectiveness of performing a focused ultrasound treatment on the untreated side of the brains of patients with residual tremors.

"There are medications to treat essential tremor patients, but often their effectiveness wanes over time, or the [side effects](#) are too profound," said Vibhor Krishna, MD, who was co-author on the paper and associate professor in the UNC Department of Neurosurgery. "Focused ultrasound can offer another route for some patients to regain their ability to live their lives the way they want. Sometimes, the positive effects are very profound."

The study is the largest yet to assess bilateral magnetic resonance-guided focused ultrasound. Clinical data from the trial was used for the approval of bilateral focused ultrasound thalamotomy by the US Food and Drug Administration. The procedure is "staged," meaning that the procedure is performed one side at a time, with several months in between each treatment.

Subjects for the trial had previously undergone a focused ultrasound treatment more than nine months ago, received a diagnosis of medication-resistant essential tremor, and had moderate to severe tremor severity in the upper extremity for the untreated side.

The trial used a focused ultrasound system called the Exablate 4000 Neuro manufactured by Insightec Inc. While patients were inside of an MRI machine, researchers ablated a part of the brain called the ventralis intermediate (VIM) nucleus of the thalamus, a common target for treating essential tremor.

The ultrasound energy was initially delivered at low energy and gradually increased to higher temperatures. The progress was continually monitored for temperature, with each sonication followed by patient evaluation to test for improvement in tremor and any side effects, such as a "pins and needles" sensation, lack of motor coordination, or speech difficulty.

Frank George, Ph.D., a neuroscientist and professional guitarist, received his second side ultrasound treatment a few months ago. His essential tremor greatly affected his ability to strum a guitar, give lectures, and eat with family and friends. He described what it was like to see his tremor improve in real-time.

"They treat you two or three times for about 20 seconds each time. Then you are asked to draw a circle and draw a line," said George. "Every time I came out of the machine, my line became less of a squiggle and finally turned into a perfect line. I had never seen anything like it."

After the procedure, George raced back home to pick up his guitar.

"It was like I was 25 again," said George. "I could instantly, one day later, go from not being able to play a note to being able to play like I

had years ago. I had tears in my eyes. It was about as close to miraculous as you can get. I'm even back to playing professionally again."

Patients were typically discharged from the hospital on the same day as the procedure. Subjects reported mild side effects within 30 days of the procedure. More specifically, 33% of subjects reported numbness or tingling, 29% reported difficulty with speech, 24% reported lack of muscle coordination, 20% reported unsteadiness or imbalance, and 14% reported changes in their sense of taste. Over a period of months to a year, 92% of patients reported improvement in their side effects.

One of the secondary benefits of the treatment is that patients no longer need to take medications, such as propranolol or primidone, to control their tremors, Krishna added. These medications carry hefty side effects that can greatly affect one's quality of life, such as fatigue, dizziness, depression, or suicidal thoughts.

Sally Richey, a 70-year-old woman from Michigan, received her second (bilateral) treatment at UNC. The avid golfer received a unilateral focused ultrasound treatment three years ago to address an [essential tremor](#) in her dominant left hand. As the tremors dissipated in one hand post-procedure, symptoms in her right hand progressively worsened.

"It got to the point to where I could no longer zip up a jacket, do my own hair, or putt," said Richey. "There were so many basic, little things I couldn't do. I would often have to ask for help from others."

With her tremors greatly affecting her daily and social life, Richey decided to reach out for focused ultrasound treatment for the residual tremors. She walked out of the procedure with some slight headaches and imbalance, which improved over time. In the 3 months' time since her bilateral focused ultrasound procedure, Richey reports a 60%—70% reduction in her tremor intensity and has returned to her favorite

pastime.

"I watched my dad suffer through this," said Richey. "He had to give up golf when he was in his seventies and that was heartbreaking. Golf was his life. Because of this procedure, I don't have to give it up. It's a wonderful thing to be able to keep doing what is important to me."

Following the clinical trial, Krishna and his colleagues are working to optimize focused ultrasound treatment to reduce the risk of side effects. Researchers in the field are now exploring the possibility of using staged bilateral focused ultrasound treatment for [patients](#) with Parkinson's disease and other movement disorders.

More information: Michael G. Kaplitt et al, Safety and Efficacy of Staged, Bilateral Focused Ultrasound Thalamotomy in Essential Tremor, *JAMA Neurology* (2024). [DOI: 10.1001/jamaneurol.2024.2295](https://doi.org/10.1001/jamaneurol.2024.2295)

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