Implanted Shoulder Stimulator Provides New Option for Post-Stroke Shoulder Pain

By Michael Schaefer, MD

A 64-year-old woman who had a stroke in 2007 presented to Cleveland Clinic's Department of Physical Medicine and Rehabilitation in 2017 complaining of hemiplegic pain and weakness in her left shoulder.

She was unable to take anti-inflammatory medications due to stroke risk. She had tried transcutaneous electrical stimulation (TENS) for her shoulder pain and underwent physical and occupational therapy, all without much relief.

She was referred by her neurologist for possible implantation of the Bioness StimRouter™, a minimally invasive implantable neuromodulation device designed to treat chronic peripheral nerve pain. The device received FDA clearance in 2015. Cleveland Clinic PM&R physicians began offering StimRouter implantation earlier this year.

The patient was a good candidate due to her prolonged shoulder pain, lack of relief from conservative measures and sufficient cognition. She had the device implanted in an outpatient procedure in June 2017 and returned for device activation one month later. Upon activation, she immediately noted relief of pain — from 7/10 to 4/10 — and an improved ability to do range-of-motion exercises. She also noted improved sensory function in her left arm. She was referred to occupational therapy for further rehabilitation.

Minimally invasive neuromodulation at a glance

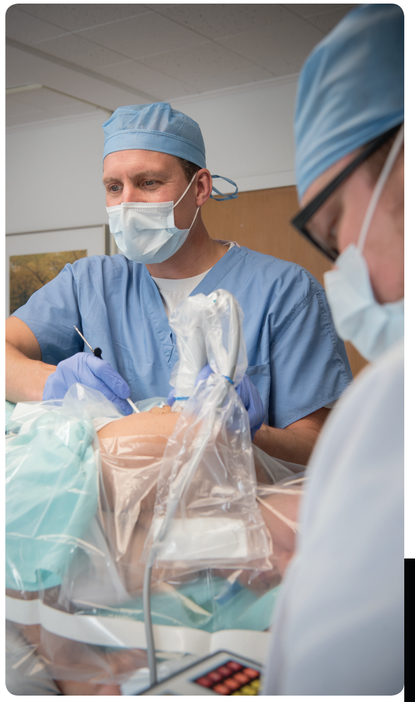
Hemiplegic shoulder pain is common after stroke, often limiting daily living activities. While many patients achieve relief from conservative interventions (e.g., physical therapy, cortisone injections, oral medication) within six months to one year, some do not. Such patients are often candidates for neuromodulation if they have adequate cognition and are free from infection and severe cardiac and pulmonary issues.

StimRouter implantation takes 30 to 45 minutes, requires light or no sedation, and involves two small puncture incisions via scalpel. Only the wire and a small receiver unit are implanted in the patient. Stimulation is provided via an external pulse generator programmed three to four weeks after implantation. Two or three programming options are designed, to provide analgesia and (separately) motor stimulation. For more on the implantation procedure, see the online version of this article at **consultqd.clevelandclinic.org/shoulderstim**.

Solid results to date

As of mid-July 2017, Cleveland Clinic PM&R physicians had implanted four such devices. Three patients had hemiplegic shoulders, and one had an above-knee amputation with neuropathic pain in the sciatic distribution. The first shoulder patient reported dramatic pain relief, and the three subsequent patients reported approximately 60 percent pain reduction, on average.

The procedure is a good option for patients with hemiplegic shoulder pain, but it may be used in both upper and lower limbs for neuropathic pain related to entrapment syndromes, neuralgias and other peripheral injuries or diseases. It is nonpharmacologic and fully adjustable and can potentially offer more complete pain relief than other therapies.



Dr. Schaefer implants the StimRouter device in the shoulder of a patient.

A good match for PM&R

The procedure is often performed by pain management physicians, but PM&R physicians are ideally suited to implant the StimRouter as well. Physicians who offer this procedure should have solid ultrasound skills and receive hands-on implantation training from an experienced clinician. There can be a steep learning curve, so patience is a must.

One other peripheral nerve stimulator is currently on the market for use in hemiplegic shoulder pain — the SPRINT PNS, a percutaneous system that attaches wires directly to an external generator for 30 days. It's designed for temporary relief during initial phases of rehabilitation.

