Outcomes of a Prospective, Multicenter International Registry of Deep Brain Stimulation for Parkinson's Disease

G. Deuschl(1), R. Jain(2), H. Scholtes(3), A. Wang(2), H.M. Mehdorn(1), A. Kühn(4), M. Barbe(5), M. Pötter-Nerger(6), P. Eldridge(7), J. Volkmann(8), J. Fitzgerald(9), A. Schnitzler(10), J. Vesper(10)

1. Univ. Hospital Schleswig-Holstein, Kiel, DE 2. Boston Scientific Corp., Valencia, USA 3. Boston Scientific Corp., Kerkrade, NL 4. Charité - Universitätsmedizin Berlin, DE 5. Univ. Hospital Cologne, Cologne, DE 6. Univ. Hospital Hamburg-Eppendorf, Hamburg-Eppendorf, DE 7. The Walton Centre, Liverpool, UK 8. Univ. Hospital Wuerzburg, Wuerzburg, DE 9. The

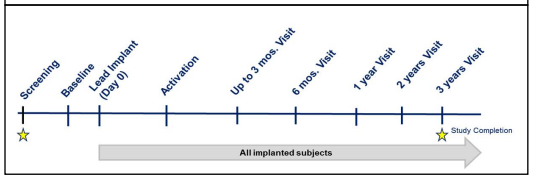
CNS 2017 ANNUAL MEETING BOSTON, MASSACHUSETTS OCTOBER 7–11, 2017

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 et al., 2013). DBS-induced motor improvement is sustained for up to 10 years (Deuschl et al. 2013). Large patient data registries describing changes in disease symptoms, overall quality of life, and other assessments may facilitate new insights regarding the real-world, clinical use and outcomes of DBS. No registry database currently exists for a multiple-source, constant current DBS system. 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/Sites	• Up to 1000 implanted subjects at up to 70 international sites
Key Study Assessments	• Parkinson's Disease Questionnaire (PDQ-39); EQ-5D 5 Level (EQ-5D-5L); • Unified Parkinson's Disease Rating Scale (UPDRS) or MDS-UPDRS • Clinical Global Impression of Change as assessed by Subjects, Caregiver and Clinician; • Schwab and England Scale (SE);



Key Inclusion Criteria:

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

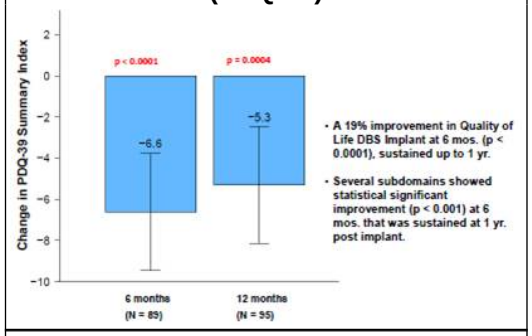
Key Exclusion Criteria:

- Meets any contra-indication in locally applicable DFU

Results

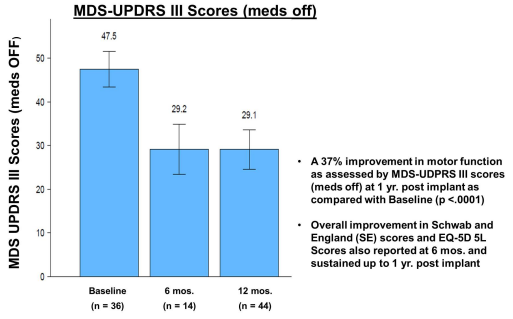
BASELINE CHARACTERISTICS (Subjects Enrolled: 203 / Implanted: 181)	
Age (years) - Mean (SD) N	59.1 (8.99) 181
Gender – Male %	69%
PD Related Symptoms	**Mean (SD) N**
UPDRS III Scores (meds OFF)	39.1 (11.93) 70
MDS-UPDRS III Scores (meds OFF)	42.3 (15.16) 62
Disease Duration (years)	10.3 (5.11) 180
PDQ-39 Summary Index Score	29.3 (13.17) 173

Parkinson's Disease Questionnaire (PDQ-39)



- A 19% improvement in Quality of Life DBS Implant at 6 mos. ($p < 0.0001$), sustained up to 1 yr.
- Several subdomains showed statistical significant improvement ($p < 0.001$) at 6 mos. that was sustained at 1 yr. post implant.

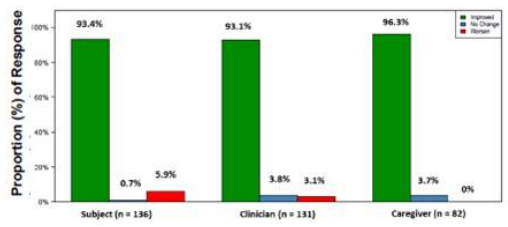
Converted* MDS-UPDRS III Scores



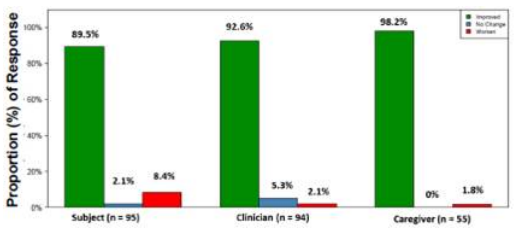
- A 37% improvement in motor function as assessed by MDS-UPDRS III scores (meds off) at 1 yr. post implant as compared with Baseline ($p < .0001$)
- Overall improvement in Schwab and England (SE) scores and EQ-5D 5L Scores also reported at 6 mos. and sustained up to 1 yr. post implant

*Based on Goetz et al., 2012, Calibration of Unified Parkinson's Disease Rating Scale Scores to MDS-Unified Parkinson's Disease Rating Scale Scores

Clinical Global Impression of change at 6 mos.



Clinical Global Impression of change at 12 mos.



Over 90% of subjects, physicians and caregivers noted an improvement in PD symptoms at 6 mos. that was sustained up to 12 mos. post implant

Serious Adverse Events	Number of events (patients)
Suicide attempt	2(2)
Implant site infection	4(3)
Implant Site hematoma	1(1)
Implant site edema	1(1)
Hemorrhage intracranial	1(1)
Suicidal Ideation	1(1)
Convulsion	1(1)
Device related infection	1(1)

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 following lead implantation:

- Overall improvement in Quality of Life as demonstrated by PDQ-39, EQ-5D-5L and SE Scores
- >90% of subjects, caregivers, clinicians reported improvement in PD symptoms
- 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.