Cleveland Clinic

Frontiers in Rehabilitation

A Newsletter for Physicians | 2014

Virtual Reality Treadmill Systems Usher in New Era of Immersive Rehab

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ON THE COVER: Cleveland Clinic's Computer Assisted Rehabilitation Environment treadmill system uses visual projection, surround sound and motion-capture technology to create a real-world setting for rehab, clinical analysis and research.

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Frontiers in Rehabilitation, published by Cleveland Clinic's Department of Physical Medicine and Rehabilitation, provides updates on diagnostic and therapeutic techniques and current research for physiatrists, neurologists and neurosurgeons.

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Dear Colleagues,

I am always hesitant to feature rehabilitation technology as the cover photo of our *Frontiers in Rehabilitation* publication. Advances in engineering science attract attention and build excitement. The risk comes when the focus on technology distracts us from the real business of rehabilitation — that is, helping our patients achieve a fulfilling and full life in the face of disabling conditions.

The disconnect in our field is quite simple: We provide rehabilitation, but our patients want recovery. At best, the technological tools that we utilize during the rehabilitation process have a modest impact on recovery, but this is not the message that is sent. A focus on expensive machines extends the rhetoric that disability is intrinsically bad and can be eliminated, given enough money and equipment.

As a national referral center, we see patients in our clinics every day who are frustrated and even angry at their "lack of progress." Typically, these individuals are two or three years post-onset of disability and are just now discovering that exercise, gadgets and platitudes are not going to cure them.

It is perfectly natural for a newly disabled person to start his or her rehabilitation with the hope of becoming "normal" again. For our patients who do not fully recover, it is our job to help them reframe their definition of rehabilitation success. A healthy return to community, home, family and work is the goal. I believe that this issue of *Frontiers* correctly characterizes our emphasis on innovation and technology that impacts more than the recovery narrative.

The scope of activities of our PM&R staff is impressive. Work described in these pages by Ela Plow, PhD; Vernon Lin, MD, PhD; Xiaoming Zhang, PhD; Andre Machado, MD, PhD; Sean Nagel, MD; Yu-Shang Lee, PhD; and Ching-Yi Lin, PhD, touches on some of the most basic questions in rehabilitation research — from the role of neuronal stimulation in treating various conditions to attempts to regrow severed spinal cord nerves.

A visit to Cleveland Clinic this spring from consultant and healthcare reform advocate Hilary Siebens, MD, is detailed in this issue. Her work helps us develop a biopsychosocial care framework for our enterprise, including the Stroke Care Path that Zeshaun Khawaja, MD, has revised and describes in his article. We also present our experience with conversion disorder patients and the ethical challenges that are involved in their care.

In our "6 Clicks" piece, we describe how modifications to our electronic medical record have allowed us to capture more discrete data that help us advocate for the best post-hospital rehabilitation care for our patients. The "6 Clicks" tool has gained considerable attention nationally.

Michael Schaefer, MD, the director of our new musculoskeletal medicine fellowship, explains how ultrasound diagnostics has become a priority in the education of our rehab professionals. Douglas Henry, MD, Director of Developmental and Rehabilitative Pediatrics at Cleveland Clinic Children's Hospital for Rehabilitation, explores the effectiveness of two types of movement therapy to help children with hemiparesis.

Finally, the work of our colleague Jay Alberts, PhD, brings us back to the technology topic, as we find ways to make exercise more relevant and effective for our patients.

In the lives of our patients, their rehabilitation treatment goes by in the blink of an eye. As rehabilitation professionals, we recognize that psychological, cognitive, socioeconomic and physical restrictions largely determine health outcomes. As you flip through the pages of *Frontiers*, I am confident that you will see our rehab professionals meeting the most important challenges head-on.

Frederick S. Frost, MD

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Virtual Reality Treadmill Systems
Usher in New Era of Immersive, Multisensory Rehab in a Controlled Environment

Imagine a patient with Parkinson disease undergoing physical therapy for neuromuscular re-education. Instead of walking in a straight line on a treadmill surrounded by the sights and sounds of a therapy suite or biomechanics lab, she has the experience of walking along a gravel path.

The path feels rocky and uneven beneath her feet, twisting, turning and meandering uphill and down. The patient is surrounded on all sides by trees, a blue sky and chirping birds, with the gravel making a crunching sound underfoot. Her senses are immersed in navigating this challenging walk.

Despite all the sights and sounds, the patient's experience is a virtual one, taking place in a controlled, safe environment on Cleveland Clinic's main campus. This scenario is repeated regularly since the installation of the CAREN (Computer Assisted Rehabilitation Environment) system in mid-2013.

The system, manufactured by Amsterdam-based Motek Medical, is a high-tech medical and research platform that allows clinicians to view and analyze patients' balance, locomotion and coordination. It serves as a valuable tool for rehabilitation, clinical analysis and research.

A second new rehabilitation treadmill system at Cleveland Clinic, called C-Mill (Forcelink, The Netherlands), projects realistic curbs, steps or other obstacles on the moving belt and is used for gait training and fall-avoidance practice.

"The combination of the CAREN system and C-Mill gives us a remarkable amount of flexibility in re-creating environments and making therapy relevant to our patients," said Frederick S. Frost, MD, Chairman of Cleveland Clinic's Department of Physical Medicine and Rehabilitation and Executive Director of Cleveland Clinic Rehabilitation and Sports Therapy. "The two treadmill systems are stable and user-friendly enough to be integrated into a busy clinical rehabilitation setting."

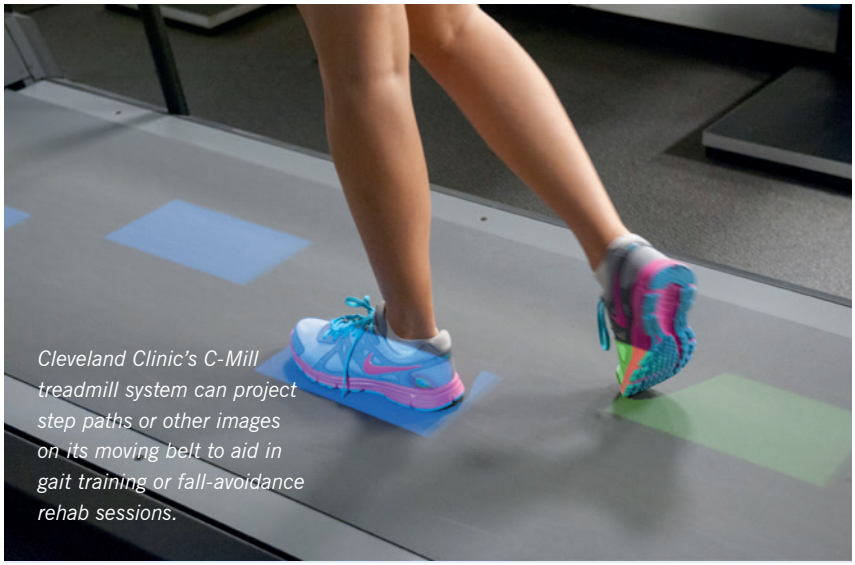
KEY POINTS

Cleveland Clinic has begun using two new virtual reality-capable treadmill systems for rehabilitation, clinical analysis and research.

The Computer Assisted Rehabilitation Environment (CAREN) and C-Mill treadmill systems are being used to assess, train and study rehabilitation patients' mobility in realistic but protected settings.

"We want physical therapy to challenge patients, but it's always a question of how to do so in a safe environment," says Jay Alberts, PhD, who is leading Cleveland Clinic's CAREN system initiative. "The CAREN system puts us on the leading edge by enabling us to safely challenge patients through different courses in an immersive, realistic virtual environment."

Cleveland Clinic's acquisition of the CAREN system, funded by a grant from the state of Ohio, marks the first nonmilitary installation of the platform in North or South America.



Cleveland Clinic's C-Mill treadmill system can project step paths or other images on its moving belt to aid in gait training or fall-avoidance rehab sessions.

How CAREN Works

The foundation of the CAREN platform is a "6 degrees of freedom" motion base that turns and moves up and down or left and right. The base is topped with force plates or an instrumented treadmill, and the system has real-time motion capture capabilities that integrate visual projection and surround sound. Not only can patients experience walking on a path, they can navigate a boat deck, stroll through an airport or simulate just about any scenario from real life — all under close monitoring and while harnessed for safety.

"Challenges can be customized, with levels of difficulty automatically based on patient performance," explains Dr. Alberts, who is Cleveland Clinic Neurological Institute's Vice Chair for Health Technology Enablement, Director of the Concussion Center and a researcher in the Department of Biomedical Engineering. "The system registers and reacts more quickly than human perception does, making micro-adjustments and even going into a soft shutdown as needed."

The system allows for the registration, evaluation, clinical analysis and rehabilitation of balance, including the body's visual, auditory, vestibular, tactile and proprioceptive systems. Its software merges data from all hardware components, enabling measurable and quantifiable evaluation, rehabilitation and research, leading to constantly monitored progression.

"Beyond the virtual immersion features, the system is a complete biomechanics laboratory — in a quarter of the size of a traditional lab," Dr. Alberts says. "It measures EMG muscle activation patterns in real time, helping identify where a patient may have a deficiency and what can be done to improve it."

Collaborative by Design, Engaging for Patients

With the CAREN system, rehabilitation specialists, neurologists, orthopaedists, occupational therapists and physical therapists can collaborate with one another — and with researchers in biomechanical engineering, pediatrics, mental health and other disciplines — to evaluate patients' functional behavior and help restore or improve that function. A computer scientist rounds out the interdisciplinary mix, writing code to customize virtual scenes and experiences beyond those provided with the system.

"Protocols and programs currently being developed using CAREN are leading the creation of groundbreaking rehabilitation techniques," Dr. Alberts notes.

Since patients began using the CAREN system in September 2013, their reaction has been enthusiastic. "Patients like the system's gamelike and interactive features," says Dr. Alberts. "From our standpoint, it offers the best of both worlds — it's engaging for patients while measuring outcomes in a highly systematic, objective way."

So far, the system has been used primarily for patients with Parkinson disease and multiple sclerosis, but it has many more potential clinical applications, including the diagnosis and treatment of various neuromuscular and other neurological conditions. Plans are underway to use the system in the Concussion Center, including for facilitation of return-to-play decisions for concussed athletes.

The system is also at the heart of translational research efforts. "Using the CAREN system for research will help us clinically, and clinical utilization certainly complements our research efforts," Dr. Alberts says.

The system also will facilitate development of mobile applications by validating measurements taken using mobile devices. "We can use information learned from the system and transfer a pared-down version to a mobile app," Dr. Alberts explains. "We're working on customized multiple sclerosis and Parkinson disease apps, and data from the CAREN system should allow us to develop them much more quickly." ■

Testing Brain Stimulation's Potential to Direct Neuroplasticity and Improve Rehabilitation Outcomes in Spinal Cord Injury Patients

By Ela Plow, PhD, PT; Kelsey Potter-Baker, PhD; and Patrick Chabra, BS

Ela Plow, PhD, PT

Kelsey Potter-Baker, PhD

Injury to the spinal cord (SCI) remains one of the most common and debilitating causes of long-term disability among young adults, particularly war veterans. With approximately 11,000 new cases every year, the prevalence of SCI has exceeded 253,000 cases in just the United States.

