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Five Year Outcomes of a Prospective, Multicenter Trial Evaluating Deep Brain Stimulation with a New Multiple Source, Constant Current Rechargeable System in Parkinson's Disease

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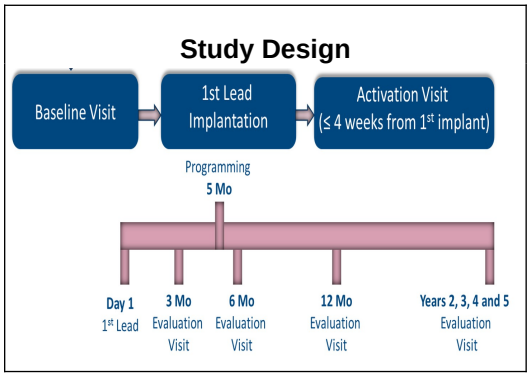
Introduction

A DBS device that enables current fractionalization using a multiple-source mode of delivery can permit the application of a well-defined, shaped electrical field. Thus, we postulated that a multiple-source, constant-current device (CE marked) that permits a well-defined distribution of current would lead to motor improvement in patients with Parkinson's disease (PD). Previously, results from the VANTAGE clinical study demonstrated highly significant improved motor function ($p < 0.0001$) as assessed by UPDRS III "meds off" at 6 months post -first lead implant as compared with Baseline "meds off," thereby successfully achieving the study primary endpoint. Here we present five year, long term results.

Methods

Study Design	Prospective, Multicenter, Non-Randomized, Open-Label
Study Device	Vercise DBS System (Boston Scientific, Valencia, CA, USA)
Subjects/Sites	40 implanted subjects at 6 European Centers
Follow-Up	Weeks 12, 21, 26 and Year 1, 2, 3, 4 and 5 post-lead placement



Key Inclusion Criteria

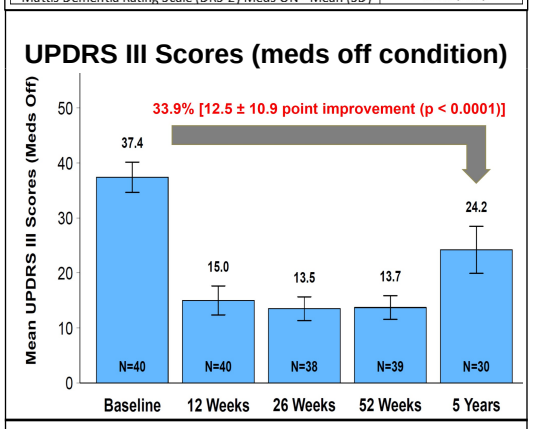
- Diagnosis of bilateral idiopathic PD = 5 years
- Modified Hoehn and Yahr in the OFF state = 2
- UPDRS III = 30 off meds that improved by = 33% with meds
- Appropriate surgical candidate for DBS

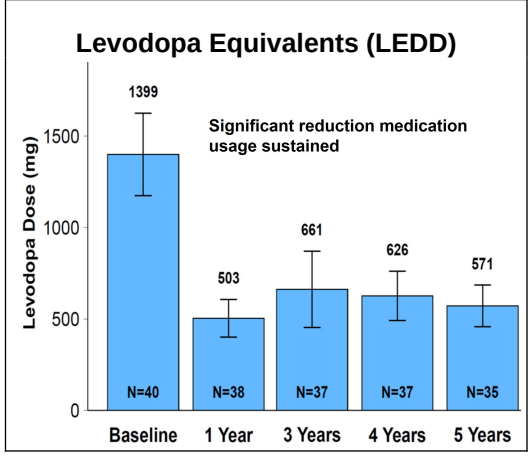
Key Exclusion Criteria

- Any intracranial abnormality or medical condition that contraindicates DBS surgery.
- Any finding in neuropsychological screening assessments that would contraindicate DBS surgery, including dementia.

