The Potential of Robotics: Making Strides in Spinal Cord Injury

In the United States alone, there are some 300,000 people living with spinal cord injury (SCI) and more than 17,000 new cases occur each year. Males account for 80 percent and generally injuries are due to vehicle crashes, falls, and acts of violence. The ability to recover functional movement – walking, standing, and balance – is difficult and often slow even for patients with incomplete injuries. However, studies have shown that activity-based therapies offer an encouraging approach to helping individuals with SCI. To that end, Sunil K. Agrawal, PhD, Professor of Mechanical Engineering and of Rehabilitation and Regenerative Medicine at Columbia University Irving Medical Center, has been leading research efforts in the development of novel robotic devices and interfaces that help patients retrain their movements.

In 2016, Dr. Agrawal’s current project – Tethered Pelvic Assist Device (TPAD) and Epidural Stimulation for Recovery of Standing in Spinal Cord Injured Patients – was awarded a five-year, $5 million grant from the New York State Spinal Cord Injury Research Board (SCIRB). The project is a collaboration with Co-Principal Investigator Susan Harkema, PhD.

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Helen Hayes Hospital: Providing a New Dimension to Rehabilitation Training

As part of their comprehensive training, residents in the Physical Medicine and Rehabilitation Residency Program at NewYork-Presbyterian benefit from a diverse and broad curriculum with exposure to clinical experiences in highly regarded institutions. “In order to train the next generation of physiatrists to be outstanding, we need to challenge them,” says Christopher J. Visco, MD, Ursula Corning Associate Professor and Vice Chair of Education in the Department of Rehabilitation and Regenerative Medicine at NewYork-Presbyterian. “And what better challenge is there than to care for patients who need rehabilitation the most – the kinds of patients cared for at Helen Hayes Hospital. These are patients with some of the most debilitating conditions, including those with spinal cord and brain injuries. Helen Hayes Hospital provides that advanced, specialized care, drawing patients from all over the country.”

Dr. Visco, who is also the Residency Program Director, cites Helen Hayes Hospital’s well-earned reputation for excellence in rehabilitation medicine. “The Hospital has exceptional educators who are...”
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and Enrico Rejc, PhD, Department of Neurological Surgery, University of Louisville, Kentucky, Spinal Cord Injury Research Center, and Joel Stein, MD, Chair of the Department of Rehabilitation and Regenerative Medicine at Columbia University Irving Medical Center. Dr. Agrawal, who is also Director of the Robotics and Rehabilitation Laboratory and Robotic Systems Engineering Laboratory at Columbia University, is focused on improving the effectiveness of stand/balance training during SCI rehabilitation by using the TPAD device developed in his Robotics and Rehabilitation (ROAR) Lab.

The TPAD is a cable-driven robot for studying force adaptation in human walking by applying external forces and moments on the human pelvis. Wearable and lightweight, the pelvic belt consists of multiple cables connected to motors, a real-time motion capture system, and a real-time controller to regulate the tensions in the cables. TPAD can be programmed to provide symmetric or asymmetric pelvic forces, as well as corrective or perturbative forces, in any direction and respond to motions of the human body.

Applying TPAD to Spinal Cord Injury

Dr. Agrawal and his team have previously conducted studies that have shown that a single session of therapy with TPAD improved gait function and reactive reactions to unexpected perturbations for a short amount of time in patients with Parkinson’s disease, the results of which were published in the December 19, 2017 issue of Scientific Reports.

In a study of children with cerebral palsy who commonly exhibit crouch gait, the Columbia researchers used TPAD to apply downward symmetric or asymmetric pelvic force. “We hypothesized that walking with a downward pelvic pull would strengthen extensor muscles, especially the soleus, against the applied downward pull and would improve muscle coordination during walking,” explains Dr. Agrawal. “We took an approach opposite to conventional therapy with these children. Instead of partial body weight suspension during treadmill walking, we trained participants to walk with a force augmentation, applying a downward force of 10 percent of their body weight while walking on the treadmill. Following training, the children were actually able to walk more erect as compared to before training.” Results of this study were published in the July 26, 2017 issue of Science Robotics.

Now in the next phase of the TPAD development, Dr. Agrawal and his team are addressing the major issue of poor body control associated with spinal cord injury. “A person with SCI may have poor control at the pelvis level, upper body chest area, or the knees,” says Dr. Agrawal. “The earlier TPAD device only augments control at the pelvis level. But in order to facilitate standing training, which is the objective of the SCIRB project, we had to provide active assistance and support at three levels of the human body. Essentially, we are creating three TPADs that cooperate with each other at different levels of the human body within the same system.”

