ABSTRACT TITLE
Clinical Outcomes of the Automated Selection of the Deep Brain Stimulation Parameters for Parkinson Disease Using Neurophysiology – A Pilot Double-blind, Randomized, Crossover Trial

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OBJECTIVE

To explore the feasibility, safety, and noninferiority of the AI-predicted DBS settings vs settings selected as usual.

BACKGROUND

DBS programming is a laborious, trial-and-error process. Recently, an AI model has been developed at UF to predict the optimal DBS settings for each patient based on recordings of his/her LFPs from the implanted electrode. However, the real-life performance of the model has not been examined prospectively.

METHODS

30 adults with advanced PD receiving DBS (15 GPI and 15 STN) at UF will be enrolled. This study consists of 2 in-person and 4 telemedicine visits over one month. At the initial in-person post-op visit (S1), each participant will be examined OFF medications; baseline questionnaires will be collected; LFPs will be recorded. Each participant will be given a wearable device and 4 DBS settings: one post-op safety setting (Group A), two new settings programmed as usual, and one
suggested by AI. The three new settings will be randomized into Groups B, C, and D, respectively. The participant will be discharged on Group A. The next day (S2), he/she will be examined via telemedicine ON medications and instructed to switch to and stay on Group B for 1 week. At the end of each week (S3-S5), the participant will fill out interval questionnaires, be examined remotely ON medications, and switch to the next Group. Afterward, he/she will switch to his/her favorite Group until returning to the clinic (S6) to be examined OFF medications on his/her favorite DBS setting and the AI-predicted setting, respectively. Follow-up questionnaires will be completed, and the wearable device data will be obtained. All exams will be recorded and graded by blinded raters. Adverse events are collected at each visit.

RESULTS

Preliminary results will be presented at the meeting.

CONCLUSION

A protocol is proposed to prospectively study the effects of AI-predicted DBS settings for PD.