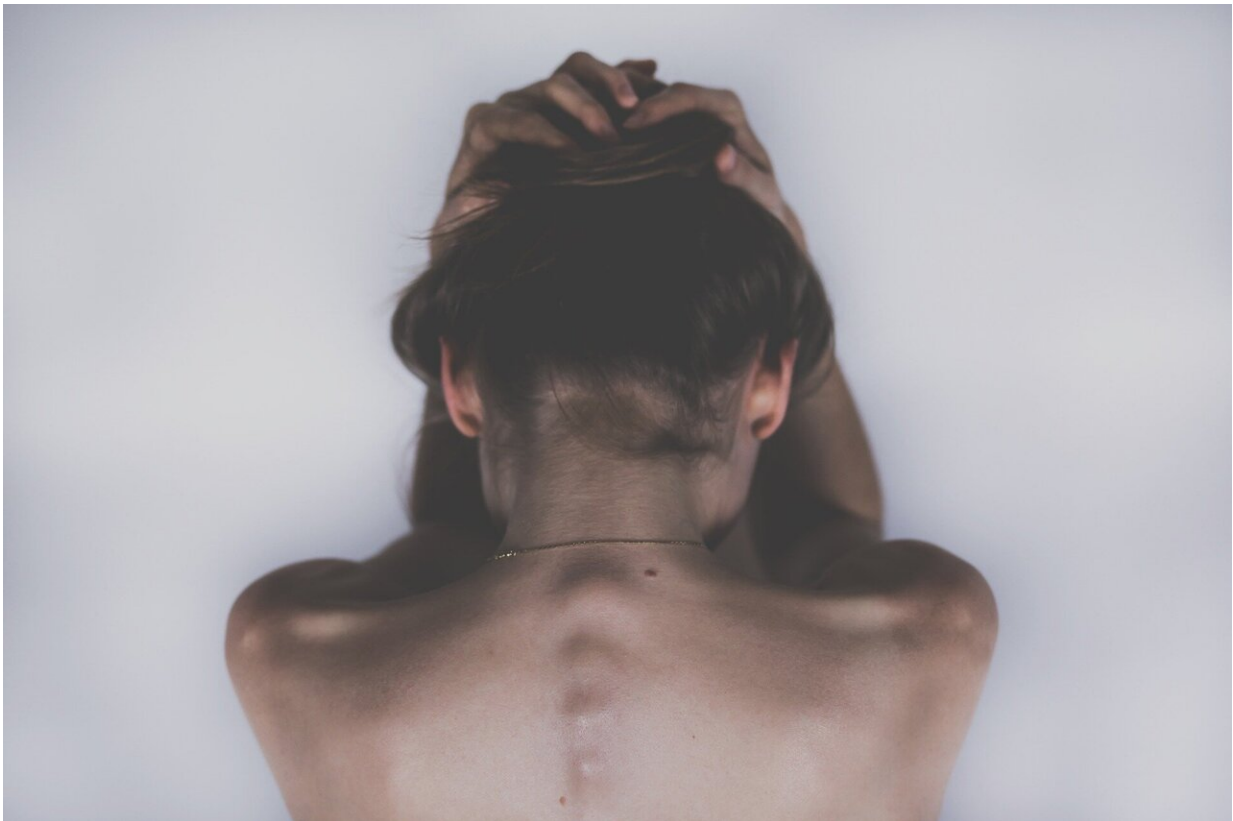


## Researchers are testing ultrasound to treat neuropathic pain

April 22 2019, by Sarah Meehan, The Baltimore Sun

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Steroid injections, nerve stimulators and spinal fusions were no match for the chronic pain in Tammy Durfee's left side—never mind the "searing-hot poker" sensation that would jab her leg without warning.

After a decade searching for relief, a four-hour procedure in Baltimore put her pain to rest.

Durfee, of Higginsville, Mo., was the first U.S. patient to be treated for neuropathic [pain](#) using focused ultrasound in a medical trial being conducted by University of Maryland School of Medicine researchers. Just as a magnifying glass can concentrate sunlight to burn holes in leaves, focused ultrasound concentrates sound waves to singe a small area of the brain, preventing neurons from overreacting and triggering pain.

Durfee's treatment is part of a broader trial in which Maryland medical school researchers are studying the use of focused ultrasound on neurological conditions including essential tremor, Parkinson's disease and other movement disorders. Proponents of focused ultrasound expect the non-invasive therapy could become a mainstream treatment for dozens of conditions ranging from cancer to Alzheimer's disease in the years ahead.

Often associated with pregnancy sonograms, ultrasound is a technique that sends sound waves through the body, often to create medical images. Focused ultrasound pinpoints the sound waves to a specific area to burn tissue.

The technique looks to be a promising treatment for neuropathic pain, a fairly common condition that is notoriously difficult to treat. The sensation is caused by damage to nerves, the spinal cord or neurons in the thalamus, the part of the brain that relays information from the body's sensory receptors.

Neuropathic pain encompasses a range of diagnoses, and symptoms affect an estimated 7-10 percent of the population. It can manifest in different ways, with both continuous and intermittent pain. The

condition does not usually respond to pain medications, and surgical remedies only work for some [patients](#).

"Even if it responds early on, the treatments eventually fail. And the side effects of treatments are many and very, very serious. Many medications lose their effectiveness," said Dr. Dheeraj Gandhi, the University of Maryland's director of interventional neuroradiology and the study's principal investigator. "Most patients don't have very many options and they have to live through this constant pain and the effect it has on the rest of their brain, including cognition, the effect on mood and unemployment. The majority of patients are not able to live their lives to their fullest."

