

NewYork-Presbyterian Advances Rehabilitation Medicine

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Recovery after Stroke: Assessing a Combined Approach of Vagus Nerve Stimulation and Rehabilitation

Although there are numerous treatments available to improve cerebral perfusion after acute stroke, there are few treatments to improve upper extremity movement in the chronic phase. “Typically, a patient would undergo a course of occupational therapy,” says **Michael W. O’Dell, MD**, Vice Chair of Clinical Services, Rehabilitation Medicine, Medical Director of the Inpatient Rehabilitation Medicine Center at NewYork-Presbyterian/Weill Cornell Medical Center, and Professor of Clinical Rehabilitation Medicine at Weill Cornell Medicine. “Constraint-induced motor therapy is somewhat effective, but very hard to implement with patients because of its intensity. Recent studies of SSRI antidepressants to facilitate stroke recovery have been disappointing. Currently, we simply don’t have many options to improve movement in the upper extremity after stroke.”

Vagus nerve stimulation (VNS) has been used to treat uncontrollable epilepsy for more than 20 years. Dr. O’Dell, in collaboration with neurosurgeon **Theodore H. Schwartz, MD**, Director of the Center for Epilepsy and Pituitary Surgery at Weill Cornell, is now assessing VNS in a pivotal placebo controlled, blinded multicenter trial to assess its safety, feasibility, and potential effects when paired with rehabilitation for improving arm function after chronic stroke.

“We’re working with a company that has compiled data initially from Scotland and just published in *Stroke* in the United States that suggests that if the vagus nerve is stimulated while somebody is doing exercise, it actually may improve the recovery of upper extremity weakness,” says Dr. O’Dell. “The theory is that the patient still has to exercise, but the VNS is felt to enhance the efficacy of that exercise.”



Ruchi Patel, MA, OTR/L, and Dr. Michael W. O’Dell

The procedure, which is performed under conscious sedation, entails implanting a pace-maker-size device under the skin in the left chest area. A very small electrode is attached to the generator device and placed under the skin; the wire is wound around the vagus nerve in the patient’s neck. The device is programmed to deliver pulses or stimulation at regular intervals.

“A week after the surgery, the patient starts their occupational therapy,” says **Ruchi Patel, MA, OTR/L**, Senior OT Stroke and Robotics Research, Department of Rehabilitation Medicine at NewYork-Presbyterian/Weill Cornell. “The protocol for this study has the patient receiving six weeks of therapy, 18 sessions, and each session is 90 minutes. This in itself is a great asset for therapists as most outpatient sessions are only 30 to 45 minutes.”

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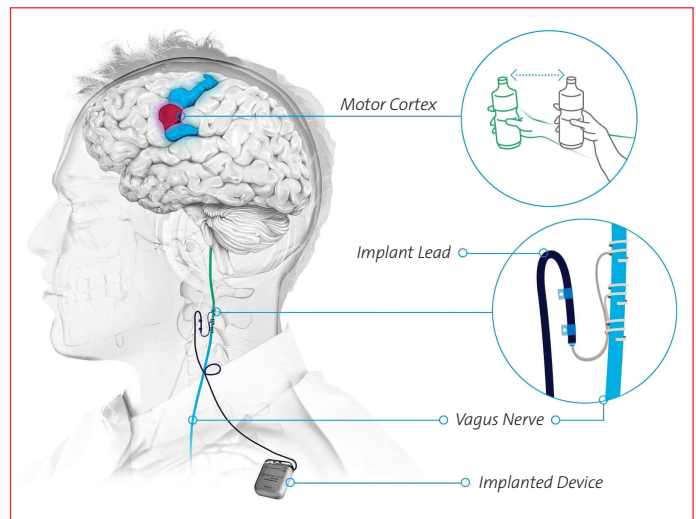
Recovery after Stroke: Assessing a Combined Approach of Vagus Nerve Stimulation and Rehabilitation (continued from page 1)

