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 understood physical and occupational therapy, all without much relief.

She was referred by her neurologist for possible implantation of the Boston StimRouter™, a minimally invasive implantable neuromodulation device designed to treat chronic peripher- nal nerve pain. The device received FDA clearance in 2015. Cleveland Clinic PM&R physicians began offering StimRouter implantation over the past 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 in its 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 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 20 to 45 minutes, requires light or no sedation, and involves two small puncture incisions via a scalp. 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 times after implantation. Two or three programming settings are designed to provide analgesia and (separately) motor stimulation.

For more on the implantation procedure, see the online version of this article at www.clevelandclinic.org/extradocents

Solid results to date

As of mid-July 2017, Cleveland Clinic PM&R physicians had implanted four such devices. Three patients had hemiplegic shoulder pain, and one had an above-knee amputation via a scalpel. Only the wire and a small receiver unit are implanted in the patient. Stimulation is provided on an external pulse generator programmed three to four times after implantation. Two or three programming settings are designed to provide analgesia and (separately) motor stimulation.

For more on the implantation procedure, see the online version of this article at www.clevelandclinic.org/extradocents

A good match for PM&R

The procedure is often performed by pain management physi- cians, 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 SPIN™ PNS, a percutaneous system that attaches wires directly to an external generator for 30 days. It’s designed for temporary use after stroke or brain injury but is not yet cleared by the FDA.

The StimRouter and SPIN™ 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 conserva- tive therapies.

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

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 hemi- paresis 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 at 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. "Her two progress has been steady — week after week, month after month, her function continues to improve. The improvement has been more than we expected."

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 Institute of Health’s BRAIN initiative. The researchers plan to enroll 12 patients. A second study window involves undersea surgery for DBS electrode implantation but hasn’t yet completed physical training with stimulation turned on.

Trial candidates are patients who have severe residual hemi- paresis 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 trying 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 the 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 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.
• Eight-week waiting period to allow for surgery to stabilize.
• Eight weeks of therapy without the DBS device turned on, to establish a new 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 continually.

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 upper limb tasks and exercise, and is the gold standard for upper extremity rehabilitation, says Arman Rosenfeld, PT, DPT, a therapist working with their subjects.

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

Continuing improvements prompt protocol revision.

For the trial’s first patient, those efforts are paying off. In addi- tion to progressive improvements in her scores on a multimodal of objective tests of arm and hand function, she is 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. "She hasn’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 study-planned four-month window. "Many questions remain," Dr. Machado notes. "We look forward to learning much more as this trial continues."

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

How do you integrate clinical care and rehabilitation research? The more you think about it, the harder the 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, thereby, their health and outcomes are not resolving their problems. These are not comforting conversations.

I imagine that many of our severely disabled patients are a vulnerable research subject for whom there are very few viable options that control minimal risk. It’s tricky to work with rehab researchers who take their goals 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 conversations narrative with patients and families, and they take personal responsibility to ensure that every research intervention is led by research-funded. In the end, this is the defined and best way for promoting treatments and technologies to gain momentum and reach the clinical stage.

Please flip through the next few 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.

Researcher

Frederick Frost, MD

Chairman, Department of Physical Medicine and Rehabilitation Executive Director, Cleveland Clinic Rehabilitation and Sports Therapy

In rehabilitation and neuroscience:

Two leaders of the team to open Cleveland Clinic Rehabilitation Hospital, Beachwood, outside the facility in September. On the left is the facility’s Chief Executive Officer/Basket Executive, Bruce Balsbaugh; on the right is the facility’s Medical Director, Patrick Stehman-Breen, MD.

Frederick Frost, MD (front left)
Chairman, Department of Physical Medicine and Rehabilitation Executive Director, Cleveland Clinic Rehabilitation and Sports Therapy

To the medical staff at Cleveland Clinic and the researchers and therapists who have worked so closely with our patients and families, and who have personal responsibility to ensure that every research intervention is led by research-funded. In the end, this is the defined and best way for promoting treatments and technologies to gain momentum and reach the clinical stage.

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 spearheading to keep up with all the invitations she receives to speak about it.