The StimRouter and SPRINT PNS are both first-generation neuromodulation devices, and the technology will continue to improve. While appropriate patient selection is key, peripheral nerve stimulation appears to be a solid option for patients with post-stroke shoulder pain who've exhausted more conservative therapies.

Dr. Schaefer is a musculoskeletal specialist in the Department of Physical Medicine and Rehabilitation and the Department of Orthopaedic Surgery.

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DBS for Stroke Recovery: First Patient's Functional Progress Continues Through 4 Months

The first patient to ever undergo deep brain stimulation (DBS) to restore motor function following hemiparesis after ischemic stroke has experienced steady and strong functional improvements in the first four months of management pairing DBS with rehabilitative therapy.

That's the word from Cleveland Clinic neurosurgeon Andre Machado, MD, PhD, who is overseeing the patient's care after surgically implanting DBS electrodes in her cerebellum in a milestone operation at Cleveland Clinic in December 2016.

"Within a few weeks of when the DBS device was turned on earlier this year, the patient reported she could move her affected arm in ways she hadn't been able to since her stroke," says Dr. Machado, Chairman of Cleveland Clinic's Neurological Institute. "And her progress has been steady — week after week, month after month, her function continues to improve. The improvement has been more than we expected."

The trial's first patient in a therapy session four months after the start of stimulation.

Part of an NIH-funded first-in-human trial

The patient is the first in a first-in-human clinical trial of DBS for stroke recovery being conducted at Cleveland Clinic with funding support from the National Institutes of Health's BRAIN initiative. The researchers plan to enroll 12 patients. A second study enrollee has undergone surgery for DBS electrode implantation but hasn't yet completed physical training with stimulation turned on.

Trial candidates are patients who have severe residual hemiparesis from an ischemic stroke 12 to 24 months earlier, in spite of rehabilitative therapy. "These are patients with chronic stroke who have failed to improve significantly after training with physical and occupational therapy," says Dr. Machado. "Our hypothesis is that DBS targeting the dentate nucleus of the cerebellum can allow these patients to regain more function from therapy than they could with therapy alone."

Therapy protocol at a glance

The first patient has completed the trial's initial protocol, as follows ("therapy" below refers to two 90-minute sessions of combined physical and occupational therapy each week):

- One month of therapy following enrollment to establish baseline function
- Surgery to implant the DBS electrodes and battery
- Four-week resting period at home to recover from surgery
- Eight weeks of therapy without the DBS device turned on, to establish a new functional baseline
- Four weeks of programming the DBS device with the assistance of transcranial magnetic stimulation to assess response
- Four months of therapy with the DBS device turned on continuously

The protocol also calls for one month of slowly weaning off the DBS device, which the first patient has not yet done.

The therapy regimen focuses on repetitive task practice and is the gold standard for upper extremity rehabilitation, says Anson Rosenfeldt, PT, DPT, a therapist working with trial subjects.

She says the main difference from regimens used for other stroke patients with hemiparesis is that compensation from the unaffected side is strictly discouraged. "We want to challenge the patient's brain in new ways to promote lasting change," Rosenfeldt explains.

Continuing improvements prompt protocol revision

For the trial's first patient, those efforts are paying off. In addition to progressive improvements in her scores on a multitude of objective tests of arm and hand function, she's now able to use her affected arm while cooking and to play games with her grandchildren. She also performs a host of daily tasks more efficiently, such as folding laundry.

"After four months of DBS plus therapy, her function hasn't plateaued," says Dr. Machado. "We haven't yet found the limits of how much she can improve."

As a result of this continuing progress, the team is revising its study design to allow patients an opportunity to continue concurrent stimulation and therapy longer than the initially planned four-month window. "Many questions remain," Dr. Machado notes. "We look forward to learning much more as this trial continues."

Frederick Frost, MD

Dear Colleagues,

How do you integrate clinical care and rehabilitation research? The more you think about it, the harder that question becomes. Several patients arrive in our clinic each week asking for experimental surgery and stem cells. Typically they are two years out from their disabling event and are coming to realize that time, therapy, hard work and platitudes are not resolving their problem. These are not comfortable conversations.