During the session, the occupational therapist asks the patient to perform six tasks that involve either reaching for or releasing items, grasp and release, turning their palm up and down, and so on. Each time the patient does the movement, the therapist presses a button that is hooked up to the implanted wireless transmitter, which then transmits a signal to the device that, in turn, stimulates the vagus nerve to release the neurotransmitters. The therapist uses the Fugl-Meyer upper extremity scale to monitor motor function of the upper extremities. “I conduct that test prior to starting therapy the day before and then record the patient’s primary endpoint the day after therapy to see if there is an improvement in the score,” says Ms. Patel. “We’re looking for a minimum of a six-point improvement to call it a responder patient.”

At one-month and three-month follow-up sessions, the patient is assessed again using the Fugl-Meyer scale to determine if there is continued improvement. “Once the patient is finished with therapy, they are given a magnet that they can swipe over the device that turns on the stimulation for 30 minutes a day, as well as exercises to do at home post-therapy,” says Ms. Patel.

Candidates for the study fall in the middle range of movement. “We’re not looking at those with very small deficits in moving their arm, nor those who have severe deficits,” adds Ms. Patel.

The study goal is to recruit 125 subjects at some 25 sites throughout the United States and the United Kingdom. “At three months, when the blinding is broken, the patients who received the placebo will receive another six weeks of occupational therapy, 90 minutes a day, with the stimulation, knowing that they’re getting the real thing,” says Ms. Patel, who invites practitioners who may have patients who qualify for the study to contact her.



“We’ve been involved in clinical trials of different medications, as well as the use of botulinum toxin, but there are still very few methods that we know work,” says Dr. O’Dell. “While we need to wait until all the data is in and analyzed for the degree of effect of VNS combined with OT, I believe the importance of the study is that we continue to seek alternate methods for patients for whom there are so few therapies to help them regain strength after a stroke.”

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Dr. Glen Gillen Appointed Director of OT Programs



Dr. Glen Gillen

Glen Gillen, EdD, OTR, FAOTA, has been named Director of the Programs in Occupational Therapy in the Department of Rehabilitation and Regenerative Medicine at NewYork-Presbyterian/Columbia. Dr. Gillen will also serve as a Vice Chair in the Department of Rehabilitation and Regenerative Medicine, as well as an Assistant Dean at the Columbia University Vagelos College of Physicians and Surgeons.

Dr. Gillen joined NewYork-Presbyterian in 1990 and has been a faculty member in the Occupational Therapy program at Columbia since 1993. Most recently, he has served as full professor, Columbia University, and Associate Program Director for Occupational Therapy.

Dr. Gillen is an accomplished academician, having authored 30 original publications and more than 100 publications. He is the editor of *Stroke Rehabilitation: A Function-Based Approach*, the definitive textbook on stroke rehabilitation for occupational therapists now in its fourth edition. He has received numerous awards and invited lectureships, including the keynote Eleanor Clarke Slagle lecture at the national meeting of the American Occupational Therapy Association.

Dr. Gillen received his undergraduate degree in occupational therapy, as well as a master of public administration in health management, at New York University. He later obtained an EdD in health education at Teachers College, Columbia University.

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Placental Allograft: A Regenerative Therapy for Osteoarthritis



Dr. Alfred C. Gellhorn

“While osteoarthritis is the most common joint disease in the world, we have extremely few effective conservative treatments available,” says **Alfred C. Gellhorn, MD**, Director of Sports Medicine for the Department of Rehabilitation Medicine at NewYork-Presbyterian/Weill Cornell Medical Center. “At this point, most guidelines only recommend steroid injections, physical therapy, and anti-inflammatories. That’s not a lot of choices. So, we’re looking to find a new class of medication.”