Unfortunately, the costs related to SCI management are rising along with the injury's prevalence. Estimated annual medical care and living expenses, without accounting for indirect costs such as lost wages and productivity, ranged from $67,415 to $181,328 per patient in 2013. This situation is further compounded by evidence that SCI primarily affects younger adults, ultimately resulting in a serious economic, social and personal burden.

The goal of our Department of Defense-funded clinical trial is to maximize the recovery potential in adults with SCI using a cost-effective and minimally invasive strategy. Within our trial, we focus on patients with quadriplegia from an injury to the cervical spinal cord, paralyzing not only the lower extremities and trunk but the upper limbs. We have chosen to emphasize recovery in quadriplegia because it imposes significantly greater healthcare costs compared with paraplegia. Further, it has been reported that 75 percent of quadriplegic patients would prefer to have their upper limb function restored more than any other deficit.

KEY POINTS

- As a result of neuroplasticity following incomplete spinal cord injury, the cortex loses memory of paralyzed muscles and limbs while magnifying representations of spared segments.
- Transcranial direct current stimulation (tDCS) is capable of modifying cortical excitability of representations of weaker muscles.
- We are evaluating whether tDCS simultaneous with rehabilitation exercises of the paralyzed extremities in patients with incomplete SCI may promote neuronal excitability and restore cortical representations of paralyzed muscle regions.

An optimistic view of SCI is that the majority of injuries are incomplete. Specifically, in more than 65 percent of patients, injury results in varying degrees of upper extremity deficit. This suggests that many patients with SCI have an ability to transmit information from the brain to affected muscles through spared, albeit fragmented, neural networks. In addition, when one considers that an injury damaging the spinal cord often spares the brain, the advantage of an incomplete injury becomes even more powerful. Our viewpoint becomes clearer below.

The Two-edged Sword of Brain Plasticity

The brain, especially its regions such as the motor cortex devoted to upper limb movement, has an extraordinary capacity for fast-paced plasticity. In the context of SCI, brain plasticity can be both beneficial and detrimental.

As SCI patients increasingly use their spared muscles at the cost of paralyzed ones, motor cortical memory of paralyzed muscles decreases. The cortex begins to lose the memory of paralyzed muscles and limbs caudal to the lesion, while magnifying representations of the more spared segments, thus often overtaking territories previously occupied by the now paralyzed muscles.

This maladaptive biological response can hinder rehabilitative efforts. Mainly, since rehabilitation often emphasizes greater use of the more affected muscles, a possible loss of paralyzed muscle cortical representations in the brain can make successful rehabilitation an arduous process.

Employing the Brain in Rehabilitating the Spinal Cord

In our clinical trial, we aim to harness the brain's fast-paced capacity to exhibit plasticity. Specifically, we intend to take advantage of the fact that the brain can still transmit information, albeit partially, via fragmented but spared pathways to affected muscles.

To do this, we first identify the brain's existing representations of muscles so that we can understand how territories previously occupied by now paralyzed muscles have been compromised. A neurophysiologic technique called transcranial magnetic stimulation (TMS) is a powerful tool to generate such assessments (see Figure 2A, where representations are being mapped with TMS). With these maps, we can determine the spread of representations of muscles in the brain, while with white matter imaging we can view the pathways they project to the spinal cord (Figure 2B).

Once these representations are mapped with TMS and imaging, we apply facilitatory transcranial direct current stimulation (tDCS) to these regions devoted to the weaker muscles while patients take part in extensive rehabilitation exercises. In doing so, we aim to promote neuronal excitability and restore cortical representations of the paralyzed muscle regions. tDCS uses electrodes placed on the scalp to deliver low levels of direct current that modify cortical excitability. Patients in the experimental group of our study receive one hour of tDCS per day for 10 days in conjunction with rehabilitation sessions.

The process of delivering stimulation during rehabilitation augments the efficacy of rehabilitation. While the brain may not be the source of deficit in SCI, we propose that cortical hindrance to rehabilitation, when removed by stimulation of the paralyzed muscle cortical regions, can result in underrepresented muscles serving as a powerful catalyst for recovery.

To gain maximum adjunctive advantage, in our study we stimulate the cortical regions of the paralyzed muscle during rehabilitation, which ensures that plasticity of weak cortical networks is augmented and that the cost-effectiveness of delivering treatments is improved.

To assess the effectiveness of tDCS in directing neuroplasticity to improve rehabilitative outcomes, we measure study participants' upper limb function at several time points and compare to baseline to determine if any changes have occurred. We also perform repeat mapping with TMS to understand whether representations of paralyzed muscles are re-established in the brain's cortical regions.

Patient Safety and Recruitment Considerations

Patient safety is an important consideration when applying brain stimulation. The noninvasive nature of tDCS, which employs extracephalic electrodes, provides a margin of safety. Currents delivered to the scalp are low, ranging from 1 to 2 mA, and since they are delivered via large electrodes (25 to 35 cm^2) in saline-soaked sponges, they are not perceived as uncomfortable. Some patients with SCI, however, present with contraindications to brain stimulation procedures. Contraindications may include history of seizures and/or use of medications/drugs that may affect a patient's threshold for seizures.

Recruiting medically stable patients who are able to travel to Cleveland Clinic to receive intensive rehabilitation and brain stimulation can be challenging. Our recruitment

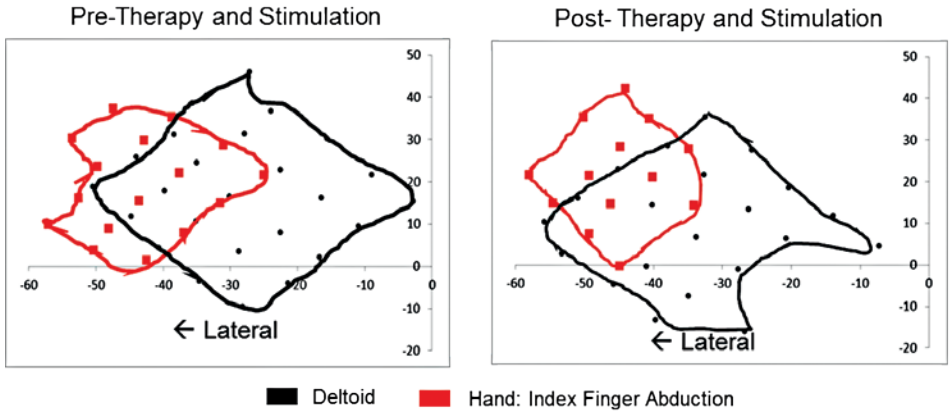
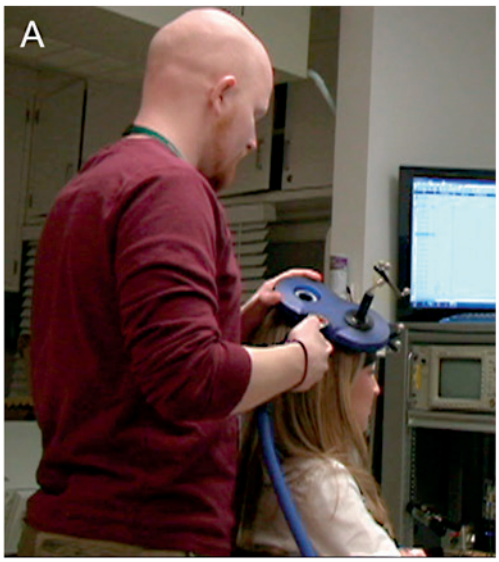


Figure 1. *Enhanced brain plasticity following stimulation results in the augmentation of spared (red) muscle cortical regions.*



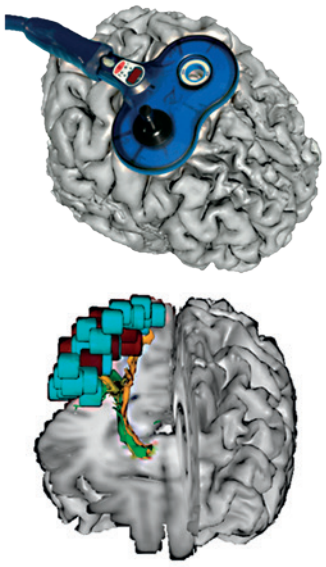


Figure 2. *(A) Stereotactically guided transcranial magnetic stimulation is used to identify muscle cortical regions. (B) White matter imaging shows the muscle cortical regions' projections to the spinal cord.*

efforts are strongly supplemented by Cleveland Clinic's Knowledge Program, a health information data collection system that includes information obtained from patients via electronic questionnaires as well as clinical data extracted from Cleveland Clinic's electronic medical record.

The Knowledge Program logs each neurological outpatient visit, providing valuable long-term and follow-up information and aiding study recruitment. We also have been able to develop pools of candidates using other electronic databases, patient support groups, national foundations and organizations such as Paralyzed Veterans of America, and the United Spinal Association.

In sum, with the use of low-cost modalities such as noninvasive brain stimulation and resource-effective strategies such as rehabilitation, we aim to mitigate the economic burden of SCI. Since we target one of the most viable and plastic substrates in patient recovery — motor cortices of the brain — we believe we will be able to harness the potential of incomplete injuries to the spinal cord to maximize improvements to patients' quality of life. ■

Dr. Plow is an assistant staff member in Cleveland Clinic Lerner Research Institute's Department of Biomedical Engineering. Dr. Potter-Baker, a postdoctoral fellow at Lerner Research Institute, and Mr. Chabra, a medical student, are working on the tDCS clinical trial. Dr. Plow can be reached at plowe2@ccf.org or 216.445.6728.

Musculoskeletal Medicine Fellowship Provides Unique Training Opportunities

After a successful first year, Cleveland Clinic's Musculoskeletal Medicine Fellowship is preparing to train more physicians to meet the increasing demand for musculoskeletal care, particularly in PM&R.

The fellowship, based in the Orthopaedic & Rheumatologic Institute's multidisciplinary Arthritis and Musculoskeletal Center at Cleveland Clinic's main campus, graduated its first fellow this summer and attracted a growing pool of applicants for its second year, says Program Director Michael Schaefer, MD.

The program focuses on the treatment of joint and muscle pain and musculoskeletal injuries and less on spine and sports medicine than do some other fellowships. Candidates are primarily sought from PM&R training programs, but Dr. Schaefer says physicians who trained in primary care programs and rheumatology are encouraged to apply, as well as those from emergency medicine, anesthesiology, occupational medicine, women's health and other board-recognized specialties.

Nonsurgical Injury Care Spurs Need for Training

"Musculoskeletal conditions such as osteoarthritis, sprains, strains, bursitis and tendinopathy are among the most common indications for visits to primary care offices today. The need for nonsurgical care of these conditions is expected to grow with an aging and obese population," says Dr. Schaefer, who also is Director of Musculoskeletal Rehabilitation, with a joint appointment in the Neurological Institute's Department of PM&R and the Orthopaedic & Rheumatologic Institute.

He says other specialties do not have enough personnel to meet those needs. Rheumatology is short-staffed nationwide, and orthopaedic surgeons don't necessarily want to do nonoperative care.

"Typical physiatry training includes musculoskeletal care, but often focuses on spine and pain medicine treatments," Dr. Schaefer says. "Rheumatology training often focuses on medical management of inflammatory and immunological conditions, but may lack exposure to acute musculoskeletal injuries, spine and neurological ailments."