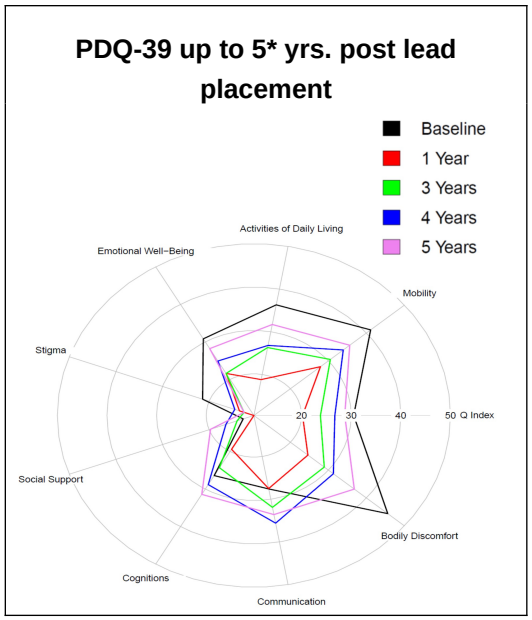
Results

Age (years) - Mean (SD)	60.2 (7.82)
Gender - n (%)	
Male	27 (67.5%)
Parkinson's Disease Related Symptoms	
Disease Duration (years) - Mean (SD)	11.7 (4.57)
H&Y scale Meds OFF - Mean (SD)	2.69 (0.71)
UPDRS III Meds OFF - Mean (SD)	37.4 (8.90)
UPDRS III Meds ON - Mean (SD)	14.0 (8.21)
Total UPDRS Meds ON - Mean (SD)	30.3 (12.74)
Duration of OFF time in motor diary (hours) - Mean (SD)	5.4 (3.13)
Neuropsyhometric Testing	
BDI-II Meds ON - Mean (SD)	9.4 (6.57)
Mattis Dementia Rating Scale (DRS-2) Meds ON - Mean (SD)	140.1 (3.55)

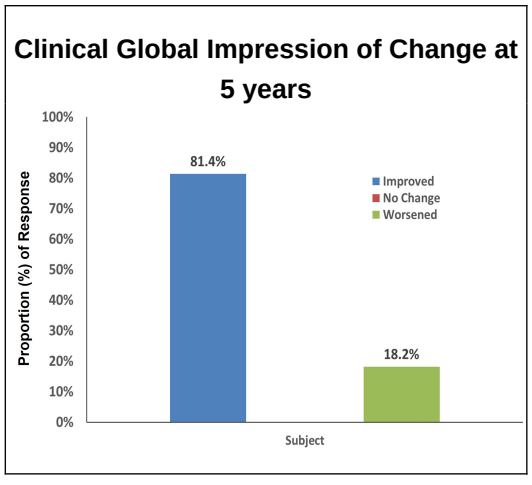




At 5 Yrs. post lead placement, a 34% improvement in UPDRS III scores (meds off) was reported

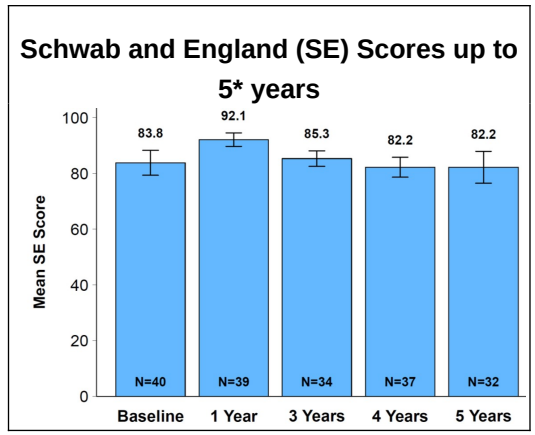


Quality of Life:
At 5 years, Quality life continues to improve following implant as supported by PDQ-39 and SE scores



At 5 years post-lead placement, over 80% of subjects reported improved symptoms compared with Baseline

*2 year data not shown as adequate data was not available (n = 24)



Safety

- A total of 176 adverse events were reported in 38 subjects
- Of these, 64 were reported as serious adverse events (SAEs)
  - 5 SAEs in 2 subjects related to device
  - 6 SAEs in 3 subjects related to procedure
  - There were no SAEs related to stimulation

Conclusions

- Results of the VANTAGE study demonstrated highly significant improved motor function ($p < 0.0001$), as assessed by UPDRS III meds off at 6 months post first lead implant as compared with Baseline meds off – successfully meeting primary endpoint (Timmermann et al., Lancet Neurology 2015).

- At 5 yrs. post lead placement, a 34% improvement ($p < 0.0001$) in UPDRS III scores (in the stim on/meds off condition) was reported ($n = 30$).

- Overall improvement in quality of life as assessed by PDQ-39, Schwab and England scores, reduction in medication usage was noted up to 5 years post-lead placement.

- The safety results associated with this study for up to 5 years are acceptable