Outcomes of a Prospective, Multi-center International Registry of Deep Brain Stimulation for Parkinson's Disease

Jan Vesper; Roshini Jain; Heleen Scholtes; Alex Wang; Michael Barbe; Steffen Paschen; Andrea Kuhn; Monika Potter-Nerger; Jens Volkmann; Günther Deuschl

1. Heinrich Heine Univ., Germany 2. Boston Scientific, USA 3. Boston Scientific, Belgium 4. Univ. Hospital Cologne, Germany 5. Charité-Universitätsmedizin, Germany 6. Univ. Hospital Hamburg-Eppendorf, Germany 7. Univ. Hospital Wuerzburg, Germany 8. Charing Cross Hospital, UK 9. Univ. Hospital Schleswig-Holstein, Germany

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Introduction

Deep Brain Stimulation (DBS) is an effective strategy in reducing the motor complications in Parkinson's disease (PD) as substantiated by several randomized controlled trials (Schuepbach, 2013). This motor improvement has shown to be sustained for up to 10 years (Deuschl et al. 2013). Large patient data registries documenting the overall improvements in PD disease symptoms, quality of life may facilitate new insights regarding the real-world, clinical use and outcomes of DBS. Hence, a large scale, on-going registry was initiated to compile effectiveness and safety-related real-world outcomes of a DBS System capable of multiple independent current source control (MICC) in the management of symptoms of levodopa-responsive PD.

Methods

Primary Objective	• To compile real-world clinical outcomes of an MICC-based DBS system (Vercise DBS System, Boston Scientific)
Coordinating Investigators	• Prof. Dr. med Günther Deuschl • Prof. Dr. med Jan Vesper
Subjects	• 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

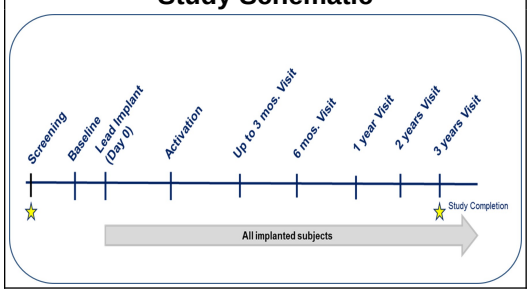
Key Inclusion Criteria:

- 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

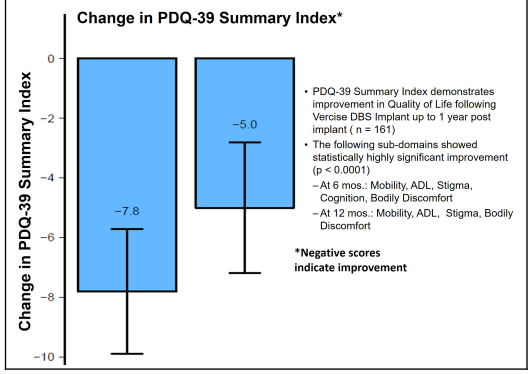
Study Schematic



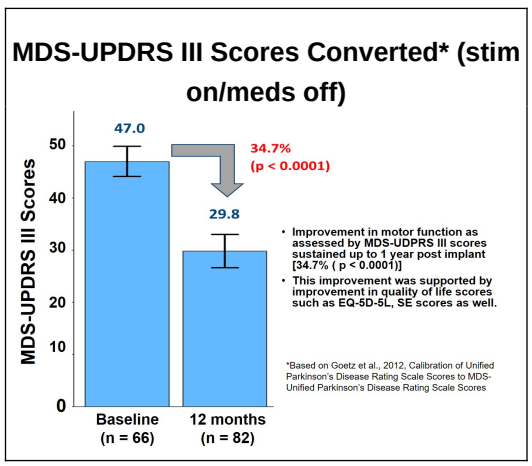
Results

BASELINE CHARACTERISTICS (Subjects Enrolled: 307 / Implanted: 275 as of March 2018)	
Age (years) - Mean (SD) N	59.5 (8.89) 277
Gender – Male %	69%
PD Related Symptoms	**Mean (SD) N**
UPDRS III Scores (meds OFF)	40 (11.6) 109
MDS-UPDRS III Scores (meds OFF)	42.3 (14.4) 103
Disease Duration (years)	10.2 (4.9) 277
PDQ-39 Summary Index Score	28.9 (13.7) 266

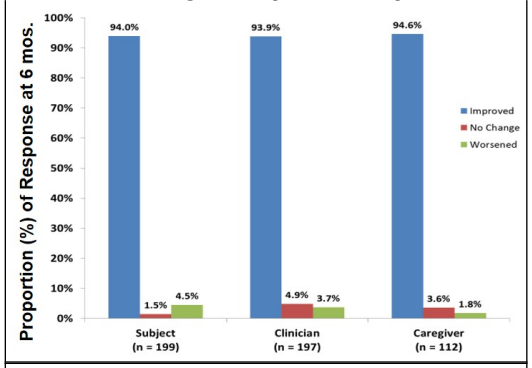
Parkinson's Disease Questionnaire (PDQ-39)



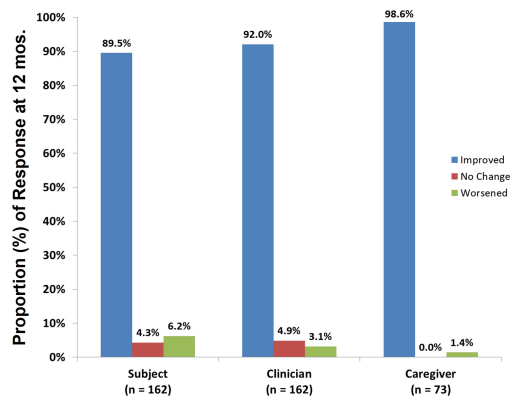
MDS-UPDRS III Scores Converted* (stim on/meds off)



Clinical Global Impression of Change as assessed by clinicians, subjects and caregivers (6 months)



Clinical Global Impression of Change as assessed by clinicians, subjects and caregivers (12 months)



Over 90% of clinicians, subjects and caregivers reported improvement in their symptoms at 6 and 12 months post-implant.

Safety

- As of March 2018, a total of 187 adverse events in 106 subjects were reported.
- Of all events, 152 events were reported as Serious Adverse Events (SAEs) in 84 subjects.
- No unanticipated adverse events

Conclusions

This registry represents the first large scale collection of outcomes using a DBS System capable of multiple independent current source control. Preliminary analysis demonstrates that at 6 and 12 months post-lead implantation:

- Overall improvement in Quality of Life (PDQ-39, EQ-5D-5L and SE Scores)
- Significant improvement in motor function demonstrated by change in MDS-UDPRS III (meds off)
- Over 90% of subjects, caregivers, clinicians reported improvement in PD symptom
- The overall safety profile and patient outcomes are in accordance with several randomized clinical trials with no major differences.

References

1) Schuepbach WM., et al. N Engl J Med. 2013 Feb 14;368(7):610-22.
2) Deuschl G. and Agid Y. Lancet Neurol. 2013 Oct;12(10):1025-34