Also, he says, many primary care providers do not have adequate training in musculoskeletal medicine and feel uncomfortable managing such conditions, especially the less common ones.

Breadth of Fellowship Is Attractive

Dr. Schaefer says the program is unique in its focus on musculoskeletal medicine.

"Quite a few fellowships emphasize spine or a combination of spine and sports through PM&R, but very few have the breadth this one does," he says.

The 2013-2014 fellow, Srikrishnac Chandran, MD, says he appreciates that variety.

"Cleveland Clinic's Musculoskeletal Medicine Fellowship has been a unique opportunity to learn from the leaders of medicine in a variety of disciplines treating the entirety of musculoskeletal disorders," he says. "Its comprehensive and innovative curriculum has allowed me to learn to diagnose and treat a varied patient population in extraordinarily diverse clinical settings."

Fellows complete subspecialty rotations in adult reconstruction (total joint replacement surgery), rheumatology, foot and ankle, hand and upper extremities, spine, and sports medicine. Experience in sports medicine is included to provide exposure to acute injury management. Exposure to electrodiagnosis and interventional spine care is available, and additional electives are encouraged. Participation in research activities is also encouraged.

The fellow also gains extensive experience in musculoskeletal ultrasound, with approximately one day per week of dedicated ultrasound exposure.

"We provide the most training in musculoskeletal ultrasound of any fellowship that I know of," Dr. Schaefer says.

Rotations also include observation time in the operating room and in physical therapy sessions.

Dr. Schaefer says the program prepares fellows for a career in an academic or large group practice as a nonsurgical musculoskeletal specialist. Dr. Chandran is moving on to a pain fellowship at a nearby hospital. The arriving 2014-2015 fellow, Enrique Galang, MD, just completed his internship and residency in PM&R at East Carolina University. ■

Physicians interested in applying for the Musculoskeletal Medicine Fellowship may contact the program coordinator, Colleen Vahcic, at vahcicc@ccf.org or Dr. Schaefer at schaefm5@ccf.org.

KEY POINTS

- Cleveland Clinic's Musculoskeletal Medicine Fellowship prepares fellows for a career in an academic or large group practice as a nonsurgical musculoskeletal specialist.
- The fellowship focuses on the treatment of joint and muscle pain and musculoskeletal injuries.
- Fellows complete subspecialty rotations in adult joint reconstruction, rheumatology, foot and ankle, hand and upper extremities, spine and sports medicine.
- Fellows also gain extensive experience in musculoskeletal ultrasound.

Musculoskeletal Ultrasound Workshop Grows, Adds Cadaver Lab

The first Cleveland Clinic Musculoskeletal Ultrasound Workshop, a half-day event, was such a success in 2013 that it was expanded to two days in 2014.

"Musculoskeletal ultrasound is a rapidly growing technology," says course co-director Michael P. Schaefer, MD. "In the past four or five years, it has become very popular."

Held in June, this conference explores diagnostic scanning and leading-edge techniques in ultrasound-guided procedures that can depict body structures in motion. One notable addition to this year's course was a cadaver lab.

"This lab brings true anatomical correlation with patient experiences and the ability to guide and practice injections on lifelike anatomy," Dr. Schaefer says.

He says many hospitals are adding musculoskeletal ultrasound capabilities because they enable bedside soft-tissue imaging without radiation. "It is relatively inexpensive compared with MRI or CT scan," Dr. Schaefer says.

The CME-certified course is designed for physicians in rheumatology, PM&R, radiology, primary care, orthopaedic surgery, pain management and sports medicine, as well as podiatrists, physician assistants, nurses and other allied health professionals.

Cadavers, Live Models Aid Training

Among the specific skills taught are optimizing ultrasound machine settings for diagnostic and interventional techniques, basic ultrasound scanning methods for each major musculoskeletal region, use of ultrasound to identify injection targets and guide needle placement in cadavers, and recognizing pathology using live models with known abnormalities.

The course's diverse faculty includes specialists in PM&R, rheumatology, neurology and sports medicine. Dr. Schaefer's 2014 co-director was Patricia Delzell, MD, Director of Musculoskeletal Ultrasound, Musculoskeletal Section, at Cleveland Clinic's Imaging Institute.

The guest speaker was Jonathan Finnoff, DO, team physician for the U.S. Ski Team and Clinical Professor, Department of PM&R, at the UC Davis School of Medicine. Dr. Finnoff is known for his work as director of training in musculoskeletal ultrasound for the American Academy of Physical Medicine and Rehabilitation. ■

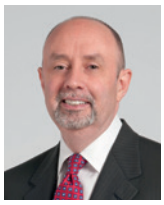
For information about the next Musculoskeletal Ultrasound Workshop, email cmeregistration@ccf.org.

Validation Studies Assess 6 Clicks Tool

By Vinoth K. Ranganathan, MSE, MBA; Mary Stilphen, PT, DPT; and Frederick S. Frost, MD

Vinoth K. Ranganathan, MSE, MBA

Mary Stilphen, PT, DPT



Frederick S. Frost, MD

Since 2011, rehabilitation professionals across Cleveland Clinic's health system have systematically employed 6 Clicks, a pair of electronically administered questionnaires designed to measure the functional status of patients in the acute care hospital. Hospital systems across the United States have embraced the device as a means of rationalizing therapy delivery and improving patient-centered discharge planning.

6 Clicks, conceived and designed at Cleveland Clinic in collaboration with Boston University's Rehabilitation Outcomes Center, is named for the six questions in two outcomes measurement tools that standardize the assessment of hospitalized patients' mobility and self-care abilities. To date, Cleveland Clinic staff have logged more than a half million outcomes measurements.

This screening instrument helps determine appropriate patient referrals for physical and/or occupational therapy, aids in discharge planning and improves allocation of treatment resources and personnel. This contributes to a reduction in hospital therapy costs while maintaining quality.

6 Clicks' queries are derived from the Activity Measure for Post Acute Care (AM-PAC™), a comprehensive set of patient outcome measures developed by Boston University researchers.

6 Clicks' questions address a patient's ability to turn in bed, sit, transfer from bed to chair, stand, walk, eat, dress, bathe, perform personal care and use the bathroom. The questions can be answered by a patient or a surrogate and are scored from 1 to 4 by physical or occupational therapists using direct observation of the activity in question or the therapist's clinical judgment about the patient's probable ability. The scores are entered into the patient's electronic medical record and kept as discrete data fields.

Tool Nurtures 'Culture of Mobility'

Our experience to date with 6 Clicks in more than 577,198 patients has produced a number of insights. The tool has:

- Increased productivity without sacrificing clinical care. We have reduced unnecessary physical therapy visits and as a result have been able to reposition resources, including an increased physical therapy presence in the intensive care unit, enabling earlier intervention.
- Streamlined the patient discharge process through early identification of discharge disposition to long-term acute care, skilled nursing facility, inpatient rehabilitation facility or home.
- Helped educate physicians and nurses about which patients are appropriate referrals for physical and/or occupational therapy.
- Nurtured a "culture of mobility" among the nursing staff by providing guidance on which patients can ambulate without a physical therapist present. Patients with a 6 Clicks score of 18 or above need only minimal help with activities, and the nursing team is tasked with mobilizing them before consulting physical therapy.

KEY POINTS

The 6 Clicks tool is a short set of questions that assesses mobility and basic functional capabilities.

Cleveland Clinic's experience with 6 Clicks in more than 577,198 patients has demonstrated its value in aiding rehabilitation referrals and discharge planning, and in improving resource allocations.

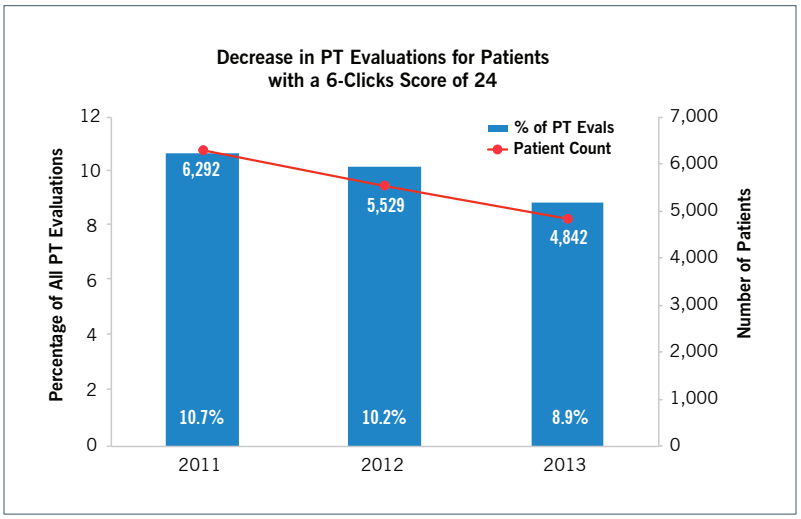
Three recent studies have confirmed 6 Clicks' accuracy and reliability.

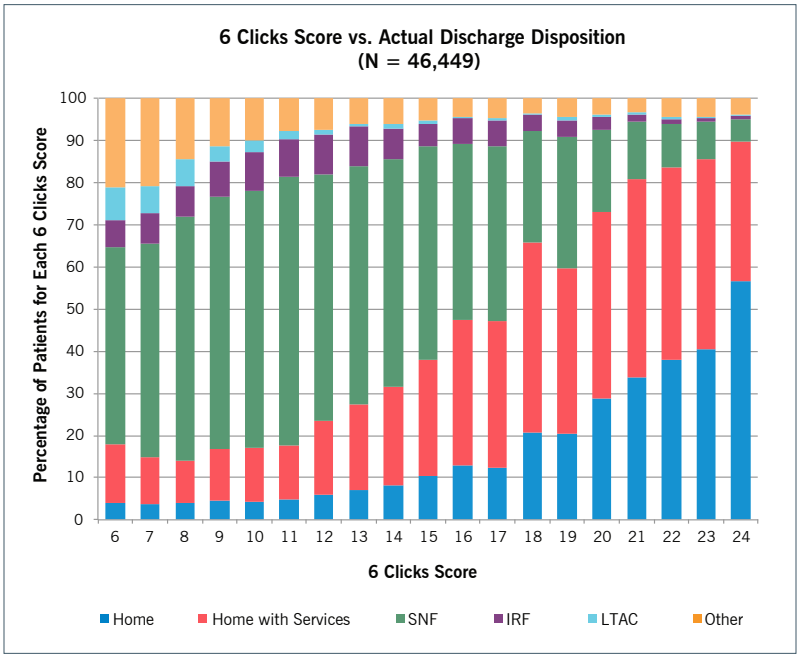
Validation Studies Confirm Value

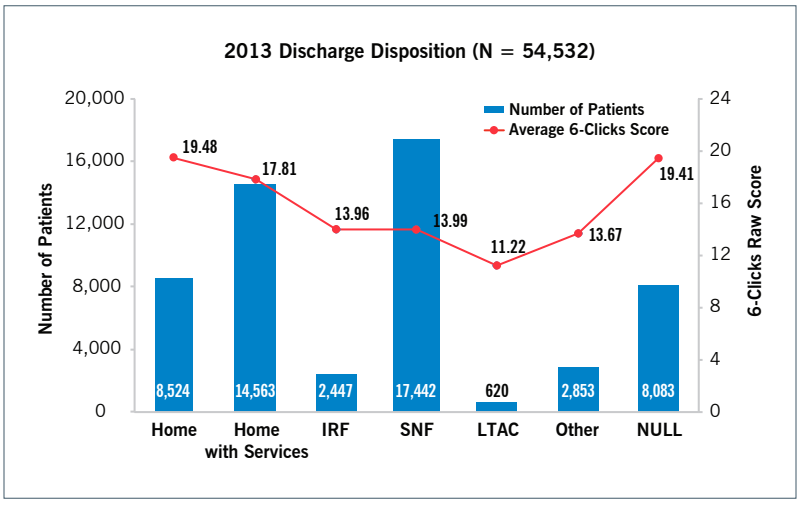
Two studies published in 2014[1,2] have validated 6 Clicks' accuracy in predicting patients' need for therapy in the acute care setting and in predicting the appropriate discharge setting. A third study[3] verified the interrater reliability of 6 Clicks' measures. The research was a collaboration involving Cleveland Clinic, Boston University and the University of Vermont.