When perturbed while standing, a person with SCI requires the assistance of several physical therapists to prevent falling. “The newest iteration of the TPAD would provide the right force assistance and the ability to rebalance and move around rather than being fixed in one position, allowing the person to maintain equilibrium, as well as the confidence of being able to stand and support oneself,” says Dr. Agrawal.

“In the first year, our goal was to put together this special device and we are very much there,” continues Dr. Agrawal. “In the next several months we plan to test TPAD on healthy individuals and then slowly transition to applying it to patients with spinal cord injury.”

Drs. Susan Harkema, Enrico Rejc, and their colleagues at the Kentucky Spinal Cord Injury Research Center have pioneered the use of activity-based rehabilitation for SCI patients and the use of epidural stimulation of the lumbosacral spinal cord during standing training. The researchers combine epidural stimulation and principles of motor learning and have successfully shown this strategy to benefit severely injured individuals. However, even though these patients are able to stand, they cannot maintain balance and therefore are unable to transfer this skill to activities of daily living.

Enter Dr. Agrawal and TPAD to provide the additional assistance needed. “When I visited Dr. Agrawal’s lab and observed their approach it was the first time that I saw something that could actually work with what we were doing scientifically.”

— Dr. Susan Harkema

it was the first time that I saw something that could actually work with what we were doing scientifically. I was incredibly impressed,” says Dr. Harkema. “We’re very excited about this collaboration. What is so powerful is that these robotic devices are tailored to work with new discoveries about the nervous system. From my perspective, Dr. Agrawal and the Columbia researchers are creating an elegant design and an interface with the individual that is as least intrusive as possible. With TPAD, a person can do as much as they are able, but if they go outside preset parameters, the device can then provide support to keep them safe.”

“Dr. Harkema and her team have designed ways to use already available spinal cord stimulators that were shown to be effective in prodding the individual’s capability to stand and do things that they could not otherwise do paralyzed,” says Dr. Agrawal. “One of the challenges in their program is that each patient undergoes 70 to 80 sessions of several hours of training over many days and months. During each session, several trainers work with the individual, trying to balance them and perturb them simultaneously so that slowly they can get their balance back.”

The approach is time and labor intensive, prompting the Kentucky researchers to look to a robotic device that would provide similar capabilities and be available to more patients over time. “We’ve been discovering that the nervous system, especially after injury, relies on

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leaders in the field. During their residency rotations at Helen Hayes, our junior and senior trainees are exposed to inpatient care, work with advanced adaptive technology solutions, and participate in high-level planning and fabrication of prosthetics and orthotics.”

Located in Haverstraw, New York, some 40 miles north of Manhattan on a 100-acre campus, Helen Hayes Hospital is renowned for its application of the most sophisticated technology and innovative research-based rehabilitation techniques to patient care. The 155-bed, New York State-operated hospital provides therapeutic care on an inpatient and outpatient basis for individuals of all ages with a wide array of disabilities and conditions, including spinal cord injury, stroke, traumatic brain injury, cardiac and pulmonary disorders, amputations, joint replacements, cerebral palsy, and neurological disorders.

The Hospital’s programs include its nationally recognized Center for Rehabilitation Technology, which provides advanced adaptive technology solutions. Aquatic therapies and a Smart Apartment – a working replica of a home outfitted with adaptive technology solutions for daily living – are among the many approaches employed to maximize recovery and help patients gain independence.

Rehabilitation Training in Complex Cases

The strength of the Spinal Cord Injury Rehabilitation Program at Helen Hayes Hospital is its capacity to address all of the complex effects of spinal cord injury, including paraplegia and quadriplegia, respiratory disorders, bowel and bladder dysfunction, wound care and spasticity, as well as emotional and psychological issues related to adjustment to a new way of life. Patients with spinal cord injury are admitted directly to a specially designed and equipped unit with round-the-clock monitoring and the capability to care for patients with feeding tubes and ventilators.

Dr. Visco believes the experience of working with patients facing life-altering injuries and diseases that challenge the human resilience and spirit is particularly educational for the residents. “At Helen Hayes, our residents experience training that can change their understanding of recovery,” says Dr. Visco. “They work with patients wrestling in many ways with some of the most challenging medical circumstances.”

Victoria Lent, MD, Director of Spinal Cord Rehabilitation Services at Helen Hayes Hospital, and Maria A. Boiano, DO, oversee the PGY2 residents, whose seven-week rotation focuses on patients with spinal cord, traumatic brain, and multi-trauma injuries, as well as amputation, burns, and cardiopulmonary issues. “These residents are very new to rehabilitation,” says Dr. Lent. “Training for the PGY2 residents at Helen Hayes Hospital is much less about service and documentation requirements and much more experiential. We want them to spend time getting to know the patients and their stories, interacting with them and observing them as they go through their therapies, and gaining an understanding of what the rehabilitation process is like for them.”