Dr. Gellhorn is hopeful that he has found just such a solution – an emerging regenerative therapy that involves the injection of micronized dehydrated human amniotic/chorionic membrane (dHACM) allograft. “AmnioFix® is a placental allograft,” explains Dr. Gellhorn. “Women donate their placenta after a scheduled cesarean section. It is then cleaned, sterilized, and checked for anything that is disease-transmissible. Next it is processed into a powder and reconstituted so that we can use it clinically through injection into diseased joints. Placental tissue contains a number of growth factors that are very important in healing and tissue repair. I’ve been using this in the clinic for about four years for both osteoarthritis and tendon disease and finding excellent clinical results.”

Dr. Gellhorn’s research on the efficacy of this treatment approach has been a case series analysis of patients he has treated. Based on the very good outcomes that he has seen, he decided to conduct a larger and more thorough trial with patients who have knee osteoarthritis. “Currently, we are leading a multicenter, double blind, randomized control trial with a very rigorous study design comparing placental allograft with a saline injection and following patients over 12 months to see how their pain levels change,” says Dr. Gellhorn.

The Weill Cornell researchers have recruited 13 centers to date, with a goal of 15 participating sites and a patient enrollment of 300. “This is a large and very powerful study,” notes Dr. Gellhorn. “We are including patients with moderate and painful osteoarthritis of the knee because knee arthritis is the number one joint affected by arthritis, and knee replacement is often not as effective as hip replacement.”

While Dr. Gellhorn by no means considers treatment with placental allograft a cure for osteoarthritis, in his experience the symptomatic effects last from 9 to 12 months. “If we can manage osteoarthritis effectively with a single injection in the knee every year – and indefinitely – then we’ve made an absolutely enormous change in the way people can manage their pain,” he says.

The Repair Process

As Dr. Gellhorn explains, within the placental material there are between 100 and 150 biologically active proteins – all of which work on different metabolic pathways within the joint. The most powerful ones work to decrease inflammation in the joint long term, which is responsible for the pain relief. “Many of the other proteins, at least theoretically, work to repair tissues within the joints such as the synovial lining and meniscus tissue,” he says. “All of those are potentially repairable tissues. I think it is likely that the long-term benefit that patients are getting from this is not just from decreased inflammation, but because the knee is actually repairing itself much more effectively.”

“If we can manage osteoarthritis effectively with a single injection in the knee every year – and indefinitely – then we’ve made an absolutely enormous change in the way people can manage their pain.”

— Dr. Alfred C. Gellhorn

Adding to the complexity of the process is the fact that the architecture of cartilage is extremely complicated. “It’s not just a flat sheet of tissue that you can lay on and repair from the top down,” says Dr. Gellhorn. “It’s got overlapping arches of collagen that comprise the matrix. It’s not enough to have a cell that produces cartilage; it has to produce it in that particular architectural way.”

The researchers’ goal, notes Dr. Gellhorn, is not to regrow cartilage with AmnioFix, but to decrease the rate at which the cartilage is broken down. “We know now that if cortisone injections are done with some regularity, there is a dose-dependent toxic effect on the cartilage. So, even though we’re trying to be helpful by decreasing someone’s pain with these injections, we are trading off a short-term benefit for a major problem down that road.”

Dr. Gellhorn emphasizes that the Weill Cornell investigators are only at the starting point of this research. “There will be many more clinical trials coming out of our group looking at the treatment of musculoskeletal disorders, including arthritis and tendon diseases. We’ll also be working closely with our colleagues in orthopedic surgery. They, too, are very interested in having effective treatment for patients who are not yet candidates for knee replacement.”

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Focus on Faculty



Mike Mizrahi, DO

Dr. Mike Mizrahi joined the Department of Rehabilitation Medicine at NewYork-Presbyterian/Weill Cornell in July 2018. He is double board certified in both physical medicine and rehabilitation (PM&R) and interventional pain

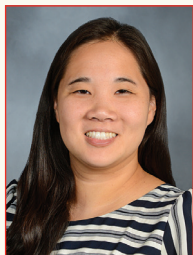
management. As a multi-sport athlete in high school and college, Dr. Mizrahi has always had a natural interest in musculoskeletal medicine, which led him to pursue his Doctor of Osteopathic Medicine degree from the New York College of Osteopathic Medicine. He completed his residency training in PM&R at the Icahn School of Medicine at Mount Sinai, where he served as chief resident. He then went on to complete a pain medicine fellowship through the Department of Anesthesiology at the University of Michigan in Ann Arbor.