We confirmed the validity of 6 Clicks' basic mobility and daily activities scores in assessing the activity limitations of patients with a wide variety of medical and surgical

PT = physical therapy;
SNF = skilled nursing facility;
IRF = inpatient rehabilitation facility;
LTAC = long term acute care







conditions in an acute care setting. We also found that 6 Clicks scores derived from the initial physical therapy and occupational therapy visits showed fair accuracy in determining patients' discharge destination. Finally, using pairs of physical and occupational therapists rating the same patients and blinded to each others' 6 Clicks scores, we found that overall intraclass correlation coefficients were very high, with levels of agreement that varied across the pairs of raters, from large to nearly perfect for physical therapists and from moderate to nearly perfect for occupational therapists.

Taken together, the findings further verify 6 Clicks' ability to provide valuable guidance in rehabilitation patient care and resource allocation decisions.

In the future, we hope to validate the use of 6 Clicks by nursing personnel and other members of the medical team. ■

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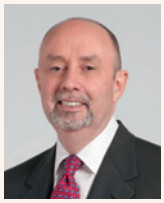
Conversion Disorder Patients on the Rehab Unit: Ethical Issues

By Frederick S. Frost, MD; and Patrick Schmitt, DO



Frederick S. Frost, MD

Patrick Schmitt, DO

A man in his early 40s arrived in the emergency department with acute onset hemiplegia. After receiving tissue plasminogen activator and a complete workup for a suspected stroke, the man was admitted to the hospital for treatment, including rehabilitation services. Subsequent diagnostic tests showed no evidence of stroke or any other neuroanatomic condition. Ultimately, notes in the medical record point to a diagnosis of exclusion: conversion disorder — a functional neurological symptom disorder typically triggered by psychological conflict. His clinical presentation is characterized by hemiplegia.

Our belief is that this patient will benefit from rehabilitation services in the rehabilitation hospital. Ethical issues arise immediately.

- What is his admitting diagnosis? What do we tell the insurance company?
- What do we tell the patient about the etiology of his disability?
- What do we tell the rehabilitation staff about the best approach to his medical care?

The Spectrum of Somatoform Disorders

Conversion disorder patients are increasingly common in the rehab setting. Ten years ago, we saw two of these patients a year. Now we see at least one a month. These are usually people of limited financial means and modest coping capacity. A combination of factors may contribute to the rising number of patients, including difficult socioeconomic conditions, a shrinking middle class job market and growing entitlement systems.

In the French medical system, the link between "mental malaise," social disparities and musculoskeletal disability is well-documented. It is important to recognize that each of these patients falls along a spectrum of factitious disorders that ranges from persons with profound psychiatric illness to malingering. Furthermore, it is extremely common, as our colleagues in the epilepsy field can attest, to encounter a patient who has "real" neurological pathology but with enormous magnification of the physical disability.

When a patient has a difficult and time-consuming problem, physicians often search desperately for a way to shunt the patient off to a specialist. The knee-jerk reaction when confronted with a conversion disorder patient is usually a psychiatry consult. Psychological conditions are common in patients with conversion disorder, but not always present. In addition, linking symptoms to discrete psychological factors reflects a view of the condition that is overly simplistic. The American Psychiatric Association characterizes conversion disorder as a biopsychosocial problem, with psychiatric care as one of many treatment modalities.

PM&R physicians, uniquely trained to address biopsychosocial conditions, are often most adept at handling these complex cases.

KEY POINTS

PM&R caregivers are increasingly encountering conversion disorder patients in the rehab setting.

Their presence raises ethical questions about disclosure to the patient, insurer and rehab staff, and about the best course of treatment.

We believe that many conversion disorder patients will benefit from treatment in an inpatient rehabilitation setting.

Disorder Raises Tough Questions

Do we tell the insurance company that the patient has a biopsychosocial condition? What insurance company pays for inpatient hospital biopsychosocial rehabilitation treatments? Do we tell the patient that we suspect the real problem relates to his or her history of child abuse? Our psychiatric colleagues tell us this is absolutely the worst approach to a person with such a history. It might take years of expert psychotherapy to safely approach such

a psychological conflict. Do we tell the rehab team a different story than we tell the patient?

There is another name for filtering and selectively dispensing information: lying. We discussed this ethical dilemma in a recent publication.[1]

Patients Can Be Helped by Rehab Care

Well-selected conversion disorder patients will benefit from a stay on the rehab unit. Although the long-term outcomes have not been studied, admitting such patients to the rehab unit removes them from the environmental vectors that promote their condition. It allows them to focus on changing the functional elements affecting their interactions with their environment. A caring, supportive, therapeutic milieu on the rehab unit is often a stark contrast to patients' home environment. Admitting patients to acute rehabilitation follows the same logic as admitting those with alcoholism to a residential treatment program.

In considering a different patient, perhaps an 80-year-old woman who has fractured her hip, no one would argue against engaging inpatient rehabilitation to help her deal with critical issues such as anxiety and loss of confidence that accompany her disability. Why is it any different for a person with conversion disorder? We make it clear to patients, families and caregivers that we address deficits in function, regardless of their etiology. That is not a lie. Mature and professional rehab team members will not be punitive to the patient; they are the best people to understand and treat any biopsychosocial condition.

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Patrick Schmitt, DO, of the Department of Physical Medicine and Rehabilitation, was recently appointed to serve on Cleveland Clinic's Ethics Committee. The committee is a multidisciplinary group of physicians, nurses and other healthcare professionals and a community representative. They work to improve the understanding of ethical issues throughout Cleveland Clinic's main campus and to promote the ethical care of patients and families. The committee reviews ethics-related policies and procedures and provides consultation to help resolve complex ethical issues. Dr. Schmitt received his medical degree from Des Moines University College of Osteopathic Medicine. He completed an internship at Millcreek Community Hospital in Erie, Pennsylvania, a PM&R residency at Temple University Hospital in Philadelphia, and a biomechanics research fellowship at Pennsylvania State University. He joined Cleveland Clinic in 2010.

Stroke Care Path Facilitates Successful Rehabilitation

By Zeshaun Khawaja, MD

Zeshaun Khawaja, MD

In 2010, Cleveland Clinic's Neurological Institute debuted its care path for acute ischemic stroke. This guide provides comprehensive protocols for evaluation and management of patients during the acute stroke phase to help optimize patient outcomes. It streamlines care, helps reduce hospital length of stay and ensures that every patient receives the same standard of care. Since its implementation, we have seen the Stroke Care Path benefit patients not only during the acute phases of care, but throughout their rehabilitation.

In the past few years, Cleveland Clinic has developed more than 25 care paths for other diseases and conditions, including congestive heart failure, knee and hip replacement, spine care, and dementia. All the guides are based on medical research, clinical guidelines, clinician experience and evidence collected via our Knowledge Program — a health information data collection system that gives physicians a comprehensive view of a patient's medical status and enables researchers to broadly and quantitatively assess the effectiveness of medical decisions and processes. The Knowledge Program includes information obtained from patients by electronic questionnaires as well as clinical data extracted from Cleveland Clinic's electronic medical record.

As we treat more patients and as medical technology advances, information in the Knowledge Program constantly evolves. So, too, must our care paths. We have just completed a revision of our Stroke Care Path to ensure that it reflects the latest evidence-based care, in addition to standards of care provided by The Joint Commission and the American Heart Association/American Stroke Association in their certification program for Primary Stroke Centers and Comprehensive Stroke Centers.

Priming Patients for Rehabilitation

Our Stroke Care Path focuses on the period from initial presentation at the emergency department or hospital with acute stroke symptoms to 90 days after hospital discharge. The care provided during that time is paramount to successful rehabilitation. It is critically important that, as soon as patients enter the hospital, we are not only thinking about their diagnosis and treatment, but their rehabilitation. Evidence indicates that the sooner patients begin rehabilitation, the better their outcome.

By utilizing the treatment guidelines in our Stroke Care Path, physicians prepare patients for rehabilitation. The following are some of the steps we take:

- Patients admitted with a stroke diagnosis are evaluated by a physical therapist and an occupational therapist as soon as they are medically able. This often occurs the day after admission. Patients with National Institutes of Health stroke scale scores between 4 and 20 receive a full PM&R physician evaluation.
- Nurses administer a dysphagia screen to all patients immediately upon admission unless they first require advanced procedures such as hyperacute MRI. If patients fail the swallow screening, they automatically are evaluated by a speech-language pathologist.
- We encourage early mobility. In the past, stroke patients often remained in bed. Now we urge them to ambulate and spend more time in a chair. We have incorporated lift devices and lift teams to help patients with limited mobility move to chairs. Early mobility has several advantages: It helps prevent urinary retention, constipation, pressure ulcers, pneumonia and deep vein thrombosis. It also is an important component of physical and occupational therapy.
- Patients undergo a comprehensive evaluation by a case manager within 24 hours of admission. The case manager examines all aspects of the patient's plan of care, including finances, insurance and family/social situations. They look for anything that might prevent or limit patients' early rehabilitation. Case managers also provide a list of rehab facilities that meet each patient's needs and work closely with families to help select the ideal one.
- Each patient receives a mood screening prior to discharge and during follow-up outpatient visits. If patients suffer from poststroke depression, they are less likely to participate in their own care, thereby hindering rehabilitation efforts. Cleveland Clinic uses the Patient Health Questionnaire for Depression and Anxiety (PHQ-4) to