“I’ve presented in 6 Clicks to the American Hospital Association, the American Physical Therapy Association, the American Medical Rehabilitation Prevention 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 through 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.”

To drive sales and systems 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. ‘Hey data show to show how to direct our resources has been validated — it really makes a difference in getting all hands on deck with these initiatives,” Stilphen says.

Inpatient rehabilitation

By the numbers: Department of Physical Medicine and Rehabilitation

<table>
<thead>
<tr>
<th>3</th>
<th>adult inpatient rehab 137 beds</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>pediatric inpatient rehab hospital 52 beds</td>
</tr>
<tr>
<td>2</td>
<td>hospitals moving to newly built facilities in late 2017</td>
</tr>
<tr>
<td>39</td>
<td>staff physicians and collaborative clinical staff</td>
</tr>
<tr>
<td>1,753</td>
<td>acute inpatient rehab admissions</td>
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<tr>
<td>4,845</td>
<td>inpatient days</td>
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<tr>
<td>426,665</td>
<td>PMAR outpatient visits</td>
</tr>
<tr>
<td>800+</td>
<td>therapists in Cleveland Clinic Rehabilitation and Sports Therapy</td>
</tr>
<tr>
<td>284,433</td>
<td>PMAR inpatient visits</td>
</tr>
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Cleveland Clinic Rehabilitation and Sports Therapy

To cut pre-certification requests for SNF transfers. Therapists perceived that these inpatient care were sometimes prompting unnecessary therapy visits and needlessly delaying skilled nursing facility (SNF) transfer and prolonging hospital stays. Discharge data supported these perceptions. So PMAR leadership proposed that inpatients with an initial 6 Clicks score below a certain threshold and for whom PMAR has reoccurring SNF transfer shouldn’t be updated a PT/OT referral for SNF admission unless required by their insurance. A pilot with one paper found the approach reduced requests for pre-certification visits, length of stay in both hospital and SNF, and administrative burden for all facility. The concept has since been implemented across multiple Cleveland Clinic hospitals.

Visit our physician website for in-depth content in rehabilitation and neuroscience: consultEd.clevelandclinic.org/neurosciences

Consult QD

Transcranial Direct Current Stimulation Improves Function in Chronic Tetraplegia

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) at the heart’s level, with key screens including a ‘hunching’ of OT visits to outpatient referred for therapy services and enterprised training of OTs in cognitive issues. A cornerstone is the new Cognitive Rehabilitation Study Group, which holds monthly training sessions covering initial updates 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 hospital’s patient is able to be discharged home or then later be at risk for readmissions,” says Frederick Frost, MD, Chief of Cleveland Clinic’s Department of PMAR. “We’re looking to elevate and engage our OTs to identify cognitive issues that may impact impaired ability to manage their medical needs after discharge.”

A common approach is medication management. When patients are identified through screening as having 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 use pills to key open the bottles, distinguish between different meds and follow intake’s instructions — and then they chart and stage tools to help patients work through any difficulties.

Therapists like this are in contrast to the flash cards and colored sheets 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 as care home,” explains Karen Green, PT, DPT.

Positive results from a pilot of the initiative on medical-rehabilitation unit have led to its expansion to cardiovascular and neurological unit. This is empowering our IOs to operate at the top of their license and bring a higher level of value to the patients who seek them from, says, Green. “And it promises to help prevent readmissions in the patient.”

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 — one 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:

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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 practical 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.

The double-blind intervention randomized 12 patients to tDCS or sham stimulation in addition to two hours of physiotherapy five days a week for two weeks. “We observed significant functional benefits in the very disabled patients in the chronic stage of injury after only a short intervention with tDCS plus massed practical training,” said lead author Dr. Peter 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, did so following treatment. This was life-changing for her.”

She adds: “Our findings provide evidence that stimulation could modify corticospinal representation of synergy and weak areas, and strongly suggest the potential for adaptive plasticity long after injury.”

tDCS is minimally invasive and easily added to patient’s normal clinical care. Dr. Peter Baker notes, her Cleveland Clinic research team is preparing for a larger phase 3 clinical trial of the intervention, with the aim of preparing the best location of intervention and tDCS dosage.

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