AAN 74th ANNUAL MEETING ABSTRACT

Media Contacts:
Renee Tessman, rtessman@aan.com , (612) 928-6137
Natalie Conrad, nconrad@aan.com, (612) 928-6164

EMBARGOED FOR RELEASE UNTIL 4 P.M. ET, TUESDAY, MARCH 29, 2022

Abstract Title: Long-Term Safety of a Fully Implanted Endovascular Brain-Computer Interface for Severe Paralysis: Results of SWITCH, a First-in-Human Study

Authors: Bruce Campbell[1], Chiu Mun Sarah Lee[2], Peter Yoo[3], Andrew Morokoff[4], Rahul Sharma[5], Christopher MacIsaac[1], Steven Bush[1], James Bennett[3], Zafar Faraz[3], Edward Karst[3], Natalie DeWitt[3], Lia Madariaga[3], Gil Rind[3], Ivan Vrljic[1], Anna Balabanski[1], Katharine Drummond[1], Patricia Desmond[1], Douglas Weber[6], Timothy Denison[7], Susan Mathers[2], Terence O'Brien[8], J Mocco[9], David Grayden[4], Nicholas Opie[3], Thomas Oxley[3], Peter Mitchell[1]

[1]Royal Melbourne Hospital, [2]Calvary Bethlehem Hospital, [3]Synchron, [4]University of Melbourne, [5]Stanford University, [6]Carnegie Mellon University, [7]Oxford University, [8]The Alfred Hospital Melbourne, [9]Mount Sinai

Objective: To assess safety of an endovascular motor neuroprosthesis (MNP) and feasibility of using the implant to control a computer by thought.

Background: The MNP provides direct communication between the brain and an external device by recording and decoding signals from the precentral gyrus as the result of movement intention. To date, implantation of MNPs has required surgery involving removal of a portion of the skull and placement of electrodes on the brain. A recently developed minimally invasive MNP reaches the brain by vascular access, without need for a craniotomy.

Design/Methods: Subjects with paralysis were implanted with the endovascular device (Stentrode, Synchron, Brooklyn, NY) using a catheter to guide placement in the superior sagittal sinus. The device was attached to an electronics unit in a subcutaneous pocket to relay brain signals from the motor cortex into commands for a laptop computer. Safety endpoints were device-related serious adverse events resulting in death or increased disability during the 12-month post-implant evaluation period, and target vessel patency and incidence of device migration at 3 and 12 months. The study also recorded signal fidelity and stability over 12 months and use of the brain-computer interface to perform routine digital tasks.

Results: The study enrolled five subjects with amyotrophic lateral sclerosis; four had suitable anatomy and underwent the implant procedure. All four subjects successfully completed the 12-month follow-up with no serious adverse events. Post-operative imaging demonstrated patent blood vessels in all subjects and no device migration. All subjects learned to use the MNP with eye tracking for routine computer use. The decoder developed during the study allowed the final participant to control a computer independently without an eye tracker.

Conclusions: In a first-in-human study, four subjects were implanted with an endovascular brain-computer interface. The study met its safety endpoints, allowing subjects with paralysis to operate a computer for daily tasks.

Study Support: The study was supported by Synchron Inc., the maker of the device, the U.S. Defense Advanced Research Projects Agency, the Office of Naval Research, the National Health and Medical Research Council of Australia, the Australian Federal Government Foundation and the Motor Neurone Disease Research Institute of Australia.