DIRECT DBS: A Prospective, Randomized, Multicenter, Double-Blinded Study on Directional DBS – Effects on Therapeutic Window

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Published: European Society for Stereotactic and Functional Neurosurgery (ESSFN) 2018.

Device Utilized: Vercise™ DBS Directional Systems*

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Steigerwald, F., et al. DIRECT DBS: A prospective, randomized, multicenter, double-blinded study on directional DBS — Effects on therapeutic window. European Society for Stereotactic and Functional Neurosurgery (ESSFN) 2018.

Background

Historically, Deep Brain Stimulation (DBS) systems have delivered stimulation using cylindrical electrodes. In this study (DIRECT DBS), testing was performed using a directional DBS lead, which adds radially segmented electrodes designed for stimulation to be moved in the plane perpendicular to the lead. This study specifically analyzes the therapeutic windows (TWs) at varying directional stimulation settings.

Methods

12 Patients and 3 sites

Starting at the best vertical location, the four Coarse directions were blindly evaluated in a randomized order. From the best Coarse direction, 5 Fine directions were tested again blindly and in a random order.

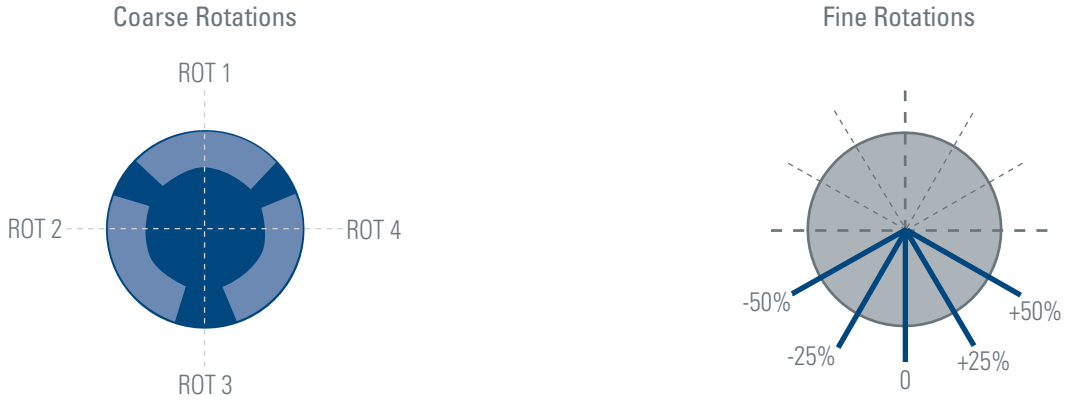

FIG 1. Depictions of Coarse (left) and Fine (right) rotational therapeutic window searches.

RESULTS

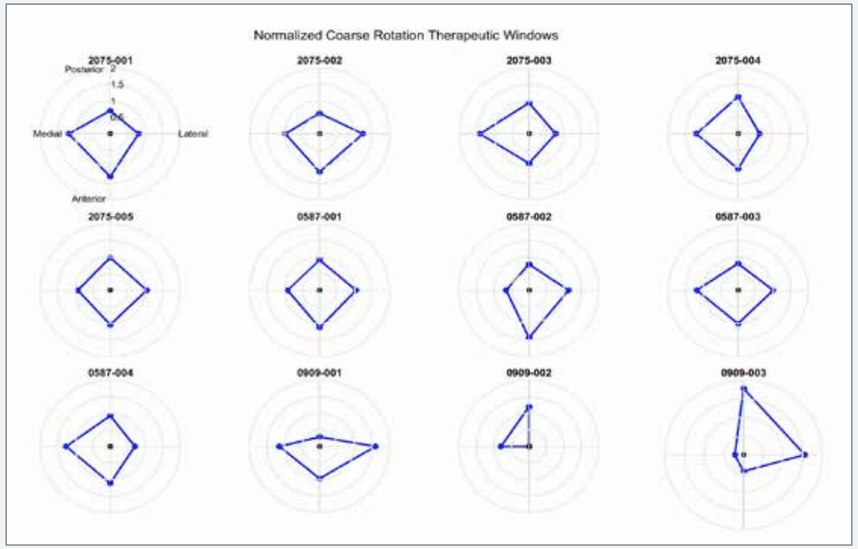

FIG 2. Therapeutic windows in the four Coarse directions (assumes that directional marker is pointed anterior) for each patient, normalized to average value.