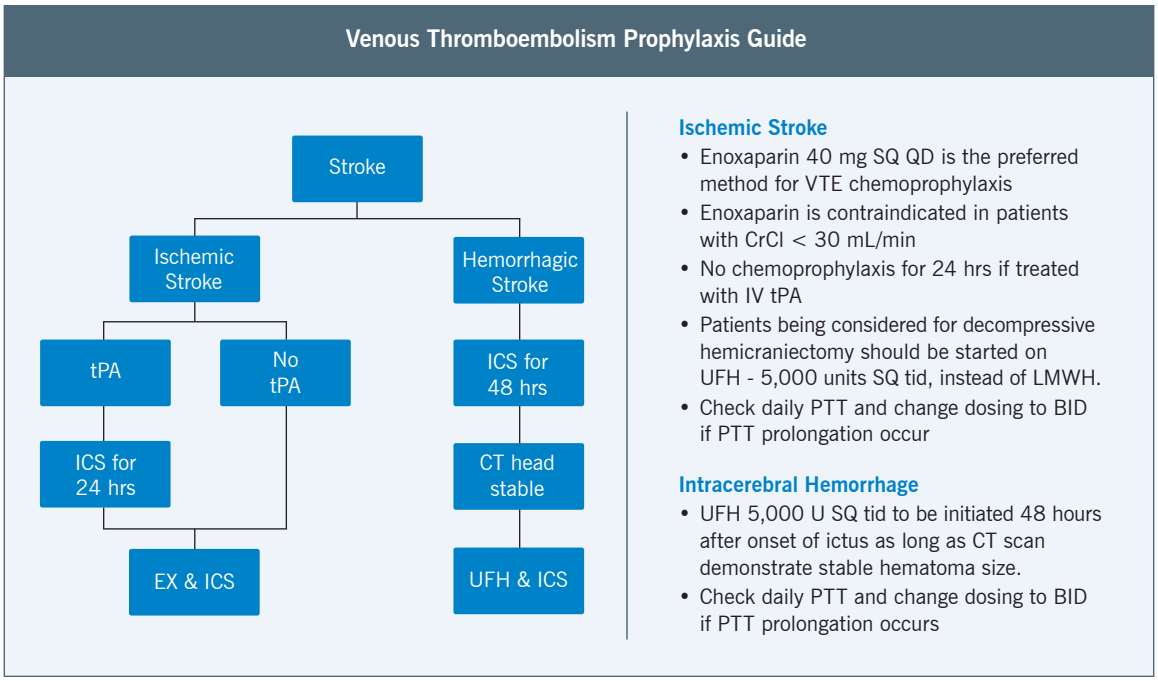

Figure 1. Cleveland Clinic's Neurological Institute has developed a care path for acute ischemic stroke that standardizes inpatient treatment (including for venous thromboembolism, as shown here) and rehabilitation to improve patient outcomes.

ICS = Intermittent Compression Stockings

EX = Enoxaparin 40mg subcutaneous daily

UFH = Unfractionated Heparin 5000 units TID

tPA = Tissue plasminogen activator

assess mood. If patients score high, a social worker or therapist intervenes and treatment is initiated.

- Prior to discharge, all medications are reviewed and coordinated to reduce the risk of recurrent stroke. In addition, the discharge summary includes advice on managing personal stroke risk factors (such as blood pressure, weight and cholesterol) and a description of stroke warning signs and symptoms.

Examining Early Urinary Catheter Removal

One recommendation in the Stroke Care Path that facilitates rehabilitation and prevents infection is removal of urinary catheters as soon as possible. However, it is important to note that the guide also cautions physicians against early removal in certain situations. They may delay removal if:

- Patients are intermittently drowsy and unable to communicate their need to urinate
- Patients are taking opiates, anticholinergic medications or other medications that cause obtundation or urinary retention
- Patients are diabetic and have a history of outlet obstruction or urinary retention that predict a failed early catheter removal
- Patients are unable to speak

In short, catheter removal requires that patients are adequately alert and physically able to say when they need to use the bathroom.

Guiding Informed Decisions

The Stroke Care Path is an invaluable tool for our physicians to provide evidence-based poststroke care and prepare patients for successful rehabilitation. It is used not only within Cleveland Clinic hospitals, but in ambulatory therapy centers and subacute and rehabilitation facilities. This allows us to implement best practices and a high standard of care through the entire course of our patients' medical and rehabilitative treatment. ■

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KEY POINTS

Cleveland Clinic's care path guide for acute ischemic stroke provides comprehensive protocols for evaluation and management of patients during the acute stroke phase to help optimize outcomes.

The Stroke Care Path focuses on the period from the patient's initial hospital presentation to 90 days after discharge, a time span that is critical to successful rehabilitation.

By utilizing the treatment guidelines in our Stroke Care Path, physicians prepare patients for rehabilitation.

Constraint Induced Movement Therapy versus Bimanual Therapy for Children with Hemiparesis

By Douglas Henry, MD

Douglas Henry, MD

Constraint induced movement therapy (CIMT) has been used for the past decade to improve the active movement and functional abilities in an upper extremity (UE) that is weak secondary to stroke or cerebral palsy.

Many centers now offer intensive therapy sessions lasting two to six weeks with three hours of therapy per day, several days per week, for children with hemiparesis. The unaffected extremity is constrained, often with a cast, while the weaker limb is subjected to intensive forced use and sensory interventions, with an attempt to activate and strengthen specific muscle groups and improve coordination, motor planning and functional abilities.

Multiple studies demonstrate that this technique improves motor outcomes in children with hemiparetic cerebral palsy, with lasting benefit.

More recently there has been interest in bimanual therapy for hemiparesis, where there is no limb restraint and which focuses more on functional tasks requiring the use of both hands. The thinking is that this may result in more practical or functional gains when compared with CIMT. One randomized trial has shown improvements in the bimanual therapy group compared with a control group.

Comparison Studies Show Advantages for Each Approach

So an obvious question is whether one method is better than the other. A few studies have sought to compare CIMT to bimanual therapy. One multicenter study enrolled 39 patients in CIMT, 33 in bimanual therapy and 33 in standard occupational therapy.[1] Not surprisingly, the CIMT group improved more in grasp, whereas the bimanual group increased in bimanual spontaneous use of play and in activities of daily living.

In another comparison study, both constraint and bimanual groups showed improvements that persisted at six months. However, the bimanual group demonstrated more progress toward goals on the Goal Attainment Scale than did the CIMT group.[2]

At Cleveland Clinic Children's Hospital for Rehabilitation, we see benefits in both strategies and incorporate them into our management of children with hemiparesis.

Certainly, children should begin some intervention as soon as their hemiparesis is detected. However, we do not think an intensive CIMT program is appropriate until a child is at least 18 months and preferably 24 months of age, depending on his or her developmental level.

Age-related Therapy Modifications Aid Progress

Before that age, we begin a modified constraint program that incorporates a moderate amount of bimanual activity, thus promoting developmental progress. When we believe a child is ready for an intensive program, we bring him or her into the CIMT program and focus strictly on that philosophy.

In the CIMT program, children receive occupational therapy for three consecutive hours, five days a week, for three weeks. This includes pool therapy three times a week. They wear a cast on the unaffected arm until the last two days of the program.

At the end of this program, we see improvements in isolated movements, strength and coordination in the affected upper extremity. Then we return the child to standard outpatient therapy and a daily home activity program, where the focus is on both independent use of the affected limb and bimanual activities. For example, they are taught to open doors and turn on light switches only with their affected limb. They also practice using both extremities in functional tasks such as dressing. We often use a similar approach with good success in patients with unilateral UE weakness secondary to other conditions such as brachial plexus injury and hemispherectomy.

In summary, our belief is that bimanual training may be more relevant for lifelong functioning but that CIMT can boost a child's bimanual abilities.

Parental Involvement in Therapy Is Essential

Regardless of the approach, in order to see long-term improvements in UE functioning, parents should view their commitment to their child's therapy not as a several-week process but as a several-year one. With our current knowledge of central nervous system plasticity, we know that the more an activity is practiced, the more the responsible neurologic pathways are strengthened, both functionally and structurally. Limited functional magnetic resonance imaging studies before and after constraint therapy support this.

But parents must also consider focusing considerable time on improving the functionality of their child's weak limb at the expense of other developmental, recreational and educational activities and family time. As with any intervention, the clinician's role is to help the parents make an educated decision. ■

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KEY POINTS

Both constraint induced movement therapy (CIMT) and, more recently, bimanual therapy have been employed in an attempt to improve active movement and functional abilities in the upper extremities of children with hemiparesis.

Comparison studies have demonstrated that each approach has advantages, though in different areas.

At Cleveland Clinic Children's Hospital for Rehabilitation, we see benefits in both therapy strategies and incorporate them into our management of children with hemiparesis, though with some modifications based on patients' age.

Parents must commit a considerable amount of time to assisting in their child's therapy to produce long-term improvements.

Spinal Cord Stimulation for Managing Treatment-Refractory Pain: Experience and Insights

By Andre Machado, MD, PhD; and Sean Nagel, MD

Andre Machado, MD, PhD

Sean Nagel, MD

As shown by an increasing body of research, spinal cord stimulation (SCS) is a safe, efficacious, cost-effective[1] and reversible treatment for select patients with severe chronic neuropathic pain.

SCS employs implanted epidural electrodes that deliver short-duration current or voltage pulses to excite sensory axons in the dorsal column. The precise mechanism of action of SCS remains unclear, and our understanding of chronic pain is incomplete. However, SCS is capable of interfering with the relay of non-nociceptive signals from the pain source, replacing painful sensation with more tolerable paresthesia and providing clinical improvement for some intractable pain syndromes affecting the extremities, with or without back involvement.[2,3]

Use in Failed Back Surgery and Complex Regional Pain Syndromes

In the United States, SCS is most frequently used in cases of failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS). SCS can alleviate axial and radicular pain, but is especially effective for patients with pain predominantly in the leg or arm. At Cleveland Clinic's Center for Neurological Restoration, we have found the best candidates for this treatment generally are patients who experience persistent pain with neuropathic characteristics (often described as burning or aching), despite having undergone adequate decompressive surgery or spinal fusion.

KEY POINTS

- Spinal cord stimulation (SCS) uses implanted epidural electrodes to stimulate the dorsal column, interfering with the relay of pain signals.
- SCS frequently is used to treat failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS).
- A Cleveland Clinic study found that SCS with paddle leads is an effective long-term treatment for a proportion of patients with FBSS and CRPS.

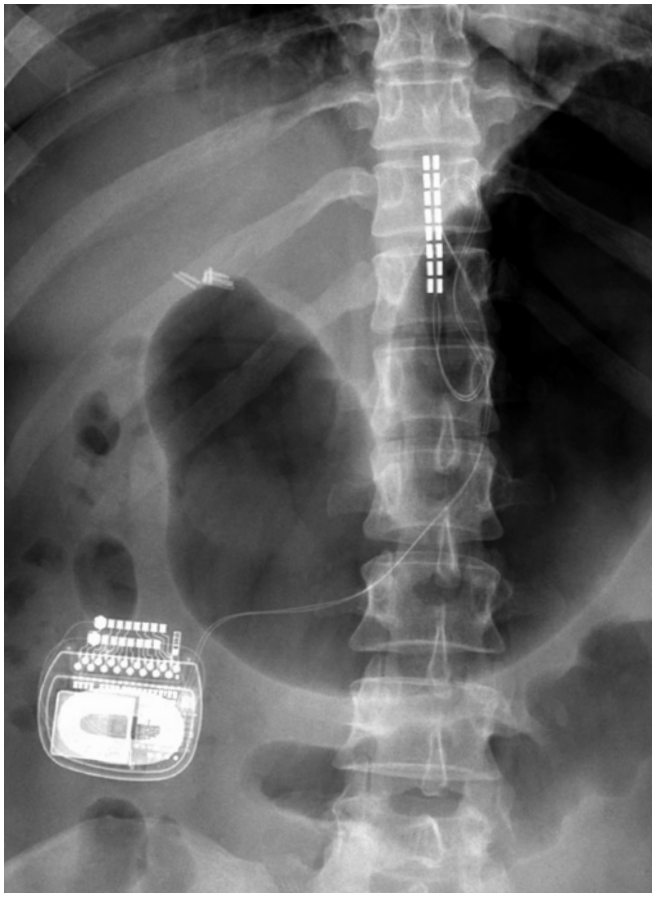
The SCS system consists of one or more electrode leads connected to an implanted pulse generator similar to a pacemaker. We prefer to use rechargeable generators because of their longevity. Recharging is done at home

— from several times per week to biweekly depending on battery size and individual patient electrical settings — by placing a charging device on the skin over the generator.