On the inpatient unit, Dr. Lent notes that residents benefit from understanding the medical issues that patients with spinal cord injuries or an amputation face. “The residents learn about the medical issues to consider acutely and down the line, and also appreciate the roles of the various team members that comprise the patient’s rehabilitation process.”

Training also emphasizes multiple modalities in pain management. “We consult with the anesthesia group, as well as the neurologists, for some of the most complex patients,” Dr. Boiano says. “Pain and spasticity management is a team effort. On the inpatient side we work with our psychiatry and psychology colleagues who offer non-pharmacological methods for managing pain. I can offer osteopathic techniques and acupuncture. Physical and occupational therapy, heat and ice, and electrical stimulation all play a role in managing pain. Our residents receive a complete picture of care in this area.”

“In addition, the residents come with us to the clinic so they can see the continuity of care in the whole spectrum of rehabilitation from acute to more chronic issues,” says Dr. Lent. The outpatient clinic experience includes participation in special programs such as the Adaptive Driving Program for hemiplegic patients, which occurs in a simulated setting and with an adapted van with hand controls.

“The technology component of training at Helen Hayes is remarkable,” notes Dr. Visco. “Voice-activated systems and motion and touch sensors available through the Hospital’s Center for Rehabilitation Technology support those activities that are so important for daily life.”

Dr. Lent is also pursuing research on exoskeletons. “Though exoskeletons have been around for some time, we’re doing research in order to find out the value beyond gait training that might come (continued on page 4)
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“Dr. Harkema and her team have designed ways to use already available spinal cord stimulators that were shown to be effective in prodding the individual’s capability to stand and do things that they could not otherwise do paralyzed.” — Dr. Sunil K. Agrawal

key sensory signals from the environment to function or relearn how to do a task,” says Dr. Harkema. “Integrating information from the environment, as well as any residual information that might still be crossing the injury from supraspinal centers, and practicing those over and over again with the right kinematic for that task, we believe one could regain the ability to do that task. The TPAD device can pay close attention to sensory cues and potentially accelerate the learning of the task, or relearning sitting, standing, sit-to-stand, or maybe, eventually, stepping and walking.”

“Devices like TPAD are valuable in so many rehabilitation settings,” adds Dr. Agrawal. “Integrating technology can be great to collect quantitative data, as well as providing a very controlled experience to individuals as they’re undergoing these therapeutics.”

“Looking to the future,” notes Dr. Harkema, “I believe that these types of robotic training devices, which are much more consistent with what we’re doing, will continue to be developed and refined, and hopefully enable people with the most severe injuries to be much more functional in the home and in the community.”

**Reference Articles**

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from using some of these devices,” she says. “There are bowel and bladder control effects, spasticity and pain reduction, and these benefits are not clearly understood.” Dr. Lent believes this type of research is another vital component of the training residents receive at Helen Hayes Hospital.

“Many of our patients have had life-changing events, but the acute care facilities they have come from do not necessarily prepare them to transition to their next phase of life,” says Dr. Boiano. “I love that the residents can see that we do our best as a team to educate and transition our patients for what comes next in their lives. They don’t simply witness this; they participate in the process.”

Neal Rakesh, MD, PGY2, has had an interest in applying technology to patient care since his undergraduate years at the University of Michigan, where he studied biomedical engineering. “I was particularly interested in the brain/computer interface at the time, which essentially can create a physical manifestation of something neurologic,” says Dr. Rakesh.

His interest in technology continued into medical school where he gravitated toward a field that involved technological advances. “Rehabilitation medicine is advancing more quickly in technology than other specialties,” says Dr. Rakesh. When considering residency programs, Dr. Rakesh was drawn to the work of Joel Stein, MD, Physiatrist-in-Chief at NewYork-Presbyterian.

“Dr. Stein had the vision of implementing technology as a means to gauge someone’s recovery or to enhance someone’s overall functioning,” says Dr. Rakesh. “That excited me as well, resulting in my foray into the rehabilitation world.”

For Dr. Rakesh, the residency rotation at Helen Hayes Hospital affords him the opportunity to further explore his passion for technology with real-life applications to help patients with injuries to the spinal cord. “I’m fascinated by the spinal cord as it relates to being able to control the function of limbs and internal organs and regulation of temperature and blood pressure,” he says. “The more you understand about the spinal cord, the better you are able to treat your patients.”

The more seasoned PGY4 residents work under the supervision of Glenn M. Seliger, MD, Director of Traumatic Brain Injury Rehabilitation Services at Helen Hayes Hospital. This rotation includes medical management of inpatient comorbidities, such as hypertension, diabetes, coronary artery disease, and COPD.

“When the residents come back from their rotations at Helen Hayes Hospital, they perform at a higher level in the subspecialty domains of spinal cord injury and brain injury,” Dr. Visco says. “We’re very pleased with our association and the extraordinary training our residents undergo with the team at Helen Hayes.”