Durfee spent her days avoiding movement after her pain began in 2010. She stayed in bed as long as possible in the morning before leaving for her job as a pharmacy technician at Walmart. In the evenings, she tried to find a comfortable seat on the couch until she went to sleep.

"It made my days very, very long," Durfee said. "I never knew when the deep, searing poker pain was gonna hit."

Steroid injections, spinal fusions, pills and nerve stimulators helped, but the effectiveness of each treatment faded eventually.

Tim Clanton, 54, had seven knee surgeries, an ankle surgery, three spinal sympathectomies—in which a nerve is cut or clamped—and three nerve blocks after a belt-loader crushed his knee as he was hauling luggage onto a commercial jet more than 30 years ago.

"Over the years I've had probably every anti-inflammatory that is known to man, along with lots of other medication," the Dallas resident said. "Being on medication is not good. I prefer not to be, but I also have to work and provide a living for my family."

Fatal overdoses, mostly related to fentanyl, continue to climb in Maryland

Gandhi said focused ultrasound could provide more lasting relief for neuropathic pain patients and help reduce their reliance on pain medications—including opioids, which are often used to manage neuropathic pain.

"If you look at overall health costs for pain-related treatments, the U.S. probably spends more than \$500 billion annually on treatments related to pain," Gandhi said. "So if this procedure works well in these types of patients, it could be a very significant alternative to what we have today."

Dr. Neal Kassell, founder and chairman of the Focused Ultrasound Foundation, said the University of Maryland trial could prove that such treatment fills the "holy grail" of improving health outcomes while decreasing costs. The risk of infection is low because there are no surgical cuts. And, because it's a one-time treatment, focused ultrasound could reduce costs for pain patients, too.

For now, Gandhi said, the procedure's cost is comparable to open-brain surgery because so many researchers are involved.

The study is one step in an arduous process toward regulatory approval. The current trial allows researchers to treat five patients with one of three types of neuropathic pain: shooting pain that does not respond to neurosurgery, pain from spinal cord injuries or phantom limb pain after an amputation.

If the treatment's safety is proven, the research team will review results with the U.S. Food and Drug Administration and request permission to treat more neuropathic pain patients.

Neuropathic pain is among more than 100 conditions being studied for treatment with focused ultrasound.

"Fields like this grow exponentially and I believe we're right now at the inflection point of that curve," said Kassell, whose organization is funding the University of Maryland trial. "Focused ultrasound will be as revolutionary to therapy as (magnetic resonance) scanning was to diagnosis."

Some doctors caution that more research is needed before focused ultrasound can be lauded as a cure-all.

Dr. Art Sedrakyan, a professor of healthcare policy and research for Weill Cornell Medical College, said such therapies as focused ultrasound, cryotherapy and microwave ablation may show promise, but their long-term effects are unknown.

"We need to ensure that we don't get too excited about them in terms of their effectiveness," Sedrakyan said.

He's developing a database of patients treated with such emerging technologies, so they can be tracked for years.

"We need to clearly encourage innovation," Sedrakyan said. "But what's critical is to ensure evaluation."

Though treating [neuropathic pain](#) with focused ultrasound is experimental in the United States, it's gained more traction in Europe, where Dr. Daniel Jeanmonod pioneered the technique in Switzerland. His team referred Durfee to the Maryland trial after she came across his work.

For the procedure, a patient's shaved head is affixed to a steel frame to

immobilize it as they lay in an MRI machine. The top of the head is submerged in a water bath and coupled to a focused [ultrasound](#) transfuser—a helmet-like contraption with more than 1,000 elements that direct sound waves to burn a 5-6 millimeter section of the brain. Doctors constantly monitor the patient, who is awake during the procedure.

"We're actually, if you will, cooking a small group of nerve cells," said Dr. Howard M. Eisenberg, chair of Maryland's neurosurgery department, who is conducting the trial.

It was uncomfortable at times, Clanton said—like a headache. But it was a small price to pay for relief from 33 years of pain that left him limping, stopped him from playing with his three children and stole his quality of life.

"As a kid, you hear people that are older and you think, how can someone live with pain? I found out at (age) 20," Clanton said. "It's been tough. And if more patients can do this, it could be life changing."

Clanton's pain has not disappeared since his treatment in December, but he said it's dulled. He's limping less and doesn't shy away from stairs. Best of all, he said, he's lowered his medication doses—something he wants for other patients in his position.

"When pain is bad you kind of sit there and you're hurting and it's an all-day thing and all night. You never get out of it," Clanton said. "So if at minimum they do the procedure and the medication that they're on works more efficiently, that's worth it. And I can tell you that that's happening with me."

Durfee had the procedure Sept. 13, and her results were immediate. After the procedure ended, she sat up on the table without assistance and

did something she hadn't done in years—she danced out of the hospital room.

"I've been pain-free ever since," she said.

Gandhi, Eisenberg and their team are monitoring the patients for a year with the aim of seeing at least a 40 percent reduction in their pain intensity and a 30 percent reduction in disabilities related to their pain. So far their patients have seen positive results, though it's too soon to tell how effective the treatment will be in the long term.

Clanton said his friends and family have commented that he's moving more easily. And Durfee can now wrestle with her dogs, play with her grandchildren and sit through a movie without wiggling to find a comfortable position.

"I like being pain-free," she said. "It's fabulous."

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Citation: Researchers are testing ultrasound to treat neuropathic pain (2019, April 22) retrieved 25 April 2024 from <https://medicalxpress.com/news/2019-04-ultrasound-neuropathic-pain.html>

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