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Synchron Announces Positive Results From Stentrode BCI Study, Plans For Pivotal Study

by Marion Webb

After announcing positive results showing that its Stentrode BCI is safe in six patients, brain-computer interface company Synchron is planning a pivotal trial to eventually file for FDA approval.

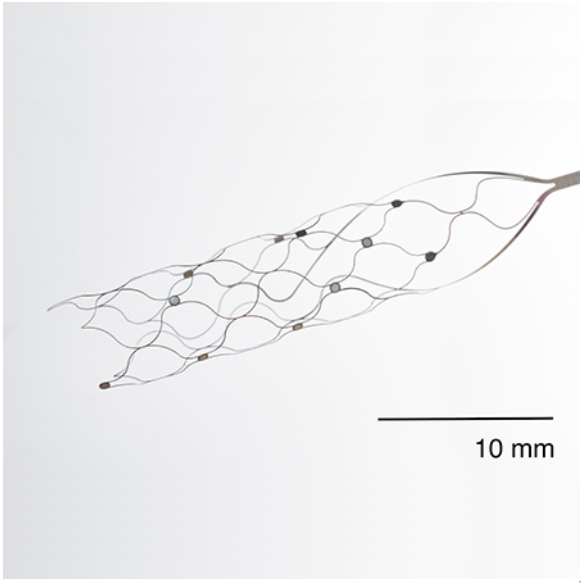
Brain-computer interface (BCI) developer *Synchron, Inc.* reached another milestone by announcing positive results of its latest study at the 2024 Congress of Neurological Surgeons today.

Elad Levy, co-principal investigator of the COMMAND study and chair of neurosurgery at State University of New York at Buffalo, presented results showing that six patients with severe chronic bilateral upper-limb paralysis, who were evaluated over a 12-month period after they received the BCI implant, reported no serious adverse events related to the Stentrode implant.

Levy describes the clinical findings as “a major milestone” and adds that Synchron’s “minimally invasive approach has the potential to unlock BCI technology at scale for the millions of patients with paralysis and other mobility challenges.”

Synchron’s BCI differs from Elon Musk’s *Neurolink, Inc.* brain implant start-up by not requiring open brain surgery. Instead, Synchron’s Stentrode is inserted through the jugular vein to the blood vessel that sits near the brain’s motor cortex, the part of the brain that controls voluntary movement. (Also see "*‘Mental Health, Beyond Medication’: Motif Targets Depression With Minimally Invasive DOT*" - Medtech Insight, 16 May, 2024.)

The stent-like device is connected by the lead to a smaller receiver-transmitter in the chest,



Source: Synchron

which wirelessly sends data to an external digital device. Once implanted, which takes about 20 minutes, the BCI aims to detect and wirelessly transmit movement intentions out of the brain, allowing patients with paralysis to control personal devices hand-free.

The study also showed that the device was successfully deployed in all six patients with 100% accuracy in targeting the motor cortex. It showed that brain signals associated with motor intent could be reliably captured and converted into digital motor outputs, enabling severely paralyzed people to complete a variety of digital tasks hand-free. Indeed, Synchron has shown with technology development partners such as *Apple Inc.* and Amazon that its BCI could be used by people with severe mobility issues to perform "a broad array of different activities to control their environment," Kurt Haggstrom, Synchron's chief commercial officer, told *Medtech Insight* in an interview today.

Synchron

In July, Synchron published a video showing a patient with amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, successfully using his thoughts to interact with Amazon's Alexa to do multiple tasks, such as turn on lights and make video calls. That same month, the company announced a 64-year-old man with ALS successfully used his thoughts to control the cursor of the Apple Vision Pro, a spatial computing system.

The COMMAND study is the first US Food and Drug Administration-approved investigational device exemption (IDE) trial of a permanently implanted BCI. (Also see "*Digital Health Roundup: Brain Talk On Seizures, Alzheimer's, Stress, Anxiety; Medtronic's OR Report; Health Care AI; UK Guidances*" - Medtech Insight, 23 Jul, 2024.)

Now that the company has completed the COMMAND study, it will move into the pivotal trial, which Haggstrom expects will be a "phased approach starting probably early next year." When asked about what the endpoints will be for the study, Haggstrom notes that this is something the

company is still discussing with the FDA.

In March, Mass General Brigham established the Implantable Brain-Computer Interface Collaborative Community (iBCI-CC), which focuses on fostering collaboration among diverse stakeholders to accelerate the development, safety and accessibility of iBCI technologies. Along with the FDA Center for Devices and Radiological Health, participating organizations include BCI developers Neuralink, *Precision Neuroscience Corp.*, Blackrock Neurotech and the BCI Society.

Last week, Haggstrom said the FDA held a workshop with all the BCI developers in attendance as well as advocacy groups, clinicians and other stakeholders, focusing on just that – clinical outcome measurements and how "to refine our thinking what need to be looking at for endpoints without making it to overly complex to get a product like this to market … and with clear lines of safety and benefit."

The next clinical studies will be using Synchron's next-generation BCI, which will replace the external battery with an internal battery and use Bluetooth wireless technology rather than the current infrared system to transmit data, he said. An internalized battery offers users the benefit of being able to "move around the house or outside," and thus, be more independent.

Haggstrom said for the remainder of this year and into early next year, Synchron's focus will be on the patient registry on Synchron's website that connects patients, cargivers, and medical professionals to learn about the company's BCI technology and help Synchron prepare for the next stage of clinical trials.

"In the next couple of years, we want to get into that pivotal trial and after that we anticipate some follow-up from a safety standpoint whether it's six-months, 12-months … and then after that we'll be in that commercial environment [pending FDA clearance]," he said.

Synchron received Breakthrough Device Designation from the FDA in August 2020 for its Stentrode BCI device. Haggstrom says Synchron has a three- to four-year head start on its competition and hopes to be on the market with a BCI device in four to five years.

Looking out 10 years from now, Haggstrom predicts that BCIs may potentially be in a broader population, such as helping people with a stroke who may not be able to move one side of their body regain independence with a motor neuroprosthesis, a device that helps restore motor function by stimulating neural structure with electricity.

"From an FDA standpoint, we have to safely go from where the highest need is and then you start to understand the risk-benefit ratio and then it starts to move to other folks that could absolutely have benefit," Haggstrom explained. He predicted that within the 10-year window we could see BCIs being developed for people with severe impairments, but also for people with more

moderate impairments.