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Cerebral Palsy: The Benefit of Multilevel Botox Injections

Spasticity in the lower limb is often painful and disabling for children with cerebral palsy and other movement disorders. Leg spasticity makes walking and maintaining balance more difficult in 80 percent of children with the condition. Today, however, with the FDA approval of Dysport® (abobotulinumtoxinA) injection for children ages 2 and older, there is a new therapy that has been shown to effectively improve muscle tone and movement ability.

For more than 20 years, Heakyung Kim, MD, A. David Gurewitsch Professor and Director of Pediatric Physical Medicine and Rehabilitation at NewYork-Presbyterian, has been a proponent of botulinum toxin injection for lower limb spasticity in children with cerebral palsy (CP). “With these injections we’ve seen that the children walk better, faster, and are less tired,” says Dr. Kim, who is currently collaborating with Adam R. Blanchard, MS, ACSM EP-C, an exercise physiologist in the Department of Rehabilitation and Regenerative Medicine at NewYork-Presbyterian/Columbia University Irving Medical Center, on a pilot study to determine the efficacy of a Single Event, Multilevel Chemoneurolysis (SEMLC) with Dysport.

The Columbia study follows a 2016 phase 3 clinical trial of Dysport conducted in children and teens ages 2 to 17 that showed improvement in walking and balance, decreased falling and tripping, and increased endurance.

“In our study we’re aiming to see if this botulinum toxin is improving balance control and gait and saving energy expenditure while the children are walking,” says Dr. Kim, who is the Principal Investigator. The single site investigation is seeking to recruit 12 to 16 children diagnosed with diplegic cerebral palsy, ages 5 to 17, who can walk independently with or without assistive devices.

“Most procedures for botulinum toxin injections to the lower limbs target a limited number of muscles,” says Dr. Kim. “My treatment approach is to do Single Event Multilevel Chemoneurolysis (SEMLC), which is a multilevel injection, including not only the major muscle groups, but also including small groups, in a single treatment session. This could include anywhere from 15 to 25 injections in one session.”

“A previous study involved administering this drug in a single muscle group in the gastrocnemius or the soleus,” says Mr. Blanchard. “The areas of Dr. Kim’s injections are selected on an individual basis. One child might have spasticity in three muscles, and another child may have spasticity in different muscles. We try to tackle each point of their spasticity in their lower limbs.”

A Multidimensional Analysis

The children are videotaped walking pre- and post-SEMLC and the tapes are reviewed using a detailed objective coding system that analyzes balance control components, postural sway, movement awareness, dynamic trunk control, motor planning, attention, foot posture, and gait parameters during walking. Range-of-motion measurements pre- and post-SEMLC are reviewed for the hip flexors, knee flexors, and ankle plantar flexors. Patients are also tested via the Modified Ashworth and Modified Tardieu scales and answer a CP quality-of-life inventory questionnaire.

“The gait analysis is performed using a gait map with sensors laid out on the floor,” explains Mr. Blanchard. “It records data such as speed and where their foot falls on the map. During walking, the child wears a mask that records oxygen consumption [VO₂] and how heavy he or she is breathing. Our hypothesis is that their oxygen consumption is going to be higher at baseline, but lower following injections and that this drug will make it easier for them to walk.”

Mr. Blanchard notes that the VO₂ equipment used is novel as well. “It is a mobile device so we are able to use it while the patients walk in a hallway. This is more natural than walking on a treadmill or riding a stationary bike, which for some of these children can be very difficult. We can also do it right in the clinic.”

At a four-week follow-up and again at three months post-injections, patients are retested with a six-minute walk with submaximal or walking oxygen consumption, gait analysis, and repeat the quality-of-life questionnaire and measurement scales for spasticity.

“The medication takes time to work; the great outcomes start to appear two to four weeks after the injections and can last up to three to four months,” says Dr. Kim.

Another goal is to not only improve function, but also maintain current function. “If we don’t control muscle stiffness with botulinum toxin or with orthopedic surgery and/or physical therapy, a certain percentage of children with CP who were once able to walk will no longer be able to walk by their teenage years,” says Dr. Kim.

“We see such a decrease in function as these children grow into adulthood,” adds Mr. Blanchard. “Hopefully, we’ll be able to combat that. By improving their oxygen consumption, they can walk easier, participate in more physical activity, and be out in the community more often.”

“This approach promises real benefits for children with CP,” says Dr. Kim. “Many times, when we recommend botulinum toxin injection, parents are afraid it will make their child weak or lose energy. I want to demonstrate through this study that the botulinum toxin will help the children to walk better and give them more energy. If this pilot study goes well, we will expand it to a multicenter trial.”

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