GREAT LAKES NEUROTECHNOLOGIES

PRESS RELEASE

GREAT LAKES NEUROTECH PILOT STUDIES DEMONSTRATE COMPUTER GUIDED ALGORITHMS FOR PROGRAMMING DEEP BRAIN STIMULATION IN PARKINSON'S DISEASE

06 FEB 2015: Valley View, OH – Great Lakes NeuroTechnologies announced today they have completed two pilot studies [http://glneurotech.com/kinesia/validation/dbs-pilot-study/] demonstrating computer-guided algorithms for programming deep brain stimulation (DBS) in Parkinson's disease. The first study, in collaboration with the University of Minnesota and recently accepted for publication in *Parkinsonism and Related Disorders* [http://glneurotech.com/kinesia/publications/], used intelligent algorithms to navigate the programming space after a clinician-guided programming session and select DBS settings to optimize motor benefit and maximize battery life. The second study, in collaboration with the University of Cincinnati, built on that success with computer-guided algorithms to both recommend stimulation changes during programming and calculate optimal final settings.

Parkinson's disease impacts quality of life for millions of people around the world. Tremor, slowed movements, episodes of freezing, gait abnormalities, and therapy side effects that result in abnormal movements can have a major impact on quality of life and activities of daily living. GLNT commercialized Kinesia [http://glneurotech.com/kinesia/] technology to assess and visualize these types of movement disorder symptoms for in-clinic and telemedicine applications. Kinesia technology is FDA cleared to market, CE marked, and is TGA and Health Canada approved. "Over the last decade our research and development team has launched several mobile applications with intelligent algorithms based on patient-worn sensors to quantify Parkinson's symptoms", says Joseph P. Giuffrida, PhD, President and Principal Investigator. "As options for therapies such as DBS and drug delivery systems become more targeted, they can also become more complicated to use. A natural extension and growth opportunity for our Kinesia platform is to integrate directly with these therapies. This may minimize setup and programming with intelligent closed-loop sensing strategies that can adjust a patient's therapy in direct response to measured symptoms."

Deep brain stimulation is a well-established treatment for Parkinson's disease. In the first study, nine PD subjects underwent clinician-guided DBS programming. Stimulation settings were assessed and subjects performed motor tasks while wearing a sensor to quantify tremor and bradykinesia. An experienced clinician determined final stimulation settings using standard practices. Sensor-based ratings of motor symptom severities collected during programming were then used to develop automated programming algorithms to optimize symptom benefit and battery life. Therapeutic benefit was compared between the final clinician-determined DBS settings and those calculated by the automated algorithm. Settings determined using the symptom optimization algorithm would have reduced motor symptoms by an additional 13% compared to clinician settings, typically at the expense of increased stimulation amplitude. By adding a battery life constraint, the algorithm would have been able to decrease stimulation amplitude by an average of 50% while maintaining the level of therapeutic benefit observed using clinician settings for a significant subset of programming sessions. This study was accepted for publication in *Parkinsonism and Related Disorders*, Feb 2015.

GREAT LAKES NEUROTECHNOLOGIES 216-361-5410 10055 Sweet Valley Drive
Valley View, OH 44125
www.glneurotech.com

The second study built upon those results with seven PD subjects utilizing computer-guided algorithms to recommend stimulation changes during a programming session as well as to determine optimal final settings. The automated computer-guided algorithms improved motor outcomes by 38%, which is similar to reported results of clinician-guided programming. “Computerized and automated systems to program deep brain stimulation can provide significant benefit to the patient care market in Parkinson’s disease” says Christopher Pulliam, PhD, Biomedical Researcher. “Kinesia technology can expand expert care to non-expert clinical centers and underserved populations, and potentially reduce required clinician time for reviewing a complex number of possible stimulation settings during a programming session”.

In 2014, Great Lakes NeuroTechnologies received allowance of claims from the U.S. Patent Office (Pat. No. 8,679,038) covering a system and method of controlling Parkinson’s therapy in response to motor symptoms. The allowed claims include a portable system for measuring, quantifying, and treating Parkinson’s disease, based on a calculated severity of tremor, bradykinesia, rigidity, or dyskinesia. The claims also include sensors for detecting Parkinson’s symptoms, calculating symptom severity, and then controlling therapy, such as deep brain stimulation or drug release in response to symptom severity.

The company thanked the National Institute of Health for supporting this development through the SBIR program, specifically the National Institute of Neurological Disorders and Stroke and the National Institute on Aging (1R43NS081902 and R44AG033520).

About Great Lakes NeuroTechnologies

Great Lakes NeuroTechnologies [http://www.glneurotech.com] is committed to pioneering innovative biomedical technologies to serve research, education, and medical communities, improving access to medical technology for diverse populations, and positively impacting quality of life for people around the world.

Media Contact

Lori Grim, 216-361-5410 - lgrim@GLNeuroTech.com

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