The SCS electrical leads, configured with four to 16 electrodes, are either cylindrical or paddle-shaped and are differentiated by their method of placement. Cylindrical (percutaneous) leads are implanted into the epidural space using large Tuohy needles, while paddle leads require a laminectomy or laminotomy. Though percutaneous leads are less invasive, paddle leads often are preferred because they are less prone to migrate and provide more efficient stimulation of the spinal cord.

Placement of the leads depends on the topography of the patient's chronic pain. They are typically implanted in the mid or lower thoracic spine for patients with leg pain (with or without back pain), and in the middle or upper cervical areas for those with upper extremity pain.

Most patients undergo a psychological evaluation to help assess the probability of a successful outcome. Patients also undergo a test of the stimulation for one week with one or more externalized, percutaneously implanted leads connected to a pulse generator to determine the degree of analgesia and to assess if the patient tolerates stimulation well. A satisfactory response — generally a 50 percent or greater reduction in pain — is usually followed by permanent implantation.



Long-term Outcomes at Cleveland Clinic

Our experience in the Center for Neurological Restoration indicates that SCS' effects seem to be long-lasting, as is patient satisfaction.

In 2011, we reported the results of a study evaluating the long-term outcomes of patients implanted with paddle lead SCS systems for FBSS or CRPS at our center between 1997 and 2008.[4] The study assessed overall satisfaction with the therapy and correlated satisfaction with pain alleviation. We accomplished this by a retrospective chart review and a questionnaire survey to gauge present efficacy. We calculated pain reduction using pre- and postoperative scores on an 11-point visual analog scale (VAS). We also asked patients if they would undergo SCS implantation again if they were to have the same outcome.

Thirty-five patients participated in the study. More than 50 percent of those with CRPS reported greater than 50 percent pain relief at a mean follow-up of 4.4 years. Approximately 30 percent of the FBSS patients reported a 50 percent or greater improvement at a mean follow-up of 3.8 years. Seventy-eight percent of patients with CRPS and 71 percent of patients with FBSS indicated they would undergo SCS surgery again for the same outcome. This disproportionately high degree of satisfaction suggests the VAS may not be the best way to measure long-term outcomes in these patients, and that improvements in quality of life may not be captured by this simplistic metric.

Our research found that patients implanted recently with SCS leads reported greater pain relief than those whose surgeries were earlier in the study period. This could represent a true decline in SCS efficacy over time, or alternatively may reflect the improvements in newer SCS equipment, with multichannel paddle leads and more programming features that may produce better outcomes than older systems.

A Multidisciplinary Approach to Pain Neuromodulation

At the Center for Neurological Restoration, we routinely implant SCS systems in patients with FBSS, CRPS and

other chronic pain conditions. Our primary goal is to reduce pain-related disability and enable patients to be as active as possible. Our pain neuromodulation program has two specialized neurosurgeons and two full-time physician assistants. We strongly believe in a multidisciplinary approach to these complex disorders, and we routinely team with primary care, pain management, and physical medicine and rehabilitation physicians to provide long-term care. The best outcomes are likely achieved by pairing SCS with long-term physical therapy and rehabilitation.

Performed appropriately and in properly selected patients, SCS can be an effective therapy for managing refractory pain. Like other treatment options, however, it is not curative and should be combined with other modalities, especially physical therapy. ■

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FIRST STEPS

Bionic exoskeletons such as this one being evaluated by a patient and staff in Cleveland Clinic's Department of Physical Medicine and Rehabilitation allow paralyzed people to stand and take steps with assistance. These devices are licensed in the United States for rehabilitation training under medical supervision but are not approved for nonhospital use. Patients trigger the computer-controlled exoskeleton to step by shifting their weight, enabling them to participate in weight-bearing exercises and gait training. Clinical studies are underway to determine exoskeletons' potential impact on circulation, bowel and bladder function, and other complications of paralysis.

The Biopsychosocial Model of Medicine and PM&R: A Logical Pairing

In 1975, to help her decide whether to enroll in medical school, Hilary Siebens spent time working in a missionary medical clinic in a remote Ethiopian village.

One of the clinic's patients was a woman who, as a child, had fallen into a cooking fire, badly burning part of her face. A surgeon had removed her nonfunctioning eye, but its glass replacement wouldn't stay in place. The empty socket's appearance was disturbing, leaving the woman isolated and sad.

Aware of the disfigurement's toll on her patient, Ms. Siebens sewed a simple eye patch. Its impact was profound. When Ms. Siebens saw the woman several months later, she was smiling and dancing and reintegrated into village life.

"The surgeon took care of her eye, and I ended up thinking about her appearance," Hilary Siebens, MD, now a respected clinician, educator and healthcare consultant, told the audience at Cleveland Clinic Department of Physical Medicine and Rehabilitation's 2014 Daurine and Sanford Noll Symposium Lecture. "This experience made a deep impression on me and my view of patients. In retrospect, she was my first rehabilitation case and my first encounter with the biopsychosocial model" of medicine.

Broadening Views of Wellness and Disease

Historically, physicians have used a series of increasingly sophisticated models to define the concept of disease and to guide their approach to providing care. The predominant version in the 20th and early 21st century remains the biomedical model, which considers disease primarily as a bodily, physiological failure resulting from injury, infection or an inherited disorder.


Hilary Siebens, MD

In his seminal 1977 *Science* essay, "The Need for a New Medical Model," University of Rochester psychiatry professor George Engel, MD, criticized the body-focused biomedical model as too reductionist. Dr. Engel argued that wellness is more than the absence of disease. He proposed a biopsychosocial model that broadened the conception of health to include patients' social and psychological status, not just their physiological condition. It stressed the interaction of mind, body and environment and their combined impact on a person's fitness.

Dr. Engel hoped that his biopsychosocial model would be a framework for better doctor-patient communication, helping physicians make beneficial connections between their patients' life situations and the medical complaints for which they seek care. That insight could enable physicians to identify larger, correctable issues affecting their patients' well-being.

PM&R and the Domain Management Model

But most segments of medicine have been slow to adopt the biopsychosocial model, Dr. Siebens said, perhaps due to concerns that addressing broad, potentially complex patient psychosocial and environmental issues might take inordinate time and resources.

PM&R is a notable exception to that hesitance. "Because of the nature of care we provide, and the diverse settings in which we deliver it, I think the biopsychosocial model is a concept that comes very easily to rehab professionals," said Frederick S. Frost, MD, Chairman of Cleveland Clinic's Department of Physical Medicine and Rehabilitation.

Dr. Siebens' Domain Management Model (SDMM)[1-3] categorizes patients' problems into four domains: medical/surgical issues, mental status/emotions/coping, physical function and living environment (© Hilary C. Siebens, MD, 2005). The goal is to guide physicians' questions to patients and their families, reveal and prioritize issues that could affect treatment outcomes, and enable efficient delivery of care. The standardized clinical approach and language facilitates teamwork among caregivers.

KEY POINTS

The biopsychosocial model of medicine stresses a broadened conception of health that includes not just patients' physiological condition but their social and psychological status.

The model can serve as a framework for improved diagnosis, treatment and patient/physician communication.

Most segments of medicine have been slow to adopt the biopsychosocial model, but PM&R is an exception.

A refinement of the biopsychosocial model into domains offers more guidance on how to incorporate a holistic assessment of a patient into everyday medical care.

"This general approach, whether it is in rehab or used to evaluate a neurological or neurosurgery patient, provides a phenotype of the patient that's predictively accurate as to how that person will do and whether he or she needs extra support," said Michael T. Modic, MD, FACR, Chairman of Cleveland Clinic's Neurological Institute. "We are changing the way we approach things. Before, we used to be absorbed by the medical event. Now we understand all the additional parameters that are going to be important factors for that person's recovery. We're convinced that a biopsychosocial approach is part of the solution to problems such as hospital readmissions and poor surgical outcomes."

Small Steps Are Key to Progress

Taking a more holistic view of a patient's situation may seem daunting, but Dr. Siebens insists that it actually saves time, decreases risk and forges a better alliance with the patient and family. "It doesn't have to be an overwhelming experience," she said. "Start small and practice, and it will get better." For example, asking patients how they're coping with their diagnosis is a simple way of starting to assess the mental status domain; noting whether they arrive in a wheelchair or walk unassisted is an entree to evaluating physical function; the presence or absence of a spouse or other family member provides insight about the living environment.

Applying the SDMM: A Patient Example

Here's a typical admission summary for a geriatric patient arriving in the emergency department:

WF is a 78-year-old man with a stage III sacral decubitus ulcer and advanced Pick disease dementia who was brought from home to the ED. His neurologist, who had not seen the patient in many months, made a home visit and recommended the ED transfer. The patient had a high fever and was minimally responsive and not in visible pain. In the ED, his glucose level is 850 mg/dL and temperature is 101 F.

Here's how gathering and organizing information in the Siebens Domain Management Model's structure could guide patient evaluation and care decisions:

I. **Medical/Surgical Issues:** Decubitus ulcer from progressive, irreversible immobility, known diabetes.

II. **Mental Status:** End-stage dementia requiring 24-hour care. Wife is healthcare proxy. She had agreed with primary care physician for no further resuscitation or hospitalizations; the focus of care was to be comfort care at home.

III. **Physical Function:** No longer ambulatory; dependent in activities of daily living.

IV. **Living Environment:** Living in own home with hospital bed. Daughter, a lawyer, caring and supportive to mother and father.

"There are a lot of problems in patients' lives that don't respond to a quick fix," Dr. Siebens said, "but the model helps narrow and focus on basic things." ■

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Research Reverses Conventional View: Magnetic Stimulation is a Potential Treatment for Medically Refractory Epilepsy, Not a Contraindication

By Ching-Yi Lin, PhD

Ching-Yi Lin, PhD

Cleveland Clinic PM&R researchers, notably Director of Rehabilitation Research Vernon Lin, MD, PhD, were early adopters of transcranial magnetic stimulation (TMS) technology for neuromodulation. Dr. Lin's initial TMS research took place at the Veterans Administration Long Beach and Palo Alto healthcare systems[1-3] and has continued at Cleveland Clinic, where he has collaborated with Neurological Institute colleagues, including this author.

Due to its ability to noninvasively modulate brain functions, TMS shows significant potential for treating neurological and psychiatric disorders, including intractable epilepsy.

Approximately 30 percent of epilepsy patients have medically refractory epilepsy, meaning anti-epileptic drugs are ineffective. These patients need nonsurgical treatment options.

Studies in healthy populations at rest have shown that low-frequency (≤ 1 Hz) repeated stimulation (rTMS) can depress cortical excitability. However, higher-frequency rTMS (> 1 Hz) is capable of the opposite effect, augmenting cortical excitability and inducing seizures.

These dual, frequency-dependent anti- and pro-convulsive properties of rTMS must be characterized to assess whether the technology is a viable treatment alternative for epileptic patients and to guide its use.