Dr. Mizrahi routinely uses fluoroscopy or ultrasound as

guidance in treating disorders of the spine, musculoskeletal, and peripheral nervous system. He believes the first step in treating any patient is using a thorough history and physical exam to establish an accurate diagnosis. "My treatment philosophy is centered upon presenting all relevant options and discussing the risk/benefit of each, thereby empowering patients to make informed decisions and actively manage their own care," he says. "I see patients predominantly with low back, neck, and musculoskeletal pain who have tried conservative management such as physical therapy and medications without success." Dr. Mizrahi also practices at NewYork-Presbyterian Medical Group Brooklyn. Being born and raised in Brooklyn, this facilitates his ambition to provide high quality care to his local community members.

For More Information

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Jennifer A. Soo Hoo, MD

Dual board certified in sports medicine and physical medicine and rehabilitation, Dr. Jennifer A. Soo Hoo believes she has the best of both worlds. "I became interested in rehabilitation because the field focuses on function and getting patients back to doing what they love

to do," says Dr. Soo Hoo, who joined the Department of Rehabilitation Medicine at NewYork-Presbyterian/Weill Cornell in August 2018. "I played soccer in college and so I had a natural affinity to sports medicine and an appreciation of the musculoskeletal system. Like most student athletes, I had a lot of injuries, so I understand the psychological and emotional aspect of injuries, in addition to the biomechanical and structural aspects."

Dr. Soo Hoo attended Case Western Reserve University's

combined seven year undergraduate and medical school program. She subsequently completed residency training in physical medicine and rehabilitation at the University of Washington, where she also served as chief resident and won the Outstanding Resident Research Award. She then completed a fellowship in sports medicine at Northwestern University, McGaw Medical Center/Shirley Ryan AbilityLab (formerly known as the Rehabilitation Institute of Chicago).

Dr. Soo Hoo specializes in image-guided procedures to aid in the diagnosis and treatment of musculoskeletal and spine injuries, including musculoskeletal ultrasound and fluoroscopy. She has also been trained in regenerative medicine procedures, such as platelet-rich plasma injections. She is currently a travel team physician for the U.S. Soccer Youth Women's National Team and the U.S. Paralympic Soccer Team.

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Placental Allograft: A Regenerative Therapy for Osteoarthritis (continued from page 3)

Benefit of Placental Allograft over PRP

Injections of platelet-rich plasma (PRP) have been under intense study over the last five years, and Dr. Gellhorn notes that the data now supports the use of PRP. "Nonetheless, one of the main concerns with PRP is that it remains a non-standardized or poorly standardized treatment," he notes. "There are a variety of kits and different ways to produce the product in clinic, which can lead to problems. Because of this the FDA will not recognize the therapy in a way that is marketable nor is it covered by insurance. Although many of the theoretical reasons to use the placental allograft are similar to PRP, placental allograft is a standardized product and, as such, it can be developed as a drug, which is a primary benefit over PRP."

Dr. Gellhorn expects that the data on AmnioFix will be collected by the end of 2019, with published results shortly thereafter. "I'm hoping that we will find very positive results that we can rapidly turn over to the FDA for approval and subsequently move forward with additional trials for its use in other joints."

Reference Article

Gellhorn AC, Han A. The use of dehydrated human amnion/chorion membrane allograft injection for the treatment of tendinopathy or arthritis: A case series involving 40 patients. *PM&R*. 2017 Dec;9(12):1236-43.

For More Information

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Focus on Faculty



Hana Azizi, MD

Dr. Hana Azizi, a pediatric physiatrist, joined the Department of Rehabilitation and Regenerative Medicine at NewYork-Presbyterian/Columbia in July 2018.

