Patients with Parkinson's disease using the Boston Scientific Corporation (NYSE: BSX) Vercise™ DBS (deep brain stimulation) System showed a significant improvement in motor scores according to interim data from the VANTAGE study. Data from the six month follow-up of up to 40 participants enrolled in the VANTAGE trial were presented at the annual International Congress of Parkinson's Disease and Movement Disorders in Sydney, Australia by Prof. Dr. Lars Timmermann, of University Hospital in Koln, Germany.

The Vercise DBS System incorporates multiple independent current control, which is designed to selectively stimulate targeted areas in the brain, providing physicians with fine control of stimulation.

Preliminary analysis of the VANTAGE study displays approximately 60 percent mean improvement in motor function at six months post implant, as assessed by UPDRS III1 when compared to baseline. The Boston Scientific sponsored study was designed to document patient outcomes. These include effectiveness, safety, and health economic data derived from bilateral stimulation of the subthalamic nucleus (STN) in the brain using the implantable Vercise DBS System for the treatment of levodopa-responsive, moderate to severe idiopathic Parkinson's disease. Forty participants with Parkinson's disease were implanted bilaterally at six European centers.

“We are pleased to see such a significant improvement in motor function,” said Prof. Dr. Francois Alesch, professor for Stereotactic and Functional Neurosurgery at Medical University, Vienna, Austria and neurosurgical principal investigator of the trial. “I believe this unique technology, with its multiple current sources, may provide us with a more adaptable form of DBS therapy. I was very pleased with the simple recharging system. All of my patients were able to recharge successfully.”

Highlights of the VANTAGE study interim data include:

All 40 participants underwent successful implantation of the Vercise DBS System. The Vercise DBS System demonstrated a significant improvement in motor function ($p<0.0001$), as assessed by UPDRS III1 (approximately 60 percent mean improvement) at six (6) months post first lead implant as compared with baseline. Preliminary analysis suggests the Vercise DBS System improved participants' ON time, as assessed by at-home motor diaries, activities of daily living2 and quality of life3 at six months. The charging of the Vercise DBS System was well tolerated by all participants. “With these data, clinicians can be confident in their decision to implant the Vercise DBS System,” said Prof. Dr. Lars Timmermann, neurological principal investigator of the trial. “The ability to utilize multiple independent current control to selectively stimulate areas within the brain may provide improved outcomes for these patients. I look forward to seeing the longer term data from the VANTAGE study.”

“The VANTAGE study is a key facet of our DBS program and emphasizes our commitment to advancing therapy through clinical research with the Vercise DBS System,” said Maulik Nanavaty, president of the Boston Scientific Neuromodulation division. “The significance of the reduction in motor scores is a testament to the capabilities of the Vercise System. We continuously strive to develop innovative technologies that improve patient outcomes.”

The Vercise DBS System has both CE Mark and TGA (Australia Therapeutic Goods Administration) approval and is available for sale in Europe, Israel and Australia. In the U.S., the Vercise DBS System is investigational and not available for use or sale.

Case series

Wolf et al. from Mannheim prospectively collected data from 11 consecutive patients (10 men, mean age at DBS implantation 52.6 ± 14.0 years) with chronic DBS for dystonia (n = 7), Parkinson disease

(n = 3), and essential tremor (n = 1) who underwent Implantable Pulse Generator IPG replacement switching from a CV NRC system (Activa® PC; Medtronic®) to a CC RC system (Vercise® RC; Boston Scientific®). Systematic assessments before and after IPG replacement were performed.

DBS technology switching at the time of IPG replacement due to battery depletion was at a mean of 108.5 ± 46.2 months of chronic DBS. No perioperative complications occurred. Clinical outcome was stable with overall mild improvements or deteriorations, which could be dealt with in short-term follow-up. Patients were satisfied with the new RC IPG.

This study confirms both the safety and feasibility of switching between different DBS technologies (CV to CC, NRC to RC, different manufacturers) in patients with chronic DBS. Furthermore, it shows how the management can be planned using available information from the previous DBS settings. Individual assessment is needed and might partly be related to the DBS target and the underlying disease. MR safety might be a problem with such hybrid systems [1].

1)
Wolf ME, Klockziem M, Majewski O, Schulte DM, Krauss JK, Blahak C. Implementation of New Technology in Patients with Chronic Deep Brain Stimulation: Switching from Non-Rechargeable Constant Voltage to Rechargeable Constant Current Stimulation. Stereotact Funct Neurosurg. 2020 Jan 16:1-7. doi: 10.1159/000505076. [Epub ahead of print] PubMed PMID: 31945765.