



Billy wasn't sure about Issue 7, then he did some homework

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## Cleveland biotech company Neuros Medical's nerve block technology for amputees nears FDA approval



The Altius high frequency nerve block has an implantable generator that sits under the skin, and is attached by a wire to an electrode that blocks pain signals from the nerve. Patients can activate the generator, which is smaller than an iPhone, with a remote when they need pain relief. The technology, developed by Neuros Medical, has helped amputees with chronic pain reduce their reliance on narcotics in early studies. (Courtesy of Neuros Medical)



By [Brie Zeltner, The Plain Dealer](#)  
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CLEVELAND, Ohio - Claude Grindstaff was 69 when the blade from a malfunctioning weed-eater nearly severed his right ankle while he worked in his Wooster garden. The



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damage was so bad that doctors had to amputate his leg below the knee, and for years, Grindstaff struggled with daily pain.

Now he's able to press a button and turn that pain off for hours at a time, after taking part in a pilot study testing an implant that cuts off electrical signals from the offending nerve. The **Altius** high frequency nerve block technology, developed by Willoughby-based **Neuros Medical**, is now one trial away from FDA approval.

Grindstaff, now 79, was one of the first patients to receive Neuros' nerve block device about two years ago, which was first delivered with an external battery and stimulator. He now has the system implanted under the skin in his abdomen, and can activate it with a small remote.

"As soon as they did the operation and I started using it, it would bring the pain down. Usually I just need to [activate] it once in the evening," he said.

The first group of 10 patients who received the implant have done so well that the FDA has approved a larger trial, which, if successful, will allow Neuros to petition for approval of the device.

Neuros, **formed in 2008 by former Steris executive Jon Snyder** with technology pioneered at Case Western Reserve University, is part of a **burgeoning Northeast Ohio biotech industry** centered on electrical nerve stimulation for treating spinal cord injury, stroke, bladder incontinence and chronic pain.

**Chronic pain in amputees** is extremely common - of the 2 million people in the U.S. with amputations of major limbs, one half have chronic pain that doesn't respond to available treatments.

"After you have an amputation, having chronic pain, whether it's phantom pain or pain on the end of the stump, is incredibly common," said Dr. Amol Soin, principal investigator of the pilot study testing the Altius device and Medical Director of the **Ohio Pain Clinic**.

This is partly because the surgery to remove a limb requires doctors to sever large nerves, which can still transmit pain signals to the brain. Nerves in the arms and legs also attempt to heal and regrow after a limb is removed with the aid of growth factors, which can lead to balls of tissue on the end of the severed nerve, called **neuromas**.

"They can get pretty big, sometimes as big as a golf ball, and and they can send signals back to the brain that are painful," Soin explained.

After allowing time for healing and trying pain medication, most amputees also use physical therapy to manage pain. There are also surgical options, which include cauterizing the end of the nerve, cutting the end of the nerve again, removing neuromas, or placing a flap of tissue around the end of the nerve to keep it from

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For 10 months, Plain Dealer reporter Angela Townsend and photographer Lynn Ischay followed 9 patients through their journey as study participants in Phase 1 trials at University Hospitals. We tell their stories here.

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regrowing.

“If all of those fail, at that point in time you’re probably a good candidate to try the electric nerve block technique,” Soin said, though the treatment is not only used as a last resort. but is also considered for others who only find marginal relief from other treatments.

Surgeons implant the Altius nerve block under general anesthesia by first using ultrasound to find the nerve that is generating pain signals from the affected limb. Then they dissect away the tissue around the nerve and place a tiny cuff electrode around the nerve. A wire from the electrode is then tunneled under the skin to an implanted generator, which is about the size of a pacemaker.

The generator can be placed anywhere on the body, but is most often implanted under the skin of the abdomen, where it can be easily accessed. Patients can recharge the device by placing a charging coil, which is connected to a recharging module, over the implanted generator. They turn on stimulation with a small remote.

The current is delivered at a very high frequency—10,000 hertz per second—high enough to block the nerve from firing.

“It essentially turns the nerve off at that point, so the point where the cuff is the nerve is turned off downstream from there. With the push of a button you’re able to turn off the nerve,” Soin said.

The device then runs for about 30 minutes, and within about 5 minutes, patients start to notice a reduction in pain. After a single activation, there is a delayed response for the nerve to be able to fire signals again, so pain relief can last from 12 to 18 hours, according to early studies.

For Grindstaff, the relief is almost immediate, though it doesn’t eliminate the pain entirely. He said he can bring his pain down by about 80 percent—from a level 4 to a level 1 on a 0 to 10 pain scale.

Of the 10 patients who took part in the pilot study, seven reported more than 50 percent pain reduction. These reported an average pain drop from 6 to 1 on a 0 to 10 scale. Of these, five were using narcotics before the study, and four were able to completely discontinue using pain medication after the implant.

Patients went from an average of 20 pain pills a week to an average of 2 pain pills a week, Soin said.

“Results have really been excellent for a pain study. After a patient has had chronic pain for a long, long time it’s very difficult to get a pain score down to a 1 or 2. It’s just very difficult to get the brain to not experience pain that it’s used to experiencing all the time every day,” he said.

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Neuros is hoping to enroll about 130 patients for the pivotal trial, and would like to begin the trial by the end of the year.

“Hopefully two years from now we’ll have this device on the market,” Soin said.

“It’s really a great Cleveland Biotech success story. The initial results have been so good that we’ve been invited to present them around the world,” he said. “Looking at how well Ohio’s been doing competing in the biotech sector, which is traditionally a sector dominated by Boston and Minneapolis - it’s nice to see Ohio get in there, too.”



The advertisement features the Cleveland Real Estate logo on the left. To the right, there are two side-by-side property listings. Each listing has a dark grey header with the text 'FOR RENT' in white. Below the header, the main body of the listing is a solid dark grey rectangle. Underneath each listing, the location is specified: 'Parma, OH' for the first and 'Cleveland, OH' for the second.

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