Deep Brain Stimulation (DBS) for Parkinson's disease

What is Parkinson's disease?

Parkinson's disease (PD) is a neurological illness which can affect one's movements and coordination. The disease is caused by a deficiency of dopamine producing cells. The shortage of dopamine, a substance that is used in the brain to transmit signals, causes the symptoms of Parkinson's disease to appear. Parkinson's disease affects approximately two million Europeans[1] and seven to ten million people worldwide[2].

What are the symptoms of Parkinson's disease?

The hallmark signs of Parkinson's disease include movement disorders such as slowness of movement (bradykinesia), inability to move (akinesia), resting tremors, parkinsonian gait and muscle rigidity. Occasionally the disease also causes depression, constipation, speech impairment, sexual dysfunction and dementia. The severity of Parkinson's disease symptoms tends to worsen over time.

What are the treatments for Parkinson's disease?

There is currently no cure for Parkinson's disease. Treatment is typically focused on restoring dopamine levels through the administration of Dopaminergic medications[3]. Current standards for patient care recommend levodopa as first-line therapy for the symptomatic control during the early, uncomplicated stages of PD. Unfortunately, chronic treatment with levodopa frequently leads to significant side effects, especially dyskinesias (involuntary movements) and motor fluctuations.[4]

Some additional therapies for the treatment of severe Parkinson's disease symptoms include a pallidotomy surgical procedure as well as deep brain stimulation. Both have been reported to help reduce some of the symptoms of PD.[5]

What is Deep Brain Stimulation Therapy?

Deep Brain Stimulation (DBS) is a surgical treatment which can help reduce some Parkinson's disease symptoms. DBS is a well-established safe and effective therapy. In 2003, the UK's National Institute for Clinical Excellence (NICE) declared DBS to be a clinically effective and cost effective intervention for Parkinson's disease.[6,7] Similarly, in 2002, France's Agence Nationale d'Accréditation et d'Évaluation en Santé declared DBS to be an effective therapy for Parkinson's disease[8].

DBS is typically used to treat people with advanced Parkinson's disease whose symptoms are no longer effectively controlled by medication.

The DBS procedure includes a modest medical device which sends signals to the brain. The signals help control the motor functions that are affected by Parkinson's disease such as tremor, slowness and rigidity. The physician will place one or two insulated wires called leads in the brain. The leads are then connected to the stimulator (similar to a pacemaker), which is typically placed under the skin in the chest. The device produces mild electrical impulses that stimulate a specific region of the brain. This may help regulate incorrect signaling in the brain, resulting in improvement of Parkinson's disease symptoms. Although DBS is not a cure, it may help improve day-to-day experiences. Most people will continue to take Parkinson's disease medications but often at a reduced dosage.[9]

Clinical Effectiveness of DBS Therapy

There are several globally recognized tools used to monitor the severity of Parkinson's disease as well as track the quality of life. The Unified Parkinson's Disease Rating Scale (UPDRS) is a globally recognized tool used to assess the severity of Parkinson's disease. The Parkinson's disease Questionnaire (PDQ-39) is used to measure the health status of people living with Parkinson's disease specifically focusing on 8 aspects related to quality of life.

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Multiple studies have demonstrated a reduction in UPDRS III and PDQ-39 scores, which correlates with an improvement in motor function & quality of life.

Key findings from these studies concluded that:

Primary Author	Study Design	Sample Size	Follow Up	Change in Mean UPDRS III Scores	% Improvement in UPDRS III & PDQ-39 Scores
Deuschl 2006[10]	Randomized pairs trial	78	6 mos.	• Baseline: 48 ± 12.3 • Post DBS: 28.3 ± 14	• 41% improvement in UPDRS III • 25% improvement in PDQ-39
Tir 2007[12]	Prospective, single-center study	103	12 mos.	• Baseline: 50 ± 16 • Post DBS: 29 ± 11.5	• 42% improvement in UPDRS III
Fraix 2006[11]	Prospective, multi-center	95	12 mos.	• Baseline: 49.2 ± 16.4 • Post DBS: 19.4 ± 11.5	• 57% improvement in UPDRS III
Lefaucheur 2008[13]	Single-center study	54	12 mos.	• Baseline: 48.2 ± 16.1 • Post DBS: 21.4 ± 8.2	• 56% improvement in UPDRS III
Follett 2010[14]	Multi-center, randomized, blinded	299	24 mos.	STN • Baseline: 43 ± 15 • Post DBS: 32.1 ± 15.6 GPi • Baseline: 41.8 ± 13.1 • Post DBS: 30 ± 14.2	• 25.3% improvement in UPDRS III • Improvement in 6 of 8 subscales
Rodriquez-Oroz 2005[15]	Blinded, multi-center study	69	3-4 yrs.	STN • Baseline: 56.7 ± 15.7 • Post DBS: 28.6 ± 15.7 GPi • Baseline: 51.7 ± 13.6 • Post DBS: 31.7 ± 12.8	• 50% improvement in UPDRS III with STN and 39% improvement with GPi at 3-4 yrs.
Gervais-Bernard 2009[16]	Prospective, single-center	23	5 yrs.	• Baseline: 43.11±14.04 • Post DBS: 19.52 ± 7.17	• 55% improvement in UPDRS III
Moro 2010[17]	Non-randomized, prospect, blinded, multi-center study	51	5-6 yrs.	STN • Baseline: 56 ± 2.7 • Post DBS: 30.1 ± 2.5 GPi • Baseline: 52.2 ± 3.5 • Post DBS: 32.6 ± 4.6	• 45.4% (STN) to 20% (GPi) improvement in UPDRS III

