Real World Clinical Outcomes Using a Novel Directional Lead from a Multicenter Registry of Deep Brain Stimulation for Parkinson's Disease

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Disclosures

- Profs. Drs. Vesper and Deuschl have consulting agreements with Boston Scientific.
- R. Jain, H. Scholtes, and A. Wang are salaried employees of Boston Scientific.
Introduction

• Deep Brain Stimulation (DBS) systems have historically used ring-shaped electrodes that produce stimulation fields with limited control over the shape of the field and volume of tissue activated.

• Directional current steering may permit a more personalized DBS approach with respect to the individualized shape and pattern of the electrical field and corresponding volume of tissue activated.

This analysis reports initial real-world outcomes using a directional lead with a DBS System capable of multiple independent current source control (MICC) for use in the management of symptoms of levodopa-responsive PD.
Primary Objective
- To compile real-world outcomes of an MICC-based DBS system (Vercise, Boston Scientific) using a directional lead (Vercise Cartesia Boston Scientific)

Coordinating Investigators
- Prof. Dr. med Günther Deuschl
- Prof. Dr. med Jan Vesper

Subjects/Sites
- Up to 1000 implanted subjects at up to 70 international sites

Key Study Assessments
- Parkinson’s Disease Questionnaire (PDQ-39)
- Unified Parkinson’s Disease Rating Scale (UPDRS) or MDS-UPDRS
- Clinical Global Impression of Change as assessed by Subject, Caregiver and Clinician
- Schwab and England Scale (SE)
- EQ-5D-5L

Safety
- Adverse events were reported

Key Inclusion Criteria:
- Understands study requirements and treatment procedures and provides written informed consent
- Meets criteria established in locally applicable Directions for Use (DFU)

Key Exclusion Criteria:
- Meets any contra-indication in applicable DFUs
## Results: Baseline Characteristics

(Implanted: 148 as of March 2018)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD) N</th>
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<tbody>
<tr>
<td>Age (years) - Mean (SD) N</td>
<td>60.4 (8.4) 148</td>
</tr>
<tr>
<td>Gender – Male %</td>
<td>67%</td>
</tr>
<tr>
<td><strong>PD Related Symptoms</strong></td>
<td></td>
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<tr>
<td>UPDRS III Scores (meds OFF)</td>
<td>38.9 (12.1) 52</td>
</tr>
<tr>
<td>MDS-UPDRS III Scores (meds OFF)</td>
<td>42.2 (13.5) 67</td>
</tr>
<tr>
<td>Disease Duration (years)</td>
<td>10 (4.85) 148</td>
</tr>
<tr>
<td>PDQ-39 Summary Index Score</td>
<td>27.3 (14.2) 139</td>
</tr>
</tbody>
</table>
**Results:**
Parkinson’s Disease Questionnaire (PDQ-39)

- PDQ-39 Summary Index demonstrates improvement in Quality of Life following DBS Implant up to 1 yr. post implant (n = 60)

- Several subdomains such as Activities of Daily Living, Bodily discomfort showed statistical significant improvement (p < 0.0001) at 6 months post-implant

*Negative scores indicate improvement*
Results:
Clinical Global Impression of Change (6 mos.)

Over 90% of subjects, physicians and caregivers noted an improvement in PD symptoms at 6 months post-implant.
Results:
Clinical Global Impression of Change (12 mos.)

Improvement in PD symptoms at 12 months post-implant was sustained as reported by subjects, physicians and caregivers.
Discussion

- A total of 91 adverse events in 50 subjects were reported in the study.
  - Of these events, 77 were reported as Serious Adverse Events in 42 subjects.

- The data described here are the initial results of an on-going registry representing the first comprehensive, large scale collection of real-world outcomes using a directional lead and an MICC-based DBS System.

- The use of directional stimulation with a MICC-based DBS System may facilitate improved outcomes while decreasing the likelihood of adverse effects. However, additional studies are required.
Summary Points

- Data presented here as part of an on-going registry represents the first comprehensive, large scale collection of real-world outcomes using a directional lead and an MICC-based DBS System.

- Preliminary analysis at 6 and 12 months post-lead implant demonstrate:
  - Overall improvement in Quality of Life (PDQ-39, EQ-5D-5L scores)
  - Improvement in motor function as demonstrated by change in MDS-UPDRS III scores (meds off condition)
  - Over 90% of subjects, caregivers and clinicians reported improvement in PD symptoms

- The overall safety profile of the directional lead appears acceptable.