A prospective, multicentre, non-randomized, open label trial of an implantable DBS device (the VANTAGE study) at six specialist DBS centres at universities in six European countries.

Patients were judged eligible if they were aged 21–75 years, had been diagnosed with bilateral idiopathic Parkinson's disease with motor symptoms for more than 5 years, had a Hoehn and Yahr score of 2 or greater, and had a Unified Parkinson's disease rating scale part III (UPDRS III) score in the medication-off state of more than 30, which improved by 33% or more after a levodopa challenge. Participants underwent bilateral implantation in the subthalamic nucleus of a multiple-source, constant-current, eight-contact, rechargeable DBS system, and were assessed 12, 26, and 52 weeks after implantation. The primary endpoint was the mean change in UPDRS III scores (assessed by site investigators who were aware of the treatment assignment) from baseline (medication-off state) to 26 weeks after first lead implantation (stimulation-on, medication-off state). This study is registered with ClinicalTrials.gov, number NCT01221948.

Of 53 patients enrolled in the study, 40 received a bilateral implant in the subthalamic nucleus and their data contributed to the primary endpoint analysis. Improvement was noted in the UPDRS III motor score 6 months after first lead implantation (mean 13·5 [SD 6·8], 95% CI 11·3-15·7) compared with baseline (37·4 [8·9], 34·5-40·2), with a mean difference of 23·8 (SD 10·6; 95% CI 20·3-27·3; p<0·0001). One patient died of pneumonia 24 weeks after implantation, which was judged to be unrelated to the procedure. 125 adverse events were reported, the most frequent of which were dystonia, speech disorder, and apathy. 18 serious adverse events were recorded, three of which were attributed to the device or procedure (one case each of infection, migration, and respiratory depression). All serious adverse events resolved without residual effects and stimulation remained on during the study. INTERPRETATION: The multiple-source, constant-current, eight-contact DBS system suppressed motor symptoms effectively in patients with Parkinson's disease, with an acceptable safety profile. Future trials are needed to investigate systematically the potential benefits of this system on postoperative outcome and its side-effects [1)].

1)
Timmermann L, Jain R, Chen L, Maarouf M, Barbe MT, Allert N, Brücke T, Kaiser I, Beirer S, Sejio F, Suarez E, Lozano B, Haegelen C, Vérin M, Porta M, Servello D, Gill S, Whone A, Van Dyck N, Alesch F. Multiple-source current steering in subthalamic nucleus deep brain stimulation for Parkinson's disease (the VANTAGE study): a non-randomised, prospective, multicentre, open-label study. Lancet Neurol. 2015 Jul;14(7):693-701. doi: 10.1016/S1474-4422(15)00087-3. Epub 2015 May 28. PubMed PMID: 26027940.