Real-World Outcomes Using a Novel Directional Lead from a Deep Brain Stimulation (DBS) Registry for Parkinson's Disease

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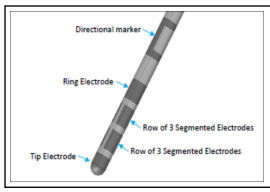
Introduction

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 managing symptoms of levodopa-responsive Parkinson's disease (PD).



The directional DBS lead has four electrode levels, of which the two middle levels are split into three segments spanning ~120° (highest and lowest levels consist of ring shaped electrodes).

Methods

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 (Subject, Caregiver and Clinician) • Schwab and England Scale (SE) • EQ-5D-5L
Safety	• Adverse events were reported

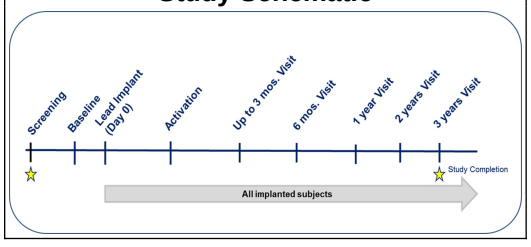
Key Inclusion Criteria:

- 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

Study Schematic

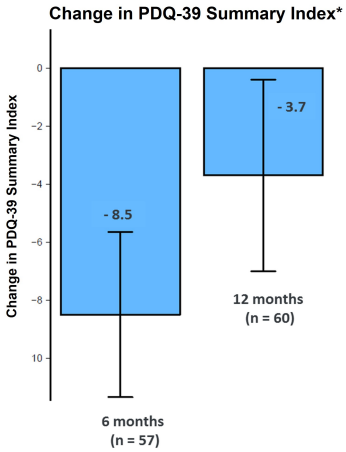


Results

BASELINE CHARACTERISTICS (Implanted: 148 as of March 2018)	
Age (years) - Mean (SD) N	60.4 (8.4) 148
Gender – Male %	67%
≤ 60 yrs.	48%
61 - 70 yrs.	37%
> 70 yrs.	14%
PD Related Symptoms	**Mean (SD) N**
UPDRS III Scores (meds OFF)	38.9 (12.1) 52
MDS-UPDRS III Scores (meds OFF)	42.2 (13.5) 67
Disease Duration (years)	10 (4.85) 148
PDQ-39 Summary Index Score	27.3 (14.2) 139

Parkinson's Disease Questionnaire

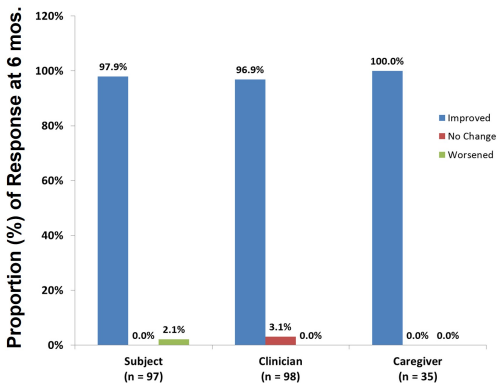
Change in PDQ-39 Summary Index*



- **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**

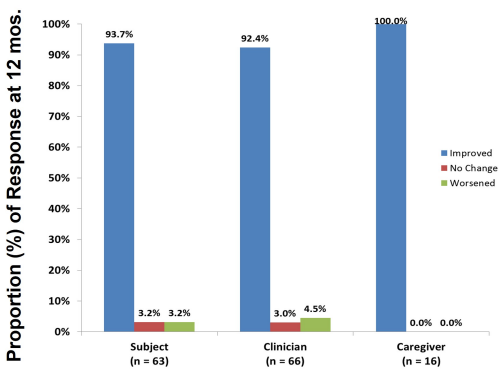
*Negative scores indicate improvement

Clinical Global Impression of Change (6 months)



Over 90% of subjects, physicians and caregivers noted an improvement in PD symptoms at 6 months post-implant

Clinical Global Impression of Change (12 months)



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

Safety

- A total of 91 adverse events in 50 subjects were reported in the study
- 77 Serious Adverse Events in 42 subjects

Conclusions

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 demonstrated by change in MDS-UPDRS III scores (meds off condition)
- >90% subjects, caregivers, clinicians reported improvement in PD symptoms

The overall safety profile of the directional lead appears acceptable.