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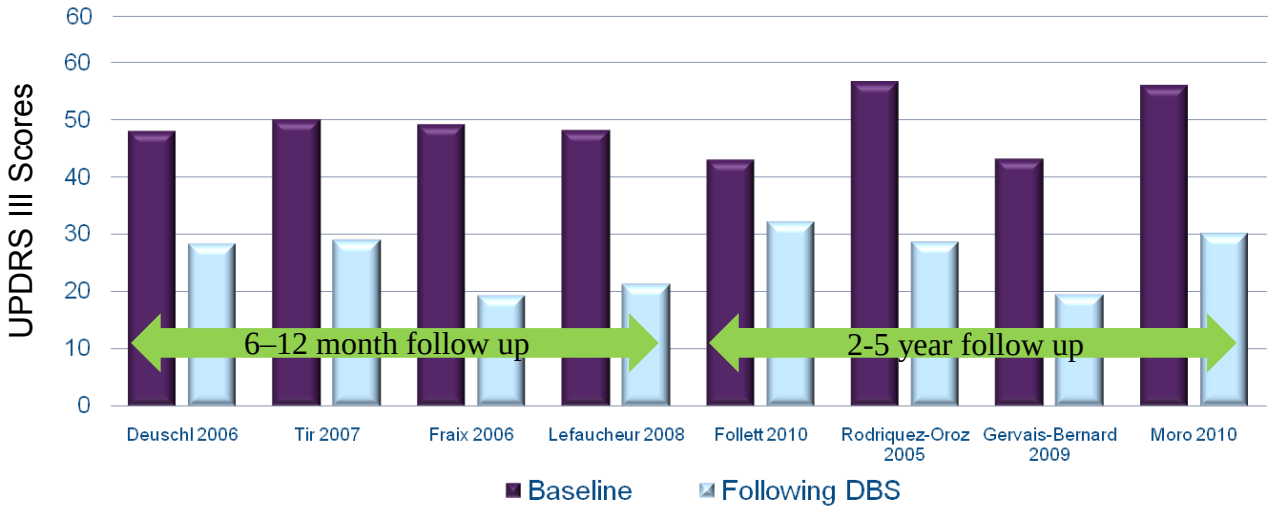
Change in mean UPDRS III Scores off Medications Following Deep Brain Stimulation[10,11,12,13,14,15,16,17]



The Vercise™ Deep Brain Stimulation System

The Vercise™ Deep Brain Stimulation System is a new DBS system for the treatment of patients with levodopa-responsive Parkinson's disease which is not adequately controlled with medication. The Vercise™ System was designed to offer ***Control, Comfort, and Convenience*** for physicians and patients.

The Vercise™ System consists of a stimulator (also referred to as an implantable pulse generator) similar in size and shape to a pacemaker. The stimulator produces small electrical signals that travel along thin wires called leads, which are connected to the stimulator. The stimulator is placed under the skin just below the collar bone, while the leads are positioned in a specific part of the brain.

From left to right: the Vercise Deep Brain Stimulation System consists of a remote control, stimulator with attached leads, and charger.

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The Vercise™ DBS system was designed to contain unique features that may help make a difference to both physicians and patients. The intended benefits include:

- **Accurate & Precise Targeting**: Multiple Independent Current Control (MICC) was designed for fine control of stimulation position and shape.
- **Innovative Design:** The Vercise lead has a robust multi-lumen construction with 8-contacts and a broad span.
- **Patient Comfort:** The Vercise IPG has a gentle contoured oval shape with the smallest footprint on the market at 20 cm^2.
- **Longevity**: The Vercise DBS System with unique rechargeable battery technology has a 25 year battery life to help reduce surgical interventions.
- **Patient Convenience:** The Vercise charging system and remote control are completely cordless and designed to make charging simple. The wireless charging system allows patients to be active while charging.
- **Reliability**: Only the Vercise DBS System offers Zero-Volt™ Battery Technology. The battery can be completely discharged without causing battery failure or damage – even when the patient forgets to recharge.
- **Quality**: At Boston Scientific we believe that best-in-class quality is essential to long-term viability of DBS therapy. Through substantial investments in R&D and quality, our engineers invented unique features designed to deliver unmatched reliability and convenience in a simple, rechargeable device.

Deep Brain Stimulation is a safe and effective therapy for the treatment of patients with levodopa-responsive Parkinson's disease which is not adequately controlled with medication. The DBS procedure includes a modest device which sends signals to the brain that help control the motor functions that are affected by Parkinson's disease such as tremor, slowness and rigidity. Although DBS does not treat the disease, it may help improve day-to-day experiences. The Vercise™ DBS System is designed to take innovation to new levels. The system has several unique features such as Multiple Independent Current Control (MICC), a robust 8 contact lead, and Zero-Volt™ battery technology. All of these attributes were designed with physicians and patients in mind, to offer ***Control, Comfort, and Convenience***.

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Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties.

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