

Brain-computer interface, developed at Brown, begins new clinical trial

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BrainGate, an investigational technology being developed to detect brain signals and to allow people with paralysis to use those signals to control assistive devices, is about to begin a second, larger clinical trial. The system is based on neuroscience, engineering and computer science research at Brown University.

The BrainGate2 pilot clinical trial is taking place at Massachusetts General Hospital (MGH), in close collaboration with an interdisciplinary team of researchers from MGH and Brown University. The study has been approved by the MGH Institutional Review Board to begin recruiting participants. The trial extends prior safety and feasibility research of the BrainGate Neural Interface System, which consists of an implanted baby aspirin-size brain sensor that reads brain signals and computer technology that interprets these signals. The BrainGate Neural System may allow people with paralysis to control assistive devices.

The new clinical trial is part of a larger BrainGate research effort, the ultimate goal of which is to help patients with spinal cord injury, stroke, muscular dystrophy, amyotrophic lateral sclerosis (ALS) or limb loss turn their thoughts into actions, restoring independence, mobility, and communication. The work to date with BrainGate trial participants has explored their ability to control robotic limbs, operate computer software and drive a wheelchair. New research will help advance the pilot system. (See also A BrainGate Timeline.)

BrainGate is based on research and technology developed in the



laboratory of John Donoghue, the Henry Merritt Wriston Professor of Neuroscience at Brown and director of the Brown Institute for Brain Science. Arto Nurmikko, professor of engineering, and Michael Black, professor of computer science, are also key research partners on this team. More than a dozen Brown undergraduate and graduate students have helped advance the research and technology.

Two Brown faculty members are leading the research: Donoghue and Dr. Leigh Hochberg, associate professor of engineering at Brown and a vascular and critical care neurologist at MGH, Brigham and Women's Hospital, and Spaulding Rehabilitation Hospital. Hochberg is also affiliated with Harvard Medical School and the VA Medical Center in Providence.

The new trial is taking place at a time of great promise for neurotechnology research. "We are entering a new age of neurotechnology. Our fundamental understanding of the nervous system, combined with advances in engineering, may help people with brain and spinal cord injuries and diseases," Donoghue said.

"We are working to develop and test new technologies that we hope will help patients with devastating illnesses that limit their ability to move or to speak," Hochberg said. "The goal of our research is to harness the brain signals that ordinarily accompany movement and to translate those signals into actions on a computer, like moving a cursor on the screen, or the movement of a robotic or prosthetic limb."

A previous clinical trial run by Cyberkinetics Neurotechnology Systems Inc., together with researchers at MGH and Brown, demonstrated that the neural signals associated with the intent to move a limb can be "decoded" by a computer in real time and used to operate external devices. The BrainGate Neural Interface System involves a sensor placed on a part of a study participant's brain called the motor cortex. During



earlier research sessions, a computer was connected to the sensor through a pedestal on the participant's head, allowing the participants to control a computer cursor by simply thinking about the movement of their own paralyzed hand.

"We learned an incredible amount with the assistance of the first participants in the BrainGate trial, not only about how the motor cortex continues to work after paralyzing illness or injury, but also about how to harness these powerful intracortical signals for controlling computers and other assistive devices," Hochberg said.

For financial reasons, Cyberkinetics stopped funding the trial and withdrew from the research. Cyberkinetics had launched in 2001, based on research and technology developed in Donoghue's lab.

The clinical research continues through this multidisciplinary, multi-institutional effort. A new academically based Investigational Device Exemption (IDE) application — BrainGate2 — was developed in 2008 to follow up on research previously published in peer-reviewed journals. Hochberg will direct the BrainGate2 <u>clinical trials</u> through MGH in close collaboration with researchers at Brown University and Providence VA Medical Center.

The BrainGate2 trials will expand on previous research, honing the hardware and software that decode the brain signals used to move a cursor on a screen. The IDE is part of a larger research effort, the goals of which include developing point-and-click capabilities on a computer screen, controlling a prosthetic limb or a robotic arm, controlling functional electrical stimulation (FES) of nerves disconnected from the brain due to paralysis, and further expanding the neuroscience underlying the field of intracortical neurotechnology. The research is focused not only on the ability to operate a computer but also to assist people with ALS, spinal cord in jury and brainstem stroke to control their



environment.

"Through ongoing development and testing, it is hoped that these technologies will eventually help to improve the communication, mobility and independence of people with severe paralysis," Hochberg said.

People with these types of paralysis have at least two characteristics in common: a brain that is capable of directing movement and a body that fails to respond. Beyond the current clinical trial, the ultimate goal of the BrainGate research effort is to provide a new pathway for brain signals to control external devices such as computers or even one's own limbs that have been "disconnected" from the brain due to paralysis or limb loss.

Source: Brown University (<u>news</u>: <u>web</u>)

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