I maintain that every one of our severely disabled patients is a vulnerable research subject for whom there are very few studies that constitute minimal risk. I'm lucky to work with rehab researchers who take great pains to carry out their work in a way that is ethical and transparent. These are scientists whose careers have been made by decades of study and commitment to doing things right. They maintain strict control over the conversational narrative with patients and families, and they take personal responsibility to ensure that every research intervention is paid for by research funds. In the end, this is the fastest and best way for promising treatments and technologies to gain momentum and reach the clinical realm.

Please flip through a few more pages and let these great staff members introduce themselves to you. The members of our research, clinical and education teams know that it's a joy — and a privilege — to be part of our patients' journeys.

Respectfully,

Frederick Frost, MD (frostf@ccf.org)
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BY THE NUMBERS: **Department of Physical Medicine and Rehabilitation**

3 adult inpatient rehab hospitals – 139 beds

1 pediatric inpatient rehab hospital – 52 beds

2 hospitals moving to newly built facilities in late 2017

STAFF

39 staff physicians and collaborative clinical staff

6 research staff

800+ therapists in Cleveland Clinic Rehabilitation and Sports Therapy

VOLUMES*

1,753 acute inpatient rehab admissions

4,845 inpatient days

426,665 PM&R outpatient visits

284,433 PM&R inpatient visits

* 2016 volumes

6 Clicks Tool: Why It's Drawing Crowds at Conferences Far and Wide

Ever since Cleveland Clinic rolled out its 6 Clicks functional measurement tool in 2011-2012, Mary Stilphen, PT, DPT, has been scrambling to keep up with all the invitations she receives to speak about it.

"I've presented on 6 Clicks to the American Hospital Association, the American Physical Therapy Association, the American Medical Rehabilitation Providers Association and a host of regional organizations," says Stilphen, Senior Director of Rehabilitation and Sports Therapy at Cleveland Clinic. "There's a lot of interest in how our PTs and OTs are using this electronically administered tool to promote a culture of mobility, reduce inappropriate therapy referrals and optimize post-acute discharge planning."

Across Stilphen's many talks on 6 Clicks — created at Cleveland Clinic as a short form of the AM-PAC™ instrument developed by Boston University — interest tends to focus on the following three ways 6 Clicks is used:

To educate physicians about therapy referrals. "We've used 6 Clicks data to show physicians throughout the organization that not all inpatients need the skills of a therapist and to teach them which patients are (and aren't) appropriate for therapy consults," Stilphen notes.

To drive value and system change. 6 Clicks is all about data: Discrete data are collected by therapists at every inpatient encounter and then used to drive clinical decisions, guide hospital resource use and help determine the most appropriate discharge disposition. "Having data to show how to direct our resources has been invaluable — it really makes a difference in getting all hands on deck with these initiatives," Stilphen says.

Stilphen at a 2016 talk on 6 Clicks.

To curb precertification requests for SNF transfer. Therapists perceived that these requests were sometimes prompting unnecessary therapy visits and needlessly delaying skilled nursing facility (SNF) transfer and prolonging hospital stays. Disposition data supported these perceptions. So PM&R leadership proposed that inpatients with an initial 6 Clicks score below a certain threshold and for whom PT has recommended SNF transfer shouldn't require an updated PT/OT note for SNF admission unless required by their insurance. A pilot with one payer found this approach reduced requests for precertification visits, length of stay in both hospital and SNF, and administrative burden for all parties. The concept has since been implemented across multiple Cleveland Clinic hospitals.

www More at **consultqd.clevelandclinic.org/6clicks**

Two leaders of the soon-to-open Cleveland Clinic Rehabilitation Hospital, Beachwood, outside the facility in September. On the left is the facility's Chief Executive Officer/Market Executive, Dave Richer; on the right is the facility's Medical Director, Patrick Shaughnessy, MD.

Finishing Touches on Two New Inpatient Rehab Hospitals

Construction is nearly complete on two new inpatient rehabilitation hospitals that Cleveland Clinic will operate in a joint venture with rehabilitation services provider Select Medical Corp. The new facilities — east of Cleveland in Beachwood, Ohio, and south of Cleveland in Bath, Ohio — are scheduled to open in autumn 2017. Each will have 60 beds.