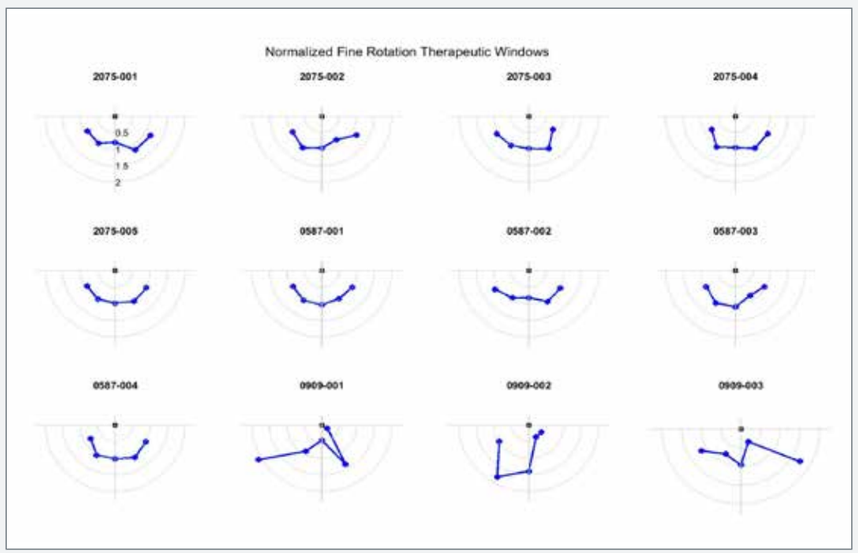

FIG 3. Therapeutic windows surrounding the best Fine direction for each patient, normalized to average value.

10/12
Subjects were programmed using a virtual contact in Ring Mode

11/12
Subjects were programmed using a virtual contact in directional mode

Figure 4. Comparison of optimal stimulation settings for Ring Mode (top) and directional mode (bottom), identified in a blinded, randomized fashion. Orange outlines indicate single-row/single-contact settings.

CONCLUSIONS

- There can be marked differences in therapeutic window with different directional stimulation settings
- This holds true even with shifts as small as 25% of the current to an adjacent contact
- 10/12 of the optimal Ring Mode settings needed multiple rows
- 11/12 of the optimal directional settings needed multiple contacts

*A System that includes the Vercise PC IPG or the Vercise Gevia IPG and Vercise Cartesia Directional Lead(s) form the Vercise Directional System.

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

Indications for Use: The Boston Scientific Deep Brain Stimulation Systems are indicated for use in bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication. Contraindications, warnings, precautions, side effects: The Deep Brain Stimulation Systems or any of its components, is contraindicated for: Diathermy as either a treatment for a medical condition or as part of a surgical procedure, Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS) as the safety of these therapies in patients implanted with the Vercise™ DBS System has not been established, patients who are unable to operate the system, patients who are poor surgical candidates or who experience unsuccessful test stimulation. Patients implanted with Boston Scientific Deep Brain Stimulation Systems without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Patients implanted with the Vercise Gevia™ or Vercise DBS Lead-only system (before Stimulator is implanted) with ImageReady MRI Technology are Full Body MR Conditional only when exposed to the MRI environment under the specific conditions defined in ImageReady MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems. Assess patients for the risks of depression and suicide. This assessment should consider both the risk of depression and suicide as well as the potential clinical benefits of DBS therapy. Monitor patients for new or worsening symptoms of depression, suicidal thoughts or behaviors, or changes in mood or impulse control and manage appropriately. Refer to the Instructions for Use provided with the Vercise DBS System or BostonScientific.com for potential adverse effects, warnings, and precautions prior to using this product.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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NM-928203-AA