Born in Iran, she earned her medical degree at Shiraz University of Medical Sciences, as well as a master's degree

in public health. She then completed residency training in physical medicine and rehabilitation at Montefiore Medical Center, followed by a pediatric rehabilitation fellowship at Rusk Rehabilitation Institute/New York University Langone Health.

Dr. Azizi, who specializes in the rehabilitation of children with brain, spinal cord, and musculoskeletal injuries, works closely with **Heakyung Kim, MD**, Chief of Pediatric Physiatry,

practicing at both Blythedale Children's Hospital – New York State's only independent specialty children's hospital – and NewYork-Presbyterian/Columbia.

"These children are not able to reach their normal milestones as other children their age," says Dr. Azizi. "By providing different treatments and therapies, we help them to achieve their milestones as much as possible to grow and develop normally. I have been able to connect with these children and their families very well. It gives me great joy to offer my help, and I often learn from them as well. They're strong-willed and they don't give up. They're resilient and try very hard to get better."

For More Information

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Monika Desai, MD

During medical school, a clinical rotation in physical medicine and rehabilitation (PM&R) opened Dr. Monika Desai's eyes to the world of rehabilitation medicine. "I was sold on the field after that rotation," says Dr. Desai, who joined NewYork-Presbyterian/Columbia in January 2018

specializing in pediatric rehabilitation. "I found myself drawn to the complexity of cases and interdisciplinary nature of pediatric rehabilitation medicine. I love working with children and developing relationships with them and their families. I am inspired by their resiliency and motivation to recover and excel."

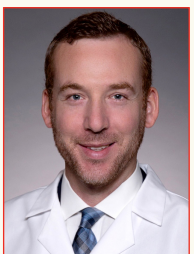
Dr. Desai earned her medical degree at St. George's University School of Medicine and completed her residency in PM&R, as well as fellowship training in pediatric rehabilitation, at Montefiore Medical Center/Albert Einstein School of Medicine.

Board certified in both physical medicine and rehabilitation and pediatric rehabilitation, her areas of clinical interest include adult and pediatric cerebral palsy, spasticity management, stroke, brain injury, concussion management, spina bifida, developmental delay, muscular dystrophy, and spinal cord injury.

In joining NewYork-Presbyterian, Dr. Desai particularly appreciates the ability to draw on the resources of a major academic medical center. "The wealth of research and the caliber of my colleagues are unparalleled," she says. "When you find experts in so many subspecialties in one institution, it helps to create continuity of multidisciplinary care and a better outcome for the patient."

For More Information

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Isaac P. Syrop, MD

Dr. Isaac P. Syrop joined the Department of Rehabilitation and Regenerative Medicine at NewYork-Presbyterian/Columbia in 2018, specializing in the treatment of patients of all ages with a wide range of musculoskeletal, sports, and spine injuries.

Double board certified in both physical

medicine and rehabilitation and sports medicine, he received his medical degree at the Albert Einstein College of Medicine, followed by residency training in PM&R at NewYork-Presbyterian and a fellowship in sports medicine at Stanford University.

Today, Dr. Syrop practices at the Department's offices in Scarsdale, Cold Spring, and Cortlandt Manor in Westchester County. "Having grown up in Westchester, it is nice to serve the community where I had my roots," he says.

Utilizing musculoskeletal ultrasound and regenerative treatments, Dr. Syrop employs a nonoperative and individualized approach that focuses on return to activity, maximizing function, and optimizing quality of life. "Everyone has their own playing field," he explains. "For a 90-year-old it might be walking out to get the mail. For professional athletes the field might be Yankee Stadium. My goal is to help all of my patients return to their highest level of function."

Dr. Syrop's research interests include regenerative medicine, musculoskeletal ultrasound, and athletic performance. He also lectures to audiences at both the local and national level and is an author of multiple journal articles, book chapters, newsletters, and academic blogs.

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