Pittsburgh-area stroke survivors among first to use breakthrough FDA-approved neurostimulation device to regain hand and arm function

NeuroAxis Rehabilitation Services Now Offers Vivistim Therapy to Boost Stroke Recovery Results

PITTSBURGH, Pa., Sept. 30, 2024 – Pittsburgh-based **NeuroAxis Rehabilitation Services** is reigniting hope for chronic stroke survivors by offering the **Vivistim® Paired VNS™ System**, the first and only intervention approved through the FDA's Breakthrough Devices Program to help ischemic stroke survivors regain 2-3 times more hand and arm function than traditional stroke rehabilitation alone.[1] After surviving ischemic strokes earlier this year, Dean Heffernan, a 45-year-old pilot, and Scott Pavlot, a 65-year-old nonprofit executive and bass guitar player, began Vivistim Therapy today to recover functional use of their hands and arms.

Stroke survivors typically experience the most recovery during the first few months of therapy, but 60 percent of stroke survivors experience upper limb issues for six months or longer. Heffernan, who had a stroke in March 2024, and Pavlot, whose stroke occurred in February 2024, have been persistent with their stroke therapy with the NeuroAxis team since being discharged from the hospital within weeks of their strokes. They experienced an initial spontaneous return of some hand and arm function, but their recovery has begun to slow.

"Since we're neuro-based stroke therapists, our clients typically experience remarkable improvements with our evidence-based therapy approach, but now, with Paired VNS Therapy, we're able to optimize stroke survivors' recovery so they can resecure their livelihoods," said Kelsey Harris, PT, DPT, CSRS, RPSFC, owner of NeuroAxis Rehabilitation Services, a mobile outpatient therapy clinic for people who have complex neurological conditions.

The Vivistim device, which is a small, pacemaker-like medical device that is placed under the skin in the upper left chest and neck areas during an outpatient procedure, was implanted in both stroke survivors on September 16, 2024, by Dr. Alexander C. Whiting at Allegheny Health Network.

"Vagus nerve stimulation implant procedures of this nature have been successfully performed for nearly three decades for epilepsy and other disorders," said Whiting, a neurosurgeon and the director of epilepsy surgery for AHN's Neuroscience Institute. "The significance is that now this type of neurostimulation is paired with neurological occupational therapy to help return functional upper extremity use to stroke survivors like Dean and Scott."

During the stroke survivors' Vivistim Therapy sessions, the occupational therapist uses a wireless transmitter to communicate with proprietary software to signal the Vivistim device to deliver a gentle pulse to the vagus nerve while the stroke survivor performs a specific task related to their goals. This simultaneous pairing of the therapy exercise with vagus nerve stimulation helps increase neuroplasticity, the brain's ability to create new neural pathways and relearn movement.

Heffernan's occupational therapist conducts his sessions at the hangar so that he can practice using his thumbs to maneuver the switches on the yoke while also pushing buttons on the plane's control panel with his pointer finger.

"I'm really looking forward to Vivistim Therapy," said Heffernan, who flies rescue missions for the nonprofit No Dog Left Behind. "It is giving me some new hope of increased gains and I'm really excited about the opportunity to take advantage of this newer technology."

For Pavlot, many of the therapy sessions at his house will include his bass guitar, or a computer so he can practice bilateral tasks with his hands and arms and improve wrist and digit extension for activities requiring fine motor skills. In addition to looking forward to being on stage again with his band, he's motivated to improve his typing proficiency to continue to write grants for the West View HUB, a community enrichment nonprofit organization he founded in West View, Pennsylvania.

"My therapy thus far at NeuroAxis has been excellent, and I'm very thankful for their support and for introducing me to Vivistim Therapy," said Pavlot. "I am very optimistic and anxious to get this new Paired VNS Therapy underway, and I feel very fortunate to have this opportunity for a quicker or better recovery."

FDA approved in 2021, Paired VNS Therapy is the first new treatment option for stroke survivors in 20 years, and it has already helped a range of ischemic stroke survivors, including some who are 6 months post-stroke and others who are 20-, 30-, and 40-years post-stroke.

"Vivistim Paired VNS Therapy is such a groundbreaking stroke intervention because it complements our evidence-based therapy principles while turbocharging the brain to foster more neuroplasticity," said Harris. "Our mobile therapy has been successful because we design tasks in stroke survivors' everyday environments instead of having to replicate limiting scenarios in a clinic and use manipulatives. Vivistim Therapy incorporates these same principles of designing salient, functional and goal-oriented tasks to improve outcomes for stroke survivors that enhance their quality of life."

Covered through Medicare without prior authorization and through some private insurance with prior authorization, Vivistim Therapy includes three 90-minute sessions for six weeks. During these 18 initial sessions, therapists are focused on high-repetition therapy tasks. The therapists also assign homework, which the stroke survivors complete by swiping the Vivistim Magnet across the implant to activate 30 minutes of paired vagus nerve stimulation.

"NeuroAxis has been such a collaborative and like-minded partner who shares our dedication to breaking from the status quo to apply innovation that actually helps stroke survivors get back to doing the day-to-day activities and hobbies that are important to them," said Richard Foust, CEO of MicroTransponder, the Vivistim manufacturer. "It's a model that revives hope not just for stroke survivors seeking independence, but also for their healthcare professionals and caregivers."

Discover more about Paired VNS™ Therapy for chronic stroke recovery and review safety information at Vivistim.com/safety. Register for a NeuroAxis in-person screening day at neuroaxisrehab.com/vivistim.

1. Dawson et al. Vagus nerve stimulation paired with rehabilitation for upper limb motor function after ischaemic stroke (VNS-REHAB): a randomised, blinded, pivotal, device trial. Lancet. 2021; 397 1545–1553.