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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Introduction

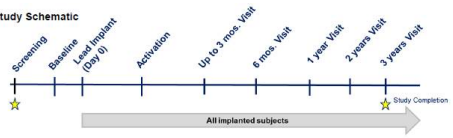
Deep Brain Stimulation (DBS) systems have historically used ring-shaped electrodes that produce stimulation fields with limited control over the shape of the field and volume of tissue activated. Directional current steering may permit a more personalized DBS approach with respect to the individualized 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.

The directional DBS lead used in this study 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

Study Type	prospective, on-label, multi-center, observational registry
Primary Objective	To compile real-world outcomes of an MICC-based DBS system (Vercise, Boston Scientific) using a directional lead (Vercise Cartesia Boston Scientific)
Subjects/Sites	Currently at N = 68 implanted subjects
Key Study Assessments	EQ-5D 5 Level (EQ-5D-5L); Parkinson's Disease Questionnaire (PDQ-39); Clinical Global Impression of Change as assessed by Subjects, Caregiver and Clinician; Schwab and England Scale (SE); Unified Parkinson's Disease Rating Scale (UPDRS) or MDS-UPDRS

Study Schematic



Key Inclusion Criteria:

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

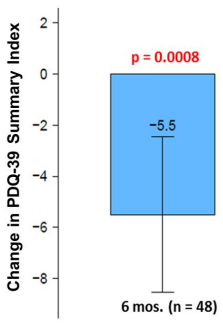
Key Exclusion Criteria:

- Meets any contra-indication in the locally applicable DFU

Results

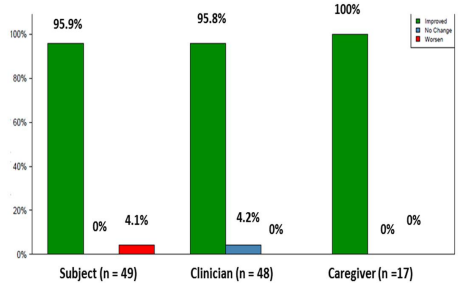
BASELINE CHARACTERISTICS (Subjects implanted with directional lead: 68)	
Age (years) - Mean (SD)	60.3 (8.1)
Gender – Male (n %)	62%
UPDRS III Scores (meds OFF) – Mean (SD)	35.3 (10.46) 8
MDS-UPDRS III Scores (meds OFF) – Mean (SD)	43.5 (12.44) , n = 16
Disease Duration (years) - Mean (SD)	10.7 (5.68) , n = 50
PDQ-39 Summary Index Score – Mean (SD)	27.8 (13.25) , n = 37

Change in Parkinson's Disease Questionnaire (PDQ)-39 Summary Index at 6 mos



- Overall Improvement in Quality of Life as demonstrated by PDQ-39 Summary Index Score (p = 0.0008)
- Several domains such as Mobility, ADL, Cognition, Bodily Discomfort showed statistical significance (p < 0.001)

Clinical Global Impression of Change at 6 mos.



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

Key Serious Adverse Events related to stimulation, Procedure or Device

Serious Adverse Events	Number of events (patients)
Suicide attempt	1 (1)
Implant site infection	3(2)
Implant Site hematoma	1(1)
Implant site edema	1(1)

- Total of 45 Adverse Events (AEs) in 29 subjects reported
- Of the 45 AEs, thirty-nine events were reported as Serious Adverse Events (SAE) in 23 subjects.

Conclusions

These are initial results using the Vercise Cartesia Lead as part 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.

This preliminary analysis at 6 months post-lead implant, demonstrated that use of an MICC-based DBS system in combination with a directional lead achieved the following in the real-world clinical setting:

- Overall improvement in Quality of Life as demonstrated by PDQ-39, EQ-5D-5L scores
- >90% of subjects, caregivers and clinicians reported improvement in PD symptoms
- The overall safety profile of the directional lead appears acceptable

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