

New Research Seeks to Restore Functional Control of Arm and Hand for Those With Quadriplegia

Grant for \$3 million from the U.S. Department of Defense supports the work being done at University Hospitals, Case Western Reserve University and the Cleveland FES Center.



ReHAB

Reconnecting the Hand and Arm to the Brain



Bolu Ajiboye, PhD, lead investigator on the study, associate professor of biomedical engineering at Case Western Reserve and research associate at the Cleveland FES Center and Louis Stokes Cleveland VA Medical FES Center.



Jonathan Miller, MD, director of Functional Neurosurgery at University Hospitals, associate director of clinical affairs at the Cleveland FES Center, and professor of neurological surgery at Case Western Reserve School of Medicine.



Robert Kirsch, PhD, executive director of the Cleveland FES Center and chair of Case Western Reserve University's department of biomedical engineering.

In science, an N of 1 is rarely enough to support any big conclusions-no matter how significant the results.

That even applies to the story of Bill Kochevar, the Cleveland man who became the first person with quadriplegia in the world to regain functional control of his arm and hand using technology implanted in his brain and limb.

Kochevar, who had been paralyzed from the shoulders down in a bicycling accident in 2006, participated in a study at the Cleveland FES Center and Case Western Reserve University, where researchers implanted two micro-electrode arrays in his motor cortex to capture his brain activity and electrodes in the muscles of his upper and lower arm to stimulate his arm and fingers. A computer interface using mathematical algorithms translated his thoughts into electrical impulses that controlled his muscles. Robert Kirsch, executive director of the Cleveland FES Center and chair of Case Western Reserve University's department of biomedical engineering

"We had a lot of success with Bill," says Robert Kirsch, executive director of the Cleveland FES Center and chair of Case Western Reserve University's department of biomedical engineering. "We learned that we could do this. We learned a lot of other things as well, including about better ways to do [this research] in the future."

When Kochevar died in December 2017, just a few months after the research was published in The Lancet and featured worldwide by the BBC, CBS News, NPR and more, it caused Kirsch and the other researchers to pause and evaluate where to go next. After more than a year of reflecting on the best ways forward, they are poised to launch a feasibility study of the Reconnecting the Hand and Arm to the Brain (ReHAB) System, a greatly enhanced version of the technology used with Kochevar.

The research, which builds upon six years worth of work, is being funded with a \$3 million grant from the United States Department of Defense. With Food and Drug Administration approval for up to 12 participants for initial 13-month trials, the first individual is expected to begin the trial in early 2020 followed by additional subjects every nine months or so.

"It's time to start doing this with more people and looking at variations across people," says Kirsch.

Here is how ReHAB builds upon previous lines of research and hopes to break new ground.

Wrap Beats

In Kochevar's case, researchers implanted electrodes through the skin into neuromuscular junctions using hypodermic needles. This allowed the electrodes to be easily removed, but they were also somewhat imprecise in their placement. "He was able, by the end, to control his hand and his forearm very precisely," says Jonathan Miller, director of Functional Neurosurgery at University Hospitals, associate director of clinical affairs at the Cleveland FES Center, and professor of neurological surgery at Case Western Reserve School of Medicine. Yet, because the electrodes were inserted directly into the muscle, there were issues controlling the strength of the contractions and limitations on what muscles were able to be activated.

The ReHAB study employs specialized nerve cuffs, developed by Cleveland FES Center investigator Dustin Tyler at Case Western Reserve, which fold around the nerve and offer much greater precision in the placement and intensity of the stimulation. "That leverages the body's own natural organization," says Miller. "By stimulating nerves, we're able to activate muscles the way that the body normally activates them."

Six Pack

Researchers working with Kochevar implanted two 96-electrode arrays in the motor cortex to capture brain activity associated with hand and arm movement. The ReHAB system includes six, smaller 64-electrode micro-arrays placed in both the motor and sensory cortex, and areas associated with intended movement. "The brain doesn't think in one straight line. It's not like information starts one place and then jumps to another place," says Miller. "It happens all at once and in a lot of different places. Everything that happens in the brain is distributed over a widespread area that works together and along these networks."

Feedback Loop

By collecting information over a larger area of the brain and tapping into a variety of neural nodes,

researchers hope to collect much more detailed information than ever before. In addition, ReHAB won't just gather information from the brain, but will also return information about touch and spatial alignment back to the brain from the hand and arm. "That's been a major problem with a lot of these prosthetic technologies," says Miller. "There's not adequate feedback to tell exactly how much force is being applied. We're hoping to stimulate the brain to mimic sensation, so participants will be able to feel again and, ideally, even recognize where the arm is in space."

Deeper Pool

Expanding the number of participants brings its own opportunities and challenges. Work with Kochevar could be individualized, while ReHAB will need to be more consistent in its methods. "Obviously, when you scale a project up, it becomes more complicated," says Miller. Yet, working across individual differences should provide a broader understanding of brain and neural function. Eventually, that knowledge could speed up the pace of development. "We're hoping we can find some more general organizing principles that aren't so sensitive to small differences in where the electrodes are placed or the person's history," says Kirsch. "If we can figure that out, then we can at least have a broad algorithm that we start with."

Broader Reach

Researchers hope to expand the ReHAB study beyond individuals with spinal cord injuries, which impacts approximately 291,000 people in the United States. So they're recruiting participants beyond that population to possibly include those affected by stroke, multiple sclerosis, or spinal cord disfunction due to tumors or radiation damage. "You need to be able to show that this isn't just something working for one person," says Miller. "There are things that are translatable and potentially generalizable across many people, because eventually our goal is to make this clinical tool."



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About the Cleveland FES Center

The Cleveland FES Center is a consortium of the Louis Stokes Cleveland VA Medical Center, MetroHealth Medical Center, Case Western Reserve University, University Hospitals, and the Cleveland Clinic Neurological Institute. With their support, researchers, engineers and clinicians collaborate together to develop innovative solutions that improve the quality of life of individuals with neurological or other muscular skeletal impairments. Through the use of neurostimulation and neuromodulation research and applications, the Cleveland FES Center leads the translation of this technology into clinical deployment.



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