Our group of researchers from Cleveland Clinic's Department of Neurosciences, the Epilepsy Center and the Department of Physical Medicine and Rehabilitation tested rTMS at various frequencies in a rat model in which cortical injections of penicillin induced seizures. We examined the effect of rTMS at 1, 5 and 10 Hz on seizure activities.

Our results[4] challenge the prevailing understanding that lower rTMS frequencies do not necessarily translate to stronger inhibitive effects. Our results showed that 5 Hz rTMS consistently outperformed 1 Hz rTMS in seizure suppression. Furthermore, our results are the first to indicate that other brain areas instead of the seizure-induction loci — specifically the contralateral motor cortex — can be used as a target to inhibit seizure development.

KEY POINTS

- Patients with medically refractory epilepsy need nonsurgical treatment options.
- Repetitive transcranial magnetic stimulation (rTMS) has shown promise in suppressing epileptic seizures, though appropriate stimulation frequencies have not been characterized.
- Our research used a rat seizure model to quantify seizure intensity and assess the impact of rTMS.
- Contralaterally delivered rTMS is found to be anti-convulsive when applied at 1 and 5 Hz; 5 Hz rTMS consistently outperformed 1 Hz rTMS in seizure suppression. However, rTMS is pro-convulsive when applied at 10 Hz.

Using Real-Time Monitoring to Examine rTMS Effects

rTMS uses electromagnetic induction to deliver pulsed intracranial electrical current, creating a focal electric field (E-field) in the brain region below the coil. This E-field depolarizes membrane potential and activates neurons, producing a sustained change (rTMS aftereffects) in cortical excitability that may persist for weeks after the stimulation.

The mechanisms underlying rTMS treatment effects in epilepsy are not fully understood. Coherence in brain activity requires integration of multimodal neuronal networks and regulation of interhemisphere competition and inhibition. rTMS has been found to both inhibit and facilitate various experimental and clinical seizures, depending on the parameters used.

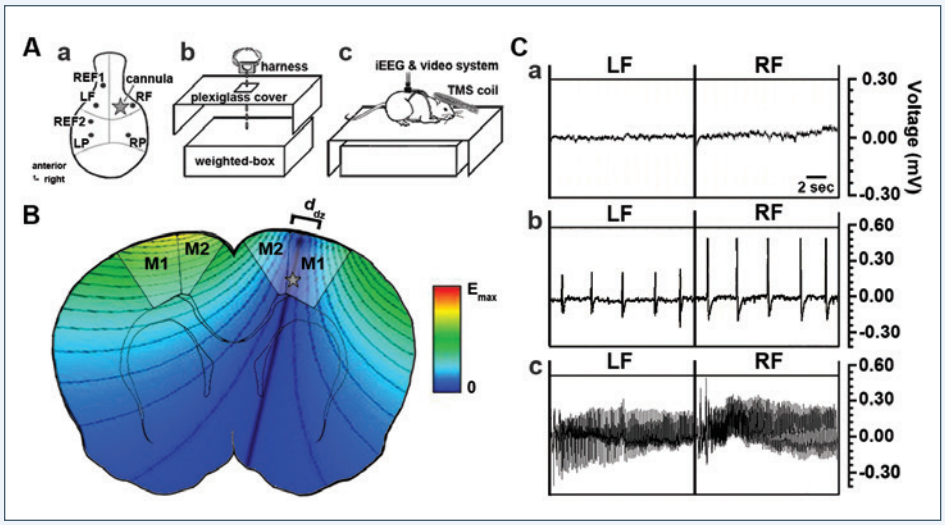

Figure 1. *iEEG recording of rTMS aftereffects on seizures. (Aa) EEG electrodes inserted at four target areas. (Ab, Ac) Rat restrained; electrodes connected; TMS coils positioned parallel to dorsum of head. (B) rTMS-induced electric field in rat brain. (C) Compared to saline-injected rats (Ca), iEEG reveals that penicillin-induced seizures were a combination of myoclonic (Cb) and GTC (Cc) seizures.*

To test this premise, we injected penicillin into our rats' right motor cortex. The injections suppressed the surrounding inhibitory interneurons and produced bilateral myoclonic and generalized tonic-clonic (GTC) seizures. We then treated the animals with rTMS at 1, 5 or 10 Hz for 800 seconds. The resultant E-field stimulated the rats' contralateral motor cortex, including cortical interneurons and the superficial horizontal motor cortex layers parallel to the head surface.

We used real-time intracranial electroencephalographic monitoring and video recording to analyze changes in seizure type, intensity, frequency and/or duration due to rTMS aftereffects.

Surprising Results for 5 Hz rTMS

As expected, low-frequency 1 Hz rTMS produced significant suppression of the penicillin-induced seizures. High-frequency 10 Hz rTMS enhanced seizure activity.

Surprisingly, the 5 Hz rTMS consistently produced the best therapeutic results, providing higher seizure-suppression rates than the 1 Hz regimen and contradicting the premise that frequencies higher than 1 Hz are seizure-facilitatory. Treatment with 5 Hz rTMS reduced the amount of GTC seizures and fully suppressed them two hours earlier than in animals treated with 1 Hz rTMS.

The mechanisms underlying the seizure-suppression effects of 5 Hz rTMS need further investigation. A possible explanation for why prolonged trains of supposedly excitatory 5 Hz rTMS instead produce seizure suppression is that the stimulation activates a homeostatic mechanism. In this scenario, penicillin injections cause increased cortical excitability and seizures; to restore equilibrium, the homeostatic mechanism inverts the direction of rTMS aftereffects from excitation into inhibition. Stimulation at 10 Hz may be beyond the ability of this homeostatic mechanism to control, allowing high-frequency rTMS to facilitate seizure-associated excitation.

The rTMS setting in our study delivered rTMS targeting the contralateral motor cortex, which due to inter-hemispheric inhibition can produce the largest effects on the most severe disturbances at the penicillin focus. The results are compelling and translatable, since there has been little knowledge or consensus on how different rTMS frequencies applied contralaterally affect the homologous brain region, and since ipsilateral treatment sites may not always be available due to direct insult or damage.

In summary, our results challenge the premise that lower frequencies of TMS do not necessarily translate to stronger inhibitive effects. Our findings support the prospect that the frequency and presumably intensity of rTMS can be fine-tuned to best treat specific seizure conditions. With well-tuned stimulation parameters, rTMS could be a powerful therapeutic tool for combating focal neocortical epilepsy.

Dr. Lin is a project staff member of Cleveland Clinic Lerner Research Institute's Department of Neurosciences. She can be reached at linc@ccf.org or 216.445.5047. ■

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Research on Nerve Regrowth in Spinal Cord Injury Shows Promise

Yu-Shang Lee, PhD

In his laboratory in Cleveland Clinic's Lerner Research Institute, neuroscientist Yu-Shang Lee, PhD, painstakingly dissects muscle and dura around the spinal cord of a rat to access the site where the cord was partially severed two months earlier.

With the help of an operating microscope, Dr. Lee locates the cavity that resulted when the rat's body responded to the cord injury by forming a cyst. He carefully clears away the scar tissue that surrounds the cavity and prevents axonal regrowth. He then grafts several segments of peripheral nerve into the cavity, injects acidic fibroblast growth factor (aFGF) and an enzyme known as chondroitinase ABC around the site, and sutures the muscle and dura.

For the next six months, Dr. Lee will monitor the animal's bladder function and locomotion. "Finding a way to improve bladder control in patients with spinal cord injury (SCI) is my near-future goal," he says.

Dr. Lee has devoted his career to finding potential treatments for SCI and the deficits in motor, sensory or autonomic function it causes. His laboratory concentrates on using nerve-bridging techniques to coax axonal regrowth.

"Pathological changes at the site of SCI create a non-permissive environment for axonal regeneration. The key to regaining functional recovery is to encourage more axons to cross the damaged site and connect with target neurons," he explains.

Hope for Improved Quality of Life

Nearly 1.3 million patients in the United States are living with SCI. While regaining motor control remains an overarching goal, patients also desire nearer-term advances that would improve their quality of life. Restoration of bladder control is high on the list.

For four years, Dr. Lee used a National Institutes of Health grant to study bladder restoration techniques in acute SCI. Working with rats whose spinal cords had been completely severed, Dr. Lee and his research collaborator, Jerry Silver, PhD, a Case Western Reserve University neuroscientist, developed a method that enabled severed nerve fibers to grow and reconnect. It involved implanting multiple peripheral nerve bridges for the axons to grow across. The site is injected with growth factor to stimulate nerve fiber growth, and enzymes to digest and eliminate scar tissue around the lesion. Dr. Lee calls this procedure the "full monty."

Now, his challenge is to determine whether the full monty will produce the same axonal growth and reconnection in animals with chronic SCI. He is seeking additional NIH funding for this phase of the project.

"There is no effective treatment for chronic SCI, which is the current status of most patients with SCI," Dr. Lee says. "These patients are still waiting. I'm excited about this project, because we have limited knowledge of biology and translational treatment for chronic SCI."

Progress in Chronic SCI

To study chronic SCI, Dr. Lee is using a clinically relevant model of partial injury, the type commonly resulting from car or sports accidents. "The advantage of a rat model is that pathological changes in rats are similar to those in humans," he says.

After injuring the spinal cord, Dr. Lee waits two months before starting treatment. At that point, lack of bladder control is apparent and continues to worsen until six months post-injury, when the deterioration plateaus. "We consider two months post-injury to be the chronic stage," says Dr. Lee.

The rats are divided into three groups. Group one receives the full monty of nerve grafts, growth factor and enzyme. Group two undergoes surgery to reveal the site of injury but receives no enzyme or growth factor. The control group receives no treatment after the SCI injury.

Six months later, the effects of treatment are clear.

In the control group and group two, locomotion remains impaired and bladder control has deteriorated.

The rats in group one, however, are significantly better off: The full monty has a limited effect on improving locomotion, but urinary function assessment reveals that a significant amount of bladder control is preserved.