They will join another new inpatient rehab hospital operated under the joint venture — opened in Avon, Ohio, west of Cleveland in December 2015 — to expand a growing regional inpatient rehabilitation footprint complementing the services offered at Cleveland Clinic's main campus hospital.

Early results out of the new 60-bed rehab hospital in Avon bode well for the joint venture with Select. In just its first year of operation (2016), the Avon facility exceeded the joint venture benchmark for patient satisfaction scores and surpassed the weighted national average in patients discharged home. This was accomplished despite a case mix index higher the national 50th percentile.

Jump-Starting Cognitive Rehab

Cognitive rehabilitation therapy (cognitive rehab) could stand some reimagining. Although this therapeutic strategy has been around for decades, its scope has rarely expanded beyond patients with neurological conditions. And the therapies used have largely remained rudimentary and divorced from patients' daily functional needs.

That need for reinvention has not been lost on Cleveland Clinic, which has launched an initiative to reimagine cognitive rehab in the inpatient setting. Occupational therapy (OT) is at the effort's heart, with key aspects including a "rescripting" of OT visits to inpatients referred for therapy services and enterprisewide training of OTs in cognition issues. A centerpiece is the new Cognitive Rehab Study Group, which holds monthly training sessions drawing robust attendance from OTs as well as physical and speech therapists, rehabilitation psychologists, physicians and other providers.

"Cognitive impairment is one of two or three predominant factors determining whether a hospitalized patient will be able to be discharged home and then later be at risk for readmission," says Frederick Frost, MD, Chair of Cleveland Clinic's Department of PM&R. "We're looking to elevate and engage our OTs to identify cognitive issues that may hamper inpatients' ability to manage their medical needs after discharge."

A common example is medication management. When inpatients are identified through screening as being at risk for cognitive impairment, OTs work with these patients using specially developed medication kits consisting of bottles of various sizes and shapes containing pills of many colors (see photo below). Therapists ask patients to try to open the bottles, distinguish between different meds and follow label instructions — and then they share tools and strategies to help patients work through any difficulties.

Therapies like this are in contrast to the flash cards and colored cones traditionally used in cognitive rehab. "We want to bring therapy around to function that's relevant to patients' daily lives and what they'll need to support their care at home," explains Karen Green, PT, DPT.

Positive results from a pilot of the initiative on medical-surgical units have led to its expansion to cardiovascular and neurological units. "This is empowering our OTs to operate at the top of their license and bring a high level of value to the patients who need them most," says Green. "And it promises to help prevent readmissions in the process."

www More at **consultqd.clevelandclinic.org/cogrehab**

Transcranial Direct Current Stimulation Improves Function in Chronic Tetraplegia

Dr. Potter-Baker demonstrates the tDCS device.

Patients with long-standing incomplete tetraplegia realized gains in motor function below the level of injury after a two-week program pairing transcranial direct current stimulation (tDCS) with massed practice training in a new Cleveland Clinic pilot study. The gains were still evident three months after the intervention, and motor map characteristics showed increased excitability of residual pathways.

Results of the study were reported at the Academy of Spinal Cord Injury Professionals (ASCIP) educational conference in September. The study abstract was selected as the conference's prestigious Jayanthi Lecture from more than 200 entries.

The double-blind investigation randomized 12 patients to tDCS or sham stimulation in addition to two hours of physical therapy five days a week for two weeks. "We observed significant functional benefits in these very disabled patients in the chronic stage of injury after only a short intervention with tDCS plus massed practice training," says lead author Kelsey Potter-Baker, PhD, a research scientist in Cleveland Clinic's Department of Biomedical Engineering. "One patient, who for years had been unable to use a computer keyboard, could do so following treatment. This was life-changing for her."

She adds: "Our findings provide evidence that stimulation helps restore cortical representation of paralyzed and weak muscles, and strongly suggest the potential for adaptive plasticity long after injury."

tDCS is noninvasive, inexpensive and easily added to a patient's normal clinical care, Dr. Potter-Baker notes. Her Cleveland Clinic research team is preparing for a larger phase 2 clinical trial of the intervention, with the aim of pinpointing the best duration of intervention and tDCS dosage.

The full study has been published in the *Journal of Spinal Cord Medicine*.

www More at **consultqd.clevelandclinic.org/tdcs**