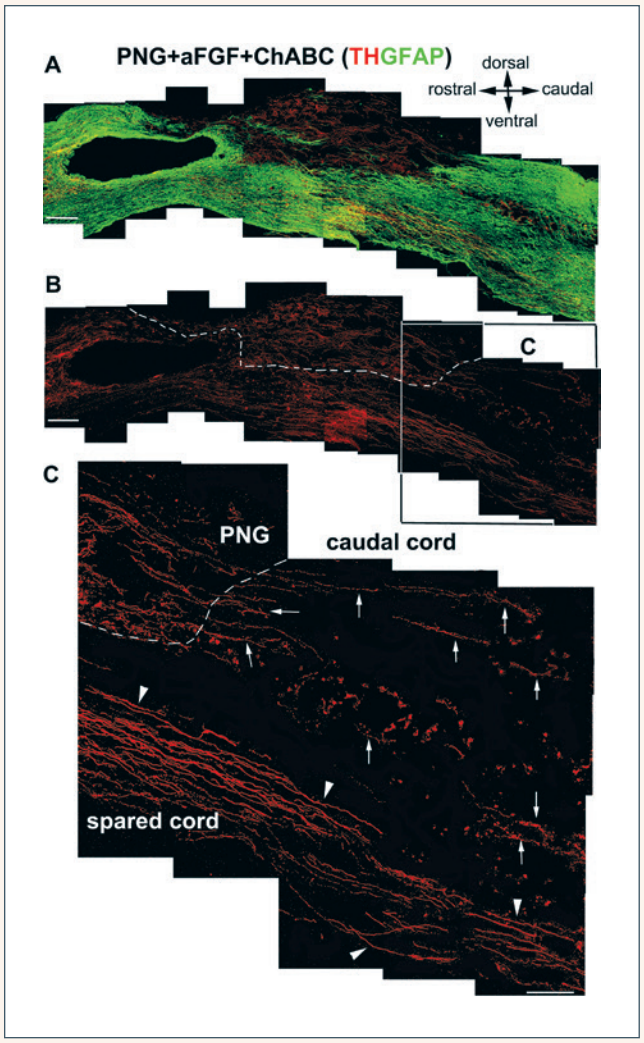


Figure 1. *Sagittal confocal reconstruction shows how PNG+aFGF+ChABC promotes robust regeneration of chronically injured tyrosine hydroxylase (TH)-positive fibers into the PNG, with many fibers regenerating beyond the PNG/cord interface (A, B). Higher magnification shows spared fibers in ventral portion (C, lower part with arrowhead), and regenerated TH fibers in PNG (C, upper part) and entering caudal cord, where they arborize (C, upper part with arrow). Dashed lines show PNG/cord interface. Scale: A and B, 450 µm; C, 350 µm.*

"At the end of the study, these rats were voiding more frequently and efficiently than those in the control groups," Dr. Lee says. "When we looked at the same rat before and after repair surgery, we could see that deterioration of bladder function had been prevented. But in the rats that didn't get the full monty, bladder function continued to decline.

"We are not satisfied with simply maintaining function, so we will work on this," he adds.

Attempts to Boost Nerve Sprouting

Next, Drs. Lee and Silver plan to add another component to the full monty: a novel molecule called intracellular sigma peptide (ISP).

"In addition to being a more powerful way to block the molecular pathway inhibiting nerve regrowth, the protein can also enhance nerve sprouting. Dr. Silver has demonstrated that ISP has a significant effect on both locomotion and bladder control after acute SCI. We'll now see if it has the same effect in chronic SCI," says Dr. Lee.

In an area of medicine in which little progress has been made, Dr. Lee's findings provide a glimmer of hope. Yet they will not move into human clinical trials anytime soon. Dr. Lee plans to move forward with caution.

"We'll consider using a large animal model to ensure the technique is both effective and safe before moving to humans," he says. ■

Dr. Lee is an assistant staff member in Cleveland Clinic's Department of Neurosciences. He can be reached at leey2@ccf.org or 216.445.5040.

KEY POINTS

- Pathological changes at the site of spinal cord injury (SCI) create a nonpermissive environment for axonal regeneration.
- In an animal model of acute SCI, implanting multiple peripheral nerve bridges and injecting the injury site with growth factor and enzymes eliminated scar tissue and stimulated axonal nerve fiber regrowth and reconnection, improving bladder control.
- Ongoing research in an animal model of chronic SCI using the same therapeutic approach has shown promising results in preventing deterioration of bladder function.

Evaluating Functional Magnetic Stimulation's Potential to Improve Expiratory Function in Multiple Sclerosis Patients

Vernon Lin, MD, PhD

Xiaoming Zhang, PhD

There are approximately 400,000 patients with multiple sclerosis (MS) in the United States. A significant number are not able to produce an effective cough to clear airway secretions, due to impairment of the central nervous system controlling the respiratory muscles. The inability to effectively cough elevates the risk of pneumonia.

Cleveland Clinic's Director of Rehabilitation Research, Vernon Lin, MD, PhD, found that a technique called functional magnetic stimulation (FMS) improves respiratory muscle conditioning and coughing in patients with chronic spinal cord injury (SCI). Dr. Lin and his team are now applying the same technique to patients with expiratory muscle dysfunction (including abdominal muscle weakness) due to MS.

"Expiratory muscle strength in patients with MS is significantly lower — 27 percent to 74 percent of predicted — than in normal subjects," says Xiaoming Zhang, PhD, of Cleveland Clinic's Department of Physical Medicine and Rehabilitation. "This can have a deleterious effect on their health, and they are more prone to develop pneumonia, which can be fatal."

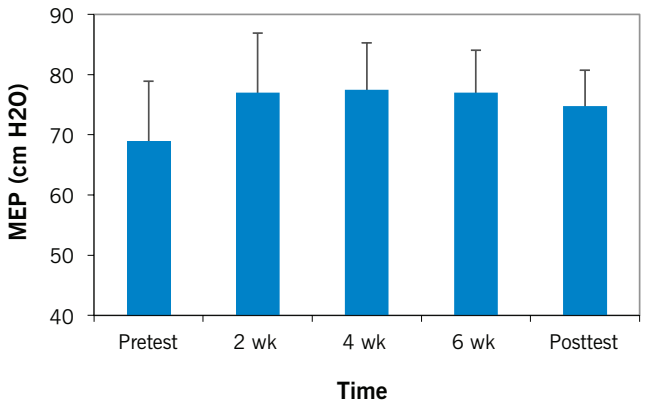
FMS is a painless, noninvasive technique that activates targeted muscles by stimulating corresponding spinal nerves where they exit the spinal cord. For patients with SCI and MS, FMS may substitute as a passive form of neuromuscular exercise.

KEY POINTS

- A significant number of multiple sclerosis (MS) patients are unable to effectively cough to clear airway secretions due to impaired respiratory muscle control, making them vulnerable to pneumonia.
- Functional magnetic stimulation (FMS) has been shown to improve respiratory muscle conditioning and coughing in patients with chronic spinal cord injury.
- Cleveland Clinic researchers are evaluating FMS' ability to increase respiratory function in MS patients and have observed preliminary improvement.

"Our laboratory has demonstrated the efficacies of FMS in improving physiological functions for patients with SCI, including improving coughing, breathing, bladder emptying, gastrointestinal motility and fibrinolysis, resulting in prevention of deep venous thrombosis," says Dr. Zhang. "We are very optimistic that FMS will prove to be an effective tool for conditioning the expiratory muscles and improving quality of life in patients with MS."

Figure 1: Changes of Maximal Expiratory Pressure (MEP) Throughout the Conditioning Protocol



How Stimulation Is Accomplished

Functional magnetic stimulators consist of two components: a pulse generator producing discharge currents of 5,000 amps and a stimulating coil producing magnetic pulses with field strength of 2 Tesla and duration of about 250 μs. The magnetic field induces an electric field that excites neurons.

Placement of the coil varies with the therapeutic goal. In previous studies of FMS in SCI, lower thoracic spinal nerve stimulation resulted in maximal stimulation of expiratory muscles. Four to six weeks of conditioning of these

expiratory muscles led to significant improvement in their voluntary expiratory functions, such as airway pressures, volumes and flow rates.

To study the effects of FMS in MS patients, researchers placed the center of the coil at the T9 spinous process and activated the stimulator for 20 minutes per day. The therapy was provided five days a week for six weeks, with stimulation intensity gradually increased from 40 percent to 70 percent of maximal capacity.

Preliminary Results Show Improvement

Pulmonary function tests performed at baseline and every two weeks measured maximal expiratory pressure, peak expiratory flow and expiratory reserve volume. The researchers observed continual improvements. At the end of the six-week study protocol, patients experienced a 20 percent increase over baseline in expiratory muscle strength, as measured by pressure.

"This increase is significant and may prevent pneumonia," says Dr. Zhang. "However, these results are preliminary and will be used to apply for external funding for a more comprehensive study. When FMS units can be used at home, patients with MS may benefit from a more long-term and more convenient way of stimulating their respiratory muscles." ■

Dr. Lin is Cleveland Clinic's Director of Rehabilitation Research. He can be reached at linv@ccf.org or 216.445.7350. Dr. Zhang is a Research Engineer in the Department of Physical Medicine and Rehabilitation. He can be reached at zhangx6@ccf.org or 216.444.5747.

Cleveland Clinic and Select Medical Announce Rehab Joint Venture

Cleveland Clinic and rehabilitation services provider Select Medical have formed a joint venture to enhance inpatient rehabilitation services in Northeast Ohio and improve access for patients with complex rehab needs.

As part of the joint venture, the two organizations will build a new 60-bed adult inpatient rehabilitation hospital in Avon, Ohio, west of Cleveland. The two organizations have also entered a management agreement, effective August 1, 2014, to enhance operations in existing Cleveland Clinic rehabilitation facilities.

The new Avon rehabilitation hospital will be located next to Cleveland Clinic's Avon medical campus. It is expected to open in late 2015.

In addition, the joint venture will establish a residency program for physicians in physical medicine and rehabilitation. Cleveland Clinic and Select Medical also share a goal of improving patient access to the highest quality postacute and rehabilitation programs, as well as enhancing opportunities for employees.

The agreement is expected to expand Cleveland Clinic's post-acute care capabilities by adding to existing home care, hospice and skilled nursing facility programming. The joint venture will explore further opportunities to expand services locally, nationally and internationally with the goal of continuing to improve post-acute care options more broadly for patients.

"This is collaboration on the latest rehabilitation research, the latest clinical protocols, and the latest educational resources and programs for our staff and patients," said Frederick S. Frost, MD, Chairman of Cleveland Clinic's Department of Physical Medicine and Rehabilitation and Executive Director of Cleveland Clinic Rehabilitation and Sports Therapy. "A joint venture such as this really allows us to take a giant leap forward. Cleveland Clinic intends to grow our rehabilitation services regionally, nationally and internationally."

Select Medical has partnered with a number of academic medical centers, including Baylor Health System in Texas, Penn State Hershey Medical Center in Pennsylvania, and both Cedars-Sinai and UCLA Health System in California.

"Between Cleveland Clinic's world-class reputation for excellence and our expertise in inpatient rehabilitation, there is terrific synergy between our two organizations," said David S. Chernow, President and Chief Executive Officer of Select Medical. "Through a shared commitment to delivering the best possible patient experience, I know that we can build something truly special in the post-acute care space."

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150+
FTEs

6
RESEARCH STAFF (physicians and PhD researchers)

700+
SPECIALTY-TRAINED PTs, OTs AND SPEECH THERAPISTS in Cleveland Clinic Rehabilitation and Sports Therapy, run in conjunction with the Orthopaedic & Rheumatologic Institute

2013 BY THE NUMBERS

1,781	acute inpatient rehab admissions
4,731	total inpatient days
393,162	total PM&R outpatient visits
337,128	total PM&R inpatient visits
730,290	total patient visits

RESEARCH FUNDING BY THE NUMBERS

11	active research projects with grant/private funding
$5m	in federal government funding (NIH/DOD)
$345k	in foundation support
$174k	in private funding support

OUTCOMES SNAPSHOTS in Acute-Care Hospital Patients (2013)

91%
Proportion of patients with stable or improved ability to perform PT functional tasks on 6 Clicks AM-PAC Short Form tool

13% → 28%
Change from admission to discharge in proportion of patients requiring minimal or no assistance in PT functional tasks on 6 Clicks AM-PAC Short Form tool

94%
Proportion of patients with stable or improved ability to perform OT functional tasks on 6 Clicks AM-PAC Short Form tool

9% → 26%
Change from admission to discharge in proportion of patients requiring minimal or no assistance in OT functional tasks on 6 Clicks AM-PAC